A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
1435	05/04/19	50	male	160	lbs
B. Adverse event	or produ	ict pi	oblem		
	Product	Prob	lem		
Outcomes attribut	ted to adv	erse e	event		
death	disab	oility			
Life-threatening	_ ~		anomaly		
hospitalization	<b>∠</b> requi	red in	tervention		
other:					
Date of event 04/2	20/04	Date	e of report	1/26/2	2005
Describe event or	-				
In April of 2004 I b	ecame infe	ested v	with lice fr	om a visit	to
the hospital.					
Relevant tests/labo	oratory da	ta			
	·				
Other relevant his					
I've got itchy "craw"		-			able
to locate any actual number of "question					ılar
basis.			5		

C. Suspect medi	cation(s)					
Name: lindane						
Dose, frequency,	route use	Thera	py da	ates		
5%		04/200	)4	to		
			to 01/2005			
Diagnosis for use		Ev	Event abated after use			
Prescription was for	or two (2)	ste	oppe	d or dose reduced		
uses/treatments.		n	0			
Lot # Exp. date		E.	vont i	reappeared after		
Anti-biotics				duction		
1 mu-010005				uutuun		
NDC # -	-	У	es			
Concomitant med	ical produ	cts				
Ive tried mayonais	e, over-the-	counte	r shai	npoos, "internet-		
ordered" shampoos				-		
quite a collection of						
_			, ui 00	mos which I have		
D. Suspect medi	cal device	9				
Brand name						
Type of device						
Manufacturer na	ne and add	lress	Oper	ator of device		
			$\square_{h}$	ealth professional		
				ser facility		
				istributor		
		Ľ	expir	ation date		
model # catalog #		<b> </b>	[f im	planted, give date		
catalog # serial #				Brie aute		
serial # lot #		,	<b>.</b>	Jantal at 1-1		
other #		<sup>1</sup>	it exp	planted, give date		
Device available f	on onel					
$\square_{\text{yes}}$ $\square_{\text{no}}$	_		ufact	urer _/_/		
Concomitant med						
	produ					
E. Reporter						
Name and address	5	nho	ne #	(781)449-6487		
The National Ped		_		(101)++7-0+07		
P.O. Box 610189,						
,			+01	Alao		
Health profession	al Occuj	pation		Also reported to		
<b>⊻</b> <sub>yes</sub> <b>□</b> <sub>no</sub>				manufacturer		
lf you do NOT wan	-	-		user facility		
disclosed to the mar	ufacturer, p	lace an		□distributor		

A. Patient Informa	ation					
Patient Identifier	Date of birth	Sex	Weight			
1432	03/16/00	female	33	lbs		
B. Adverse event	or product p	roblem				
Advers	e Event & Prod	luct Proble	m			
Outcomes attribut	_	event				
☐ death ☐ disability						
$\Box$ life-threatening $\Box$ congenital anomaly						
hospitalization	required in	ntervention				
other:						
Date of event 01/1 Describe event or		e of report	1/22/2	2005		
believe. This has be		ttle.				
Relevant tests/labo				48-000		
Other relevant his	, including	5 precisti	ng conur	.1011		

C. Suspect med	lication(s)	
Name: malathion	n	
Dose, frequency,	route use	Therapy dates
one time for less t	han 1 hour	01/17/05
		to 01/17/05
Diagnosis for us	e	Event abated after use
head lice	•	stopped or dose reduced
nead nee		
T . 4 #		yes
Lot #	Exp. date	Event reappeared after
		reintroduction
NDC # -		yes
Concomitant me	dical produ	rts
	-	ritation and itching
INIX - also caused i	less severe ir	ritation and itening
D. Suspect med	lical device	
Brand name		<i>,</i>
Type of device		
	me and add	Iress Operator of device
	inc una uat	health professional
		$\square$ user facility
		Expiration date
model # catalog #		If implanted, give date
catalog # serial #		
lot #		If explanted, give date
other #		
Device available	for evaluati	ion?
	_	to manufacturer _/_/
Concomitant me	dical produ	cts
	uicai prouu	
	ulcal produ	
E. Reporter		
E. Reporter		
Name and addres	ss	<b>phone #</b> (781)449-6487
Name and addres The National Pe	<b>ss</b> diculosis A	<b>phone #</b> (781)449-6487 ssociation
Name and addres The National Pe P.O. Box 610189	ss diculosis A , Newton, N	<b>phone #</b> (781)449-6487 ssociation 1A. 02461
Name and addres The National Pe P.O. Box 610189 Health profession	ss diculosis A , Newton, M nal Occuj	phone # (781)449-6487 ssociation IA. 02461 pation Also reported to
Name and addres The National Pe P.O. Box 610189	ss diculosis A , Newton, M nal Occuj	phone # (781)449-6487 ssociation IA. 02461 Dation Also reported to

A. Patient Information						
Patient Identifier	Date of b	irth	Sex	Weight		
1430	11-27-58		female	140	lbs	
B. Adverse event	B. Adverse event or product problem					
Advers	e Event &	Prod	luct Proble	m		
Outcomes attributed to adverse event						
□ death						
□ life-threatening □ congenital anomaly						
$\Box$ hospitalization $\blacksquare$ required intervention						
other: paychological trauma and loss of wages over a lo						
Date of event         10/03/         Date of report         1/18/2005					2005	
D						

#### Describe event or problem

My family was exposed to head lice at their public school and all three of them brought it home. It spread to myself, my daughter's grandmother and our friend's two children. Each of those individuals had a case of it twice after which we have had no furter contact with them. It also spread to several of my children's classmates at the YMCA gymnastics. We were asked to leave the programs at the YMCA per-manently. My oldest daughter is a gymnast and cannot continue her career unless I enroll them at much more expensive academy. A local social service agency has threatened a dependency hearing for the girls based on their missing weeks of school. A meeting is being held with them and the local school officials,myself and several other members of the community. I have retained a lawyer to

advise me of my rights as I feel they have already been Relevant tests/laboratory data

Other relevant history, including preexisting condition We have been using the treatments prescribed by our family physicians over and over and they have caused pain in the scalp and behavioral changes in my daughter such as severe acting out, temper tantrums and severe, uncontollable anger. Triage Unit Sequence #

#### C. Suspect medication(s)

Ovide,lindane,Rid, mayonaise

Dose, frequency	, route use	The	erapy date	s
1 bottle per family once per week	y member,	10-2	2004 t	o 1-2005
Diagnosis for us pediculosis	e			ated after use r dose reduced
Lot #	Exp. date		Event rea reintrodu	ppeared after action
NDC #			yes	

#### **Concomitant medical products**

all medications used frequently over the 2 and a half year period since the inception of this infection

#### D. Suspect medical device

Brand name	
Type of device	
Manufacturer name and address	Operator of device health professional user facility distributor
	Expiration date
model # catalog # serial #	If implanted, give date
lot # other #	If explanted, give date
<b>Device available for evaluation?</b> yes no returned to ma	nufacturer / /
Concomitant medical products	
E. Reporter	
Name and address ph	one # (781)449-6487
The National Pediculosis Associ	ation
P.O. Box 610189, Newton, MA. 02	2461
Health professionalOccupation	manufacturer
If you do NOT want your identity disclosed to the manufacturer, place a	user facility

A. Patient Inform	ation			
Patient Identifier		Sex	Weight	
1416	11/13/89	female	136	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Prod	luct Proble	m	
Outcomes attribut death life-threatening hospitalization other: intense it Date of event 11/2 Describe event or We have been treating between lice shamp her with the shampor out in a rash on her rash stayed there here he took one look a make sure. He said results. Not happy. of the scabies. I have 5 two (4years old) see	ced to adverse of disability         disability         congenital         required in         required in         24/2004       Date         problem         ng headlice for coos and strictly         oo she started ito         stomach, legs, a         reskin itches. W         nd said scabies,         the treatment w         did the on going         o other children	event anomaly ntervention e of report over a year g combing. A ching all ov and bottom. Then I took no tests we ould be the g headlice p and only th	12/22/2 going After treati er and bro Although her to the ere done to same for roblem ca he younges	ing oke or the dr. o any use st
Relevant tests/labo         Other relevant his         The child with scab:         (mild) and is allergi         have no preextisting	em to catch head pratory data story, including ies, 15years old c to erythromiad	g preexisti , has bronch cin. The twi	ng condin nial asthm	tion a

C. Suspect med	dication(s)					
Name: generic l	Name: generic lice shampoo					
Dose, frequency	, route use	The	rapy d	ates		
use entire bottle. t	hick hair.	11/2	24/04	to		
no more than once	e a month.			12/21/04		
Diagnosis for us	e			abated after use		
once headlice.			stopped or dose reduce			
			no			
Lot #	Exp. date		Event	reappeared after		
				duction		
			doorn	topply		
NDC # -	-		uoesii	t apply		
Concomitant me	dical produ	cts				
D. Suspect med	dical device	•				
Brand name						
Type of device						
Manufacturer na	ame and add	lress	6 Oper	ator of device		
			$\square_{h}$	ealth professional		
			$\square_{\rm u}$	ser facility		
			$\square_d$	istributor		
			Expir	ation date		
model #						
catalog #			If im	planted, give date		
serial #						
lot #			- If exp	planted, give date		
other #						
Device available						
$\square_{\text{yes}} \square_{\text{no}}$				urer _/_/		
Concomitant me	uicai produo	cis				
E. Reporter						
Name and addre	SS	р	hone #	(781)449-6487		
The National Pe	diculosis A	sso	ciation			
P.O. Box 610189	, Newton, M	1A. (	02461			
Health professio	nal Occup	oatio	n	Also reported to		
$\mathbf{V}_{\text{yes}}$ $\square_{\text{normalized}}$	)			manufacturer		
If you do NOT wa	nt your identi	ty	[	$\Box$ user facility		
disclosed to the ma	anufacturer, p	lace	an 🔳	□distributor		

A. Patient Inform	ation					
Patient Identifier	Date of bi	rth	Sex	Weight	ţ	
1413	03/30/196	6	female	150	lbs	
B. Adverse event	or produ	ct p	roblem			
Advers	e Event &	Prod	luct Probl	em		
Outcomes attribut	_		event			
death	<b>∠</b> disab	•				
$\blacksquare$ life-threatening $\square$ congenital anomaly						
hospitalization			terventior	1		
other: Hodgkin		cance	r			
Date of event 199	3-1994	Date	e of report	t 12/15	/2004	
seems. All of us de condition. Relevant tests/labo	oratory dat	ta			lition	

C. Suspect medication(s)				
Name: Kwell				
Dose, frequency, route us	se The	erapy d	ates	
nothing regular, just	197	8		
shampoo it on and leave it			to 1980	
there about an hour Diagnosis for use		Event	abated after use	
Lice on head of foster child	living		d or dose reduced	
with family.	nving			
,		doesn	t apply	
Lot # Exp. date	e		reappeared after	
		reintro	oduction	
NDC #		doesn	t apply	
Concomitant medical pro	ducto			
	aucts			
None.				
D. Suspect medical dev	vice			
Brand name	100			
Type of device				
Manufacturer name and	addres	s Oper	ator of device	
		Ē	ealth professional	
			ser facility	
			istributor	
		Expir	ration date	
model #				
catalog #		If im	planted, give date	
serial #		-		
lot #		_ If exp	planted, give date	
other #				
Device available for evalu				
<b>Concomitant medical pro</b>		anufact	urer//	
Conconntant metical pro	ouucis			
E. Reporter				
Name and address	p	hone #	(781)449-6487	
The National Pediculosi	s Asso	ciation		
P.O. Box 610189, Newtor	n, MA.	02461		
Health professional Oc	cupati	on	Also reported to	
<b>✓</b> <sub>yes</sub> □ <sub>no</sub>			manufacturer	
If you do NOT want your id	entity		user facility	
disclosed to the manufacture		an 🔲	□distributor	

	ation			
atient Identifier	Date of birth	Sex	Weight	
1411	07/11/2000	male	37	lbs
. Adverse even				
	se Event & Prod		m	
utcomes attribu		event		
death	∐ disability			
☐ life-threatening		-		
hospitalization	□ required in	itervention		
other:				
ate of event 12/	10/04 <b>Date</b>	e of report	12/13/2	004
Relevant tests/labo Dther relevant his		g preexisti	ng condit	ion

C. Suspect med	ication(s)					
Name: lindane						
1%						
Dose, frequency,	route use	The	rapy d	ates		
ONCE		12/1	0/04	4		
				to 12/10/04		
Diagnosis for use	<u>,</u>	ŀ	Event	abated after use		
SCABIES TREAT				d or dose reduced		
TREATMENTS (						
	-	2	yes			
Lot #	Exp. date			reappeared after		
			reintro	oduction		
NDC # -			yes			
	-					
Concomitant mee	-					
ELIMITE NOV 22	IST UNTIL	12/0	8/04 U	NSUCCESSFUL		
D. Suspect med	Ical device	÷				
Brand name						
Type of device			0			
Manufacturer na	me and add	iress	Ē			
				ealth professional		
				ser facility istributor		
			Expi	ration date		
model #			Ifim	planted, give date		
catalog #				planteu, give uate		
serial # lot #			If over	planted, give date		
other #				nanicu, give uale		
Device available	for avaluet	ion?	1			
	returned		anufact	urer / /		
Concomitant med	lical produ	cts	andraed			
······································						
E. Reporter						
	Name and address phone # (781)449-6487					
The National Pe						
P.O. Box 610189,						
Health profession	nal Occup	patio	n	Also reported to		
<b>⊻</b> <sub>yes</sub> □ <sub>no</sub>				manufacturer		
If you do NOT war	•	•		User facility		
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor		

A. Patient Inform	ation							
Patient Identifier	Date of b	irth	Sex	Weight				
1406	03/02/91		female	90	lbs			
B. Adverse event	B. Adverse event or product problem							
Product Problem								
Outcomes attribut	ed to adv	erse e	event					
death	□disat	oility						
□ life-threatening □ congenital anomaly								
hospitalization required intervention								
other: continued	d reinfesta	tion o	f lice					
Date of event 11/1	12/04	Date	e of report	11/16/2	2004			
Decenthe energy on								

#### Describe event or problem

After treating my daughter with Nix for the third time in six weeks, I found live, crawling lice--dozens of them--on her head the very next morning. (I used a battery-powered Robicomb, which is the only thing I'll ever use again!) That is when I realized that all the previous treatments must also have failed, allowing the lice to reproduce and multiply with abandon. This, despite having spent hours and days washing, drying, bagging, vacuuming and nitpicking until I was nearly blind. I am beyond outraged. In desperation, I called the pediatrician for "something stronger" and she prescribed Ovide, which was absolutely horrible. It smelled like turpentine, and the fumes nearly knocked us out. It made us gag, cough and choke, and even caused one of my kids to have a nosebleed. When will the schools and doctors stop perpetuating the lies about these poisons'

#### Relevant tests/laboratory data

Other relevant history, including preexisting condition
All three of my children have Crohns' diseasea form of
Inflammatory Bowel Diseasethat is a chronic autoimmune
disorder requiring lifelong medication.

C. Suspect me	dication(s)			
Name: Nix				
Dose, frequency	, route use	Thera	apy d	ates
followed package		9/29/0		
instructions exac		2722770	, ,	to 11/12/04
Diagnosis for u		 		abated after use
_	50			d or dose reduced
head lice				a or absorreaded
	<b>I</b>	r	10	
Lot #	Exp. date			reappeared after
		re	eintro	oduction
NDC # -		y	ves	
	-			
Concomitant m	edical produ	cts		
D. Suspect me	dical device	9		
Brand name				
Type of device		,	0	
Manufacturer n	ame and add	iress	Ē	ator of device
				ealth professional
				ser facility
				istributor
			Expi	ration date
model #			Tf :	nlantad aiva data
catalog #			II IM	planted, give date
serial # lot #			TE and	lantal stra data
other #			II exp	planted, give date
Device available	o for oveluet	ion?		
$\square_{\text{yes}} \square_{\text{no}}$			nufact	urer / /
Concomitant m				
	•			
E. Reporter				
Name and addr				(781)449-6487
The National P	ediculosis A	ssoci	ation	
P.O. Box 61018	9, Newton, N	1A. 02	461	
Health profession	onal Occu	pation		Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{n}$	0			manufacturer
If you do NOT wa	ant your ident	ity		user facility
disclosed to the m	anufacturer, p	lace ar	1 🔲	distributor

A. Patient Inform	ation				
Patient Identifier	Date of bi	rth	Sex	Weight	
1401	02/10/199	95	female	86	lbs
B. Adverse event	or produ	ct pi	oblem		
	Product	Prob	lem		
Outcomes attribut	ted to adve	erse e	event		
death	disabi	ility			
□ life-threatening	$\Box_{\text{conge}}$	enital	anomaly		
hospitalization		red in	tervention		
other:					
Date of event 10/1	17/2004	Date	of report	11/4/	/2004
treatment, which sai reinfested up to 2 w head. None of these don't think that they smothering. It's all Lindane, which I D	eeks, we sa e products l / would. W that's left v O NOT wa	aw ac have /e are vitho unt to	tually live helped my now tryin ut getting a	lice on h child an g olive o prescrip	d I il for
Other relevant his			y preexisti	ng cond	ition

Triage Unit Sequence #

#### C. Suspect medication(s)

#### Name: Nix

R&C and Equate Brand Lice Shampoo

Dose, frequency, route use The		erapy dates	
R&C used once on Oct 12 Nix used once on Oct		10/1	17/2004 to
10 Equate Drond 1 Diagnosis for us			11/01/2004 Event abated after use
<b>Diagnosis for use</b> Letter sent home from school saying daugther had nits.			stopped or dose reduced doesn't apply
Lot #	Exp. date		Event reappeared after reintroduction
NDC #			doesn't apply

#### Concomitant medical products

R&C, Nix and equate brand lice shampoo....all used within 3 weeks...from Oct 17 to Nov 1, 2004

#### D. Suspect medical device

Type of device			
Manufacturer name and address	Operator of device		
	health professional		
	$\square$ user facility		
	Expiration date		
model #			
catalog #	If implanted, give date		
serial #			
	If explanted, give date		
other #			
<b>Device available for evaluation?</b> yes no returned to ma	nufacturer / /		
Concomitant medical products			
-			
E. Reporter			
Name and address ph	one # (781)449-6487		
The National Pediculosis Associ	ation		
P.O. Box 610189, Newton, MA. 02	2461		
Health professional Occupation	Also reported to		
<b>⊠</b> <sub>yes</sub> □ <sub>no</sub>	manufacturer		
If you do NOT want your identity	user facility		
disclosed to the manufacturer place a	n distributor		

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1394	07/05/1999	female	55	lbs
B. Adverse event				
	e Event & Pro		em	
Outcomes attribut		event		
$\Box_{\text{death}}$	☐ disability	1		
$\Box$ life-threatening $\Box$ hospitalization	Congenital	anomaly ntervention		
other:	— Tequilea I			
Date of event 10/2	21/2004 <b>Det</b>	e of report	10/28/2	2004
Describe event or		e of report	10/20/	2004
lice returned less that weeks. No reaction Relevant tests/labo	the first time n			51X
Other relevant his	tory, includin	g preexisti	ng condi	tion

C. Suspect med	lication(s)					
Name: Ovide						
Dose, frequency, route use The			apy d	ates		
used as directed by		10/05	5/2004	to.		
physiscian, using				to 10/21/2004		
bottle per application Diagnosis for use		F	Event	abated after use		
School reported th		s	toppe	d or dose reduced		
lice and nits.			ves			
Lot #	Exp. date	yes				
LOI #	Exp. uate			reappeared after		
		r	eintro	oduction		
NDC # -			doesn'	't apply		
Concomitant me	dical produ	cts				
RID - 9/21/2004	Licar produc					
PRONTO - 9/29/2	2004 & 10/28	8/2004	4			
Mayonayse - 9/25		<i>, 2</i> 00	•			
D. Suspect med		<u> </u>				
Brand name		, 				
Type of device						
			$\square_{\rm u}$ $\square_{\rm d}$	ealth professional ser facility istributor		
			Expii	ration date		
model #			Tf im	planted, give date		
catalog #			11 1111	planteu, give date		
serial # lot #			Tf own	alantad aive data		
other #			II ext	planted, give date		
Device available yes no Concomitant me	returned	to ma	nufact	turer <u>/ /</u>		
E. Reporter						
Name and addre	SS	ph	one #	(781)449-6487		
The National Pe	diculosis A	ssoci	ation			
P.O. Box 610189	, Newton, M	1A. 02	2461			
Health professio ✓ yes □ no		pation	1	Also reported to manufacturer		
If you do NOT wa	nt your identi	ity		user facility		
disclosed to the ma	anufacturer, p	lace a	.n 🔳	distributor		

Patient Inform	ation			
tient Identifier	Date of birth	Sex	Weight	
1393	11/20/1960	female	130	lbs
Adverse event	or product p	roblem		
	Product Prob			
tcomes attribut		event		
death	∐ disability			
life-threatening		•		
hospitalization	required in	ntervention		
other:				
te of event 10/2 scribe event or		e of report	10/25/2	004
evant tests/labo		g preexisti	ng aondit	

C. Suspect med	ication(s)				
Name: Kwell					
Nix-1%					
Dose, frequency,	route use	Ther	rapy d	ates	
Nix applied on 10/	23/04	10/23	304		
Lindane applied or				to 10/24/04	
Diagnosis for use	<u>,</u>		Event	abated after use	
1				d or dose reduced	
Ŧ			doesn'	t apply	
Lot #	E-m data				
Lot #	Exp. date			reappeared after	
		I	reintro	oduction	
NDC # -	-		yes		
Concomitant med	lical produ	cts			
	neur prouu	eus			
D. Suspect med	ical device	÷			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			□ h	ealth professional	
				ser facility	
				istributor	
			Expir	ration date	
model #			_		
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
<b>Device available for evaluation?</b>					
Concomitant medical products					
-					
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189,	Newton, N	1A. 0	2461		
Health professional Occupation Also reported to					
<b>V</b> ves □no				manufacturer	
yes □no	t vour identi			■manufacturer ■user facility	
Concomitant med E. Reporter Name and addres The National Ped	<b>lical produ</b> ss diculosis A	cts ph	<b>none</b> # iation		

A. Patient Information						
Patient Identifier	Date of b	irth	Sex	Weight		
1392	02/03/96		female	50	lbs	
B. Adverse even	t or produ	ict pi	oblem			
	Product	Prob	lem			
Outcomes attribu	ted to adv	erse e	event			
death	□disat	oility				
□ life-threatening	$\Box_{\rm cong}$	enital	anomaly			
hospitalization	□ <sub>requi</sub>	red in	tervention			
other:	-					
Date of event 10/	<b>Date of event</b> 10/18/04 <b>Date of report</b> 10/25/2004					
Describe event or	problem					
The Kwell (prescri	ption) didn	't wor	k. I combe	ed out hair	,	
<b>.</b> .	· · ·				·	
<b>.</b> .	e house, w	ashed	everything	g put stuff	ed	
nits etccleaned th animals in bag. Dry night. etc treated	e house, w ved pillow myself an	ashed each r d still	everything ight. Vacc found a liv	g put stuffe uumed eac re adult lic	ed ch ce	
nits etccleaned th animals in bag. Dry night. etc treated on my daughter on	e house, w yed pillow of myself an Friday 10/2	ashed each r d still 22/04.	everything iight. Vacc found a liv I found a l	g put stuffe uumed eac e adult lic ive lice or	ed ch ce	
nits etccleaned th animals in bag. Dry night. etc treated on my daughter on me Saturday, 10/23	e house, w ved pillow myself an Friday 10/2 /04. Treate	ashed each r d still 22/04. ed Kw	everything hight. Vacc found a liv I found a l vell shampo	g put stuffe uumed eac re adult lic ive lice or po again.	ed ch ce 1	
nits etccleaned th animals in bag. Dry night. etc treated on my daughter on me Saturday, 10/23 Combing hair night	e house, w ved pillow myself an Friday 10/2 /04. Treate	ashed each r d still 22/04. ed Kw	everything hight. Vacc found a liv I found a l vell shampo	g put stuffe uumed eac re adult lic ive lice or po again.	ed ch ce 1	
nits etccleaned th animals in bag. Dry night. etc treated on my daughter on me Saturday, 10/23	e house, w ved pillow myself an Friday 10/2 /04. Treate	ashed each r d still 22/04. ed Kw	everything hight. Vacc found a liv I found a l vell shampo	g put stuffe uumed eac re adult lic ive lice or po again.	ed ch ce 1	
nits etccleaned th animals in bag. Dry night. etc treated on my daughter on me Saturday, 10/23 Combing hair night	e house, w ved pillow myself an Friday 10/2 /04. Treate	ashed each r d still 22/04. ed Kw	everything hight. Vacc found a liv I found a l vell shampo	g put stuffe uumed eac re adult lic ive lice or po again.	ed ch ce 1	

Relevant tests/laboratory data

#### **Other relevant history, including preexisting condition** My daughter is adhd. Has some breathing problems at times. Over the counter treatments

Triage Unit Sequence #

#### C. Suspect medication(s)

Name:	Kwell

Dose, frequency	, route use	The	erapy date	es
Twice, Monday 1 10/25/04. Enough		10/2	18/04 t	o 10/25/04
Diagnosis for us	e		Event aba	ated after use
Hope the second of	dosage worke	ed.	stopped o	or dose reduced
			no	
Lot #	Exp. date		Event rea reintrodu	ppeared after action
NDC # -	-		no	

#### **Concomitant medical products**

Not sure, checking head nightly. Drying hair after combing each night. Drying bedding (pillows, blankets, sheets before bed each nigh) Called school to report head lice.

#### D. Suspect medical device

Brand name	
Type of device	
Manufacturer name and address	Operator of device health professional user facility distributor
model #	Expiration date
	If implanted, give date
	If explanted, give date
<b>Device available for evaluation?</b> Use no returned to ma	nufacturer ///
Concomitant medical products	
E. Reporter	
Name and address ph	one # (781)449-6487
The National Pediculosis Associ	ation
P.O. Box 610189, Newton, MA. 02	2461
Health professionalOccupation	manufacturer
If you do NOT want your identity disclosed to the manufacturer, place a	$ \square user facility \\ \square distributor $

A. Patient Inform	ation					
Patient Identifier		th Sex	Weight			
1388	05/11/1995	male	82 lbs			
3. Adverse event	or product	t problem				
	Adverse					
Outcomes attribut						
⊔ death ⊔ disability						
$\blacksquare$ life-threatening $\Box$ congenital anomaly						
hospitalization		d intervention				
Date of event 20/0			10/10/2004			
Date of event 20/0 Describe event or		ate of report	10/19/2004			
Relevant tests/labo	oratory data					

C. Suspect med	lication(s)			
Name:				
perithrin				
Dose, frequency,	route use	Ther	apy d	ates
1 time		2000		
				to 2000
Diagnosis for use	9		Event	abated after use
sister had lice				d or dose reduced
sister had nee			doesn'	t apply
Lot #	Exp. date			
	Exp. uate			reappeared after oduction
dont know		ľ	reintro	auction
NDC # -	-	$\neg$	yes	
Concomitant mee	dical produ	cts		
D. Suspect med	ical device	;		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			h	ealth professional
				ser facility
			⊔d	istributor
			Expii	ration date
model #			T£ :	-landad atau dada
catalog #			II IM	planted, give date
serial # lot #			If over	planted, give date
other #			n ext	Janteu, give uate
Device available	for evaluati	ion?		
$\square_{\text{yes}}$ $\square_{\text{no}}$			anufact	urer _/_/
Concomitant mee				
E. Reporter				
Name and addres	ss	nh	one #	(781)449-6487
The National Pe		Ē.		(,.) 0101
P.O. Box 610189.				
Health profession				Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$				manufacturer
If you do NOT war	nt your identi	ty		user facility
disclosed to the ma	•	•	in 🔲	distributor

atient Identifier	Date of bi	irth	Sex	Weight	
1386	01/04/55		female	138	lbs
3. Adverse event	or produ	ict pi	roblem		
Advers	e Event &	Prod	luct Prob	lem	
Outcomes attribut	ed to adve	erse e	event		
death	🗹 disab	ility			
□ life-threatening	$\Box_{\text{conge}}$	enital	anomaly		
hospitalization	_		nterventio	n	
other: its drivin	g me insan	e			
Date of event 10/1	5/04	Date	e of repo	rt 10/16/	2004
Describe event or	problem				
	at feels like	e our	skin is be	eing eaten f	rom
	at feels like	e our	skin is be	ing eaten f	ìrom
the head lice???th the inside. Relevant tests/labo			skin is be	ing eaten f	Ìrom

C. Suspect me	dication(s)	
Name: Rid		
Dose, frequency	. route use	Therapy dates
As directed on the		10/15
	e puekuge	to 10/16
Diagnosis for us	se	Event abated after use
doctor said it was	head lice bu	t it stopped or dose reduced
isn't responding:	itching,	no
Lot #	Exp. date	Event reappeared after
7430000414		reintroduction
		VAS
NDC # -	-	yes
Concomitant me	edical produ	cts
none		
D. Suspect me	dical device	2
Brand name		
Type of device		
Manufacturer n	ame and add	Iress Operator of device
		health professional
		user facility
		distributor
		Expiration date
model #		If inveloped a size data
catalog #		If implanted, give date
serial # lot #		
other #		If explanted, give date
Device available	for evaluat	 ion?
	_	
$\square_{\text{yes}}$ $\square_{\text{no}}$	returned	to manufacturer//
$\square_{\text{yes}}$ $\square_{\text{no}}$	returned	to manufacturer//
Uyes no Concomitant me	returned	to manufacturer//
Uves no Concomitant mo	returned edical produ	to manufacturer//
Uyes no Concomitant me E. Reporter Name and addre	edical produ	to manufacturer <u>/ /</u> cts phone # (781)449-6487
Device available yes no Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189	edical produ	to manufacturer// cts phone # (781)449-6487 .ssociation
Ves no Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	edical produ ess ediculosis A 9, Newton, M onal Occu	to manufacturer / / / cts phone # (781)449-6487 .ssociation
Ves no Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	ediculosis A 9, Newton, M 0 0 0	to manufacturer / / cts phone # (781)449-6487 .ssociation IA. 02461 Dation Also reported to manufacturer

A. Patient Inform					
Patient Identifier				Weight	
1383	11/16/1972		ale	140	lbs
3. Adverse event					
	e Event & l			em	
Outcomes attribut			nt		
death	✓ disabi		1		
$\Box$ life-threatening $\Box$ hospitalization			-		
other: CAN'T S		eu inter	vention		
				10/10/0	
Date of event 10/0 Describe event or		Date of	report	10/12/2	2004
Relevant tests/labo Other relevant his N/A			reexisti	ng condit	tion

C. Suspect med	lication(s)			
Name: lindane				
Dose, frequency,	route use	The	rapy d	ates
2 TWICE A DAY		1/1/2		
WITH BATHS.	ALONU	1/1/2	2005	to
				10/10/2004
Diagnosis for us	e			abated after use
GET RID OF LIC	GET RID OF LICE		stopped or dose reduc	
			no	
Lot #	Exp. date		Event	reappeared after
				duction
NDC # -	-		doesn	t apply
Concomitant me	dical produ	cts		
	· · · · ·			
D. Suspect med	lical device			
		;		
Brand name				
<u>Type of device</u> Manufacturer na			0	aton of dontos
Manufacturer na	ime and add	iress	<u> </u>	ator of device
				ealth professional
				ser facility
			-	istributor
			Expir	ation date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device available			0	, ,
	returned		anufact	urer _/_/
Concomitant medical products				
E. Reporter				
Name and address phone # (781)449-6487				
The National Pe				
P.O. Box 610189	, Newton, N	1A. (	02461	
Health professio		oatio	n	Also reported to
⊻ <sub>yes</sub> □ <sub>nc</sub>				
If you do NOT was	•	•	_	user facility
disclosed to the ma	unufacturer, p	lace	an 🔲	□distributor

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
1375	02/17/1997	female	60 lbs
B. Adverse event	or product p	roblem	
	Product Prob	olem	
Outcomes attribut	ed to adverse	event	
death	∐ disability		
☐ life-threatening		-	
hospitalization	required in	ntervention	
other:			
Date of event 04/0	04-10/0 <b>Dat</b>	e of report	10/1/2004
Describe event or	-		
From april 04 thru o		-	
head lice on and off			<b>^</b>
Nothing seems to w everyday, cut her ha			
product we see live			
		ry mustilite	
Relevant tests/labo	oratory data		
		• .•	1.4
Other relevant his		g preexisti	ng condition
She has juvenile dia	betes.		

C. Suspect medication(s)					
Name: Nix					
kwell,rid	l,pronto				
Dose, frequency,	, route use	The	rapy d	ates	
nix about 15times	nix about 15times. kwell		4		
2x,rid about 15 tir	nes,pronto			to 10/04	
Diagnosis for us	e	ŀ	Event	abated after use	
Doctor suggested nix each week				d or dose reduced	
for 6 weeks.		ĸ		t apply	
Lot#	E-m Jo4a				
Lot #	Exp. date			reappeared after	
			reintro	oduction	
NDC # -			doesn	t apply	
Concomitant me	-	ote			
Concomitant me	dical produ	cis			
D. Suspect med	lical device	÷.			
Brand name					
Type of device					
Manufacturer na	ame and add	iress	_	ator of device	
				ealth professional	
				ser facility	
				istributor	
			Expi	ration date	
model #				ulantad stra data	
catalog #				planted, give date	
serial #			Te		
lot # other #			If exp	planted, give date	
	e 1 4				
<b>Device available</b>			onufoot	uror / /	
Concomitant me			anuraci	ulei _/_/	
	uicui prouu	eus			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	1A. (	02461		
Health professio	nal Occu	patio	n	Also reported to	
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$	)			manufacturer	
If you do NOT was	nt your ident	ity		user facility	
disclosed to the ma	unufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
1374	01/26/1992	female	100 lbs
B. Adverse event	or product p	roblem	
	Adverse Eve	ent	
Outcomes attribut	ted to adverse o	event	
death	∐ disability		
☐ life-threatening	$\Box_{\text{congenital}}$	anomaly	
hospitalization	required ir	ntervention	
other: hair loss			
Date of event 9/04	4 Date	e of report	10/1/2004
Describe event or	problem		
This child used a lic			-
on the back of her h	ead and has lost	big patche	s of hair.
Relevant tests/labo	oratory data		
Other relevant his	story, including	p preexisti	ng condition
None known			a
None known			

C. Suspect med	lication(s)			
Name:				
unsure				
Dose, frequency, route use The			rapy da	ates
Used once or twic	e a month	2000	0	to 2004
Diagnosis for use	e	<u> </u>	Event a	abated after use
several years of lid	ce shampoo	use	stoppe	d or dose reduced
			doesn'	t apply
Lot #	Exp. date			reappeared after oduction
NDC # -	-		doesn'	t apply
Concomitant me	dical produ	cts		
unsure if hair will	grow back			
D. Suspect med	lical device	÷		
Brand name				
Type of device				
Manufacturer na	ime and add	iress		ator of device ealth professional ser facility istributor
model #			Expir	ation date
catalog #			If im	planted, give date
serial #				
lot # other #			If exp	olanted, give date
Device available	Image: The second se	to m		urer <u>/ /</u>
E. Reporter Name and addres	20	n	hone #	(781)449-6487
The National Pe				(781)449-0487
P.O. Box 610189				
Health profession				Also reported to

A. Patient Inform	ation				
Patient Identifier	Date of bi	irth	Sex	Weigh	ıt
1367	5/18/99		female	32	lbs
B. Adverse event	or produ	ict p	oblem		
	Product				
Outcomes attribut	_		event		
death	∐ disab	•			
☐ life-threatening	<u> </u>		anomaly		
hospitalization	□requi	red ir	terventior	1	1
other:					
Date of event 9/23	3/04	Date	e of repor	t 9/2	3/2004
Describe event or p This was my second started combing the Yesturday the 22nd and afternoon and th and afternoon and th Relevant tests/labo	I treatment louse out a I combed a hey were s	and th my da till al	ney were s aughter tw	till alive ice, mor	ning
<b>Other relevant his</b> None			g preexist	ing con	dition

	n(s)			
Name: Ovide				
Dose, frequency, route v	ise [	Ther	apy d	ates
		9/13/		
	-	/15/	04	to 9/23/04
Diagnosis for uso		- 1.	Front	abated after use
Diagnosis for use				d or dose reduced
LICE		2	stoppe	u of dose reduced
			yes	
Lot # Exp. da	te	1	Event	reappeared after
		r	eintro	oduction
			yes	
NDC #				
Concomitant medical pr	oduc	ts		
Currently I am combing m	ornin	g an	d after	noon.
D. Suspect medical de	vice			
-	100			
Brand name Type of device				
Manufacturer name and	hhe	rocc	Oner	ator of device
Manufacturer name and	auu	1 033	Ē	
				ealth professional
				ser facility
			$\square_d$	ser facility istributor
			$\square_d$	ser facility
			□d Expi	ser facility istributor ration date
catalog #			□d Expi	ser facility istributor ration date
catalog # serial #			□d Expin If im	ser facility istributor ration date planted, give date
model # catalog # serial # lot # other #			□d Expin If im	ser facility istributor
catalog # serial # lot # other #			□d Expin If im	ser facility istributor ration date planted, give date
catalog # serial # lot # other # Device av <u>ail</u> able for eval			Expin If im	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for eval	med t	o ma	Expin If im	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for eval	med t	o ma	Expin If im	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for eval	med t	o ma	Expin If im	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for eval $\Box_{yes}$ $\Box_{no}$ $\Box_{retur}$ Concomitant medical pr	med t	o ma	Expin If im	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for eval  yesnoretur Concomitant medical pr E. Reporter	med t	<u>o ma</u> ts	Expin If im If exp	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for eval $\Box_{yes} \Box_{no} \Box_{retur}$ Concomitant medical pr E. Reporter Name and address	rned t	o ma ts ph	Expir Expir If im If exp	ser facility istributor ration date planted, give date planted, give date
catalog # serial # other # Device available for eval Device available for e	rned to roduc	o ma ts ph ssoc	Expir If im If exp anufact	ser facility istributor ration date planted, give date planted, give date
catalog #	is As	o ma ts ph ssoc	Expir Expir If im If exp anufact anufact anufact 2461	ser facility istributor ration date planted, give date olanted, give date urer _/_/ (781)449-6487
catalog #	rned to roduc	o ma ts ph ssoc	Expir Expir If im If exp anufact anufact anufact 2461	ser facility istributor ration date planted, give date olanted, give date urer _/_/ (781)449-6487
catalog #	is As	o ma ts ph ssoc: A. 0 atio	Expir Expir If im If exp anufact anufact anufact 2461	ser facility istributor ration date planted, give date olanted, give date urer _/_/ (781)449-6487

A. Patient Inform	ation				
Patient Identifier		irth	Sex	Weight	
1362	1/17/1994		female	78	lbs
B. Adverse event					100
	Product				
Outcomes attribut	ed to adv	erse e	vent		
$\Box_{\text{death}}$	disat		( chit		
□ life-threatening		•	anomaly		
hospitalization			tervention	1	
other:					
Date of event 199	0 2004	Data	of report	9/16/	2004
Describe event or		Date	orreport	, 9/10/	2004
be good for her) I ha they wont go away	-	er hao	r, I have d	one it all	and
Relevant tests/labo Other relevant his none			preexist	ing cond	ition

C. Suspect medication(s)						
Name: Ovide						
All of the	e stuff!!!					
Dose, frequency,	, route use	Ther	Therapy dates			
As much as necessary, at 199						
least once a week				to 2004		
Diagnosis for us	e	I	Event	abated after use		
NONE WORK!!!		s	toppe	d or dose reduced		
			no			
Lot#	E-m data					
Lot #	Exp. date			reappeared after		
		r	reintro	oduction		
NDC # -	-	-	yes			
Concomitant me	dical produ	cts				
all medications, as	=					
an medications, a	s oncen as pos	551010				
D. Suspect med	dical device	<del>)</del>				
Brand name						
Type of device						
Manufacturer name and address Operator of device						
	ame and add	lress	Oper	ator of device		
	ame and add	lress	<u> </u>			
	ame and add	lress		ealth professional ser facility		
	ame and add	lress		ealth professional		
	ame and add	lress	□h □u □d	ealth professional ser facility		
	ame and add	lress	□h □u □d Expin	ealth professional ser facility istributor <b>ration date</b>		
Manufacturer na	ame and add	lress	□h □u □d Expin	ealth professional ser facility istributor		
Manufacturer na model # catalog # serial #	ame and add	lress	Expin	ealth professional ser facility istributor <b>ration date</b> planted, give date		
Manufacturer na model # catalog # serial # lot #	ame and add	lress	Expin	ealth professional ser facility istributor <b>ration date</b>		
Manufacturer na model # catalog # serial # lot # other #			Expin	ealth professional ser facility istributor <b>ration date</b> planted, give date		
Manufacturer na model # catalog # serial # lot # other # Device av <u>ail</u> able	f <u>or</u> evaluat	  ion?	Expir If im	ealth professional ser facility istributor ration date planted, give date planted, give date		
Manufacturer na model # catalog # serial # lot # other # Device available □_yes □_no	for evaluat	  ion? to ma	Expir If im	ealth professional ser facility istributor ration date planted, give date planted, give date		
Manufacturer na model # catalog # serial # lot # other # Device av <u>ail</u> able	for evaluat	  ion? to ma	Expir If im	ealth professional ser facility istributor ration date planted, give date planted, give date		
Manufacturer na model # catalog # serial # lot # other # Device available □ Ves □ Concomitant me	for evaluat	  ion? to ma	Expir If im	ealth professional ser facility istributor ration date planted, give date planted, give date		
Manufacturer na model # catalog # serial # other # Device available Device available Uyes Dno Concomitant me E. Reporter	for evaluat returned dical produ	to ma	Expin If imp	ealth professional ser facility istributor ration date planted, give date olanted, give date urer/_/		
Manufacturer na model # catalog # serial # lot # other # Device available Device available Device available Concomitant me E. Reporter Name and addre	for evaluat returned dical produ ss	ion? to ma cts	Expin If imp	ealth professional ser facility istributor ration date planted, give date planted, give date urer/_/		
Manufacturer na model # catalog # serial # other # Device available Uyes Uno Concomitant me E. Reporter Name and addre The National Pe	for evaluat returned dical produ ss sdiculosis A	to ma cts	Expin If imp If exp inufact	ealth professional ser facility istributor ration date planted, give date olanted, give date urer/_/		
Manufacturer na model # catalog # serial # other # Device available Uves Uno Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189	for evaluat returned dical produ ss diculosis A 9, Newton, M	to ma cts	Expin If imp If exp inufact	ealth professional ser facility istributor ration date planted, give date olanted, give date urer/_/		
Manufacturer na model # catalog # serial # other # Device available Uyes Uno Concomitant me E. Reporter Name and addre The National Pe	for evaluat returned dical produ ss diculosis A 9, Newton, M nal Occuj	ion? to ma cts ph sssoci	Expin Expin If imp If exp unufact iation 2461	ealth professional ser facility istributor ration date planted, give date olanted, give date urer/_/		
Manufacturer na model # catalog # serial # other # Device available Uves Uno Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	for evaluat returned dical produ ss diculosis A b, Newton, N nal Occuj	ion? to ma cts ph .ssoci IA. 02	Expin Expin If imp If exp unufact iation 2461	ealth professional ser facility istributor ration date planted, give date planted, give date urer/_/ (781)449-6487 Also reported to		

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weigh	t
1360	04/25/92		female	85	lbs
B. Adverse event	or produ	lct p	roblem		
	Product				
Outcomes attribut	ed to adv	erse (	event		
$\Box_{\text{death}}$	□disat	oility			
□ life-threatening		•	anomaly		
$\square$ hospitalization			nterventior		
· ·	- requi	red II	nerventior	1	
other:					
Date of event 09/1	4/04	Date	e of repor	t 9/15	5/2004
Describe event or	problem				
Patient was found to					
lice (and numerous	,				
the lice. After the lice					
nits remained. We c					
two treatments with				-	iter
these two treatment					
combing (with a me		-	-	-	
plastic combs provi			-		-
inadequate), the pat					
hair and could not r					
that this is a comple				-	
serve its intended p	-				
to the letter each tim					
attempted a home re	-				
cooking oil and vine			nsiderably	more su	ccess.
Relevant tests/labo	oratory da	ita			
Other relevant his	story, incl	udin	g preexist	ing con	dition

C. Suspect medic	cation(s)			
Name:				
Dose, frequency, r	oute use	Ther	apy d	ates
				to
Diagnosis for use				abated after use d or dose reduced
Lot # E	xp. date			reappeared after oduction
NDC # -	-			
D. Suspect medic Brand name Type of device Manufacturer nan				ator of device ealth professional ser facility istributor
				ration date
model # catalog # serial #			If im	planted, give date
lot # other #			If exp	planted, give date
Device available fo yes no Concomitant medi	returned	to ma	unufact	turer/_/
E. Reporter				
Name and address		ph	one #	(781)449-6487
The National Pedi	iculosis A	ssoci	iation	
P.O. Box 610189, 1	Newton, N	1A. 0	2461	
Health professiona yes no If you do NOT want disclosed to the man	your identi	ity		Also reported to manufacturer user facility distributor

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
1359	06/23/1995	female	110 lbs
B. Adverse event	or product p	roblem	
	Product Prob	olem	
Outcomes attribut	ed to adverse	event	
$\Box_{\text{death}}$	disability		
□ life-threatening	Congenital	anomaly	
hospitalization	required in	ntervention	
other:			
Date of event 09/1	1/2004 <b>Dat</b>	e of report	9/13/2004
I treated my daught I treat with a psticic daughter has asthma mom did. Relevant tests/labo	le. The product a. I do not want	did not kil	l the lice.My
Other relevant his	story, includin	g preexisti	ng condition

C. Suspect med	lication(s)			
Name: Rid				
tea tree o	oil			
Dose, frequency,	, route use	The	erapy d	ates
one bottle of RID	and I add	09/1	1/2004	
tea tree oil to my				to 09/13/2004
Diagnosis for us	- e		Event	abated after use
				d or dose reduced
There was not an reaction but I am a		ere		
1JL-:£TL	<u>. 1</u>		doesn	t apply
Lot #	Exp. date			reappeared after
			reintro	oduction
NDC # -			doesn	t apply
	-			
Concomitant me	dical produ	cts		
D. Suspect med	lical device	•		
Brand name				
Type of device				
Manufacturer na	me and add	lress	6 Oper	ator of device
			$\square_{h}$	ealth professional
				ser facility
			$\square_d$	istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #			_	
lot #			_ If exp	planted, give date
other #				
<b>Device available</b>				urer / /
Concomitant me	dical produ	cts		
· · · · · · · · · · · · · · · · · · ·				
E. Reporter				
Name and addre	SS	р	hone #	(781)449-6487
The National Pe	diculosis A	sso	ciation	
P.O. Box 610189	, Newton, N	1A. (	02461	
Health professional Occupation Also reported to ↓ yes □no □manufacturer				
-				□ manufacturer □ user facility
If you do NOT was		-		
disclosed to the ma	inutacturer, p	lace	an 📖	

A. Patient Informa	ation					
Patient Identifier	Date of birth	Sex	Weight			
1354	11/16/97	female	50	lbs		
B. Adverse event	or product p	problem				
Product Problem						
Outcomes attribut	_					
death	∐ disability					
□ life-threatening		l anomaly				
hospitalization		intervention				
other:						
Date of event 8/23	5/04 <b>Da</b>	te of report	9/5/	2004		
to get rid of the head						
Relevant tests/labo	ratory data					
Other relevant his	tory, includii	ng preexisti	ing condi	tion		

C. Suspect medication(s)					
Name: lindane					
rid,nix,vi	nager				
Dose, frequency,	route use	The	rapy d	ates	
once every three t	o seven	8/23/	/04		
days				to 9/5/04	
Diagnosis for us	e		Event	abated after use	
head lice		s	stoppe	d or dose reduced	
neud nee			doesn'	t apply	
Lot #	Even data				
LOI #	Exp. date			reappeared after	
		1	reintro	oduction	
NDC # -	-		yes		
Concomitant me	dical produ	icts			
	aron prou				
D. Suspect med	lical devic	е			
Brand name					
Type of device					
Manufacturer na	me and ad	dress	Oper	ator of device	
				ealth professional	
				ser facility	
				istributor	
			Expir	ration date	
model #			TC		
catalog #			II Im	planted, give date	
serial # lot #			TE ann	lantad aina data	
other #			n exp	planted, give date	
Device available		ion?	1		
$\square_{\text{yes}} \square_{\text{no}}$			anufact	urer / /	
Concomitant me					
E. Reporter	F. Reporter				
Name and addre	SS	nł	none #	(781)449-6487	
The National Pe		<u> </u>		(/01)113 0107	
	P.O. Box 610189, Newton, MA. 02461				
Health professio	nal Occu	patio	n	Also reported to	
$\mathbf{V}_{\text{yes}}$ $\square_{\text{normalized}}$		-		manufacturer	
If you do NOT was	nt your ident	ity		user facility	
disclosed to the manufacturer, place an distributor				distributor	

A. Patient Inform	ation				
Patient Identifier	Date of bir	th Sex	W	eight	
1351	07/22/1989	fema	le 12	25	lbs
B. Adverse event	t or produc	t proble	m		
Advers	se Event & P	roduct P	roblem		
Outcomes attribut	_				
death	<b>∠</b> disabili	-			
$\Box$ life-threatening		ital anom	-		
hospitalization	□ require	d interver	ntion		
other:					
Date of event 05/2 Describe event or		Date of re	port	9/4/2	004
disabilities and beha and I don't even kno may have.	-	-	•		ne
Relevant tests/labo Other relevant his			existing	condit	ion

C. Suspect med	dication(s)				
Name: Rid					
Nix, tea	tree oil, gen	eric li	ce trea	tment	
Dose, frequency	, route use	Ther	apy da	ates	
When she was a b	aby, after	1989	,		
her parents split u	•		to 1992		
time she come to a Diagnosis for us	e de la companya de l	I	Event (	abated after use	
i don't know how				d or dose reduced	
I don't know now	to answer				
<b>*</b>			doesn	t apply	
Lot #	Exp. date			reappeared after	
		r	eintro	oduction	
NDC # -	l	-	doesn'	t apply	
	- 	-			
Concomitant me	dical produ	cts			
D. Suspect med		9			
Brand name					
Type of device Manufacturer na	maandada	Imaga	Oner	aton of dortoo	
	ante anti aut	11 655	L Â	ator of device	
				ealth professional ser facility	
				istributor	
			Expir	ation date	
model # catalog #			If im	planted, give date	
catalog # serial #				planteu, give unte	
lot #			If exr	planted, give date	
other #			псяр	Juniceu, give uute	
<b>Device available</b>			nufact	uror / /	
Concomitant me	dical produ		muraci	uici//	
Conconnunt me	arear produ	~~			
E. Reporter					
Name and addre	ss	ph	none #	(781)449-6487	
The National Pe	diculosis A	ssoci	iation		
P.O. Box 610189	, Newton, M	1A. 0	2461		
Health professio ✓ <sub>yes</sub> □ <sub>nc</sub>		patio	n	Also reported to manufacturer	
If you do NOT wa	nt your ident	ity		user facility	
disclosed to the ma	-		in 🔲	distributor	

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
1348	06/07/199	98	female	60	lbs
B. Adverse event	or produ	ict p	roblem		
	Product	Prob	lem		
Outcomes attribut	ed to adv	erse e	event		
death	□disab	oility			
□ life-threatening	$\Box_{\rm cong}$	enital	anomaly		
hospitalization	□ <sub>requi</sub>	red ir	ntervention	ı	
other:					
Date of event 8/7/	04	Date	e of repor	t 9/2/	2004
Describe event or	problem				
treated with Nix, Ri					
live lice (most small					
removal, another in			later treate	ed with oli	ve
oil this time. Still fi	nding live	lice.			
Delevent testa/lebs	motone do	to			
Relevant tests/labo	oratory da	ta			
Other relevant his	tory, incl	uding	g preexist	ing condi	ition
	U,			U	

C. Suspect med	dication(s)			
Name: Nix				
Dose, frequency	, route use	Ther	apy d	ates
shampooed every	night for a	8/7/0	4	
week	U			to 9/2/04
Diagnosis for us	e	F	Event	abated after use
lice killer				d or dose reduced
			doesn'	t apply
Lot #	Exp. date	F	Event	reappeared after
		r	eintro	oduction
			yes	
NDC # -	-		,	
Concomitant me	dical produ	cts		
D. Suspect med	dical device	9		
Brand name				
Type of device				
Manufacturer na	ame and add	lress	Oper	ator of device
			Ē	ealth professional
				ser facility
				istributor
			Expi	ration date
model #			Tf im	planted, give date
catalog #			11 1111	planteu, give uate
serial #			70	
lot # other #			If exp	planted, give date
<b>Device available</b>	for evaluat		nufact	urer / /
Concomitant me				
E. Reporter				
Name and addre	SS	ph	one #	(781)449-6487
The National Pe	diculosis A	ssoci	ation	
P.O. Box 610189	, Newton, M	1A. 02	2461	
Health professio	nal Occuj	patior	1	Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{normalized}}$	)			manufacturer
If you do NOT wa	nt your ident	ity		user facility
disclosed to the ma	anufacturer, p	lace a	n 🔲	□ distributor

A. Patient Inform	ation				
Patient Identifier	Date of bi	irth	Sex	Weigh	t
1347	08/19/94		female	54	lbs
B. Adverse even	t or produ	ict pr	oblem		
	Product	Prob	lem		
Outcomes attribut	ted to adve	erse e	event		
death	∐disab	ility			
□ life-threatening		enital	anomaly		
hospitalization		red in	tervention		
other:					
Date of event 08/0	01/04	Date	e of report	8/3	1/2004
complained for two had a dry scalp fror two-three weeks aft just please scratch r had maybe 50 head We treated her head 5%,Ovide 0.5% and today, I am still pull washed everything, for the last 9 days a spray. Relevant tests/labo	n swimmin ter her first ny head mo lice and pro l with RidX l with RidX l with the a ling live lic vaccumed nd sprayed	g in t componentiation obably (, olivenithe e off the e l prob	he pool so plaint, she e and I the y 500 eggs ve oil, pern otic bactrir of her head ntire house	much. A asked m n realize in her h nethrin n. As of d. I have e twice a	About ne to ed she nair.
Other relevant his	-				

C. Sus	pect med	dication(s)			
Name:	malathio	n			
	permethr	in 5%, olive	oil, l	ice sray	/
Dose, fi	requency	, route use	The	rapy d	ates
malatior	n 0.5% use	ed 3/4 of a	8/24	/04	
bottle,pe	ermethrin	5% 1 dose,			to 8/30/04
Diagno	doco_oliv sis for us	e		Event	abated after use
head lice	2			stoppe	d or dose reduced
				no	
Lot #		Exp. date		Event	reappeared after
					oduction
NDC #				yes	
	-	-			
Concon	nitant me	dical produ	cts		
D. Sus	pect med	dical device	Э		
Brand 1	name				
Type of	device				
Manufa	ncturer na	ame and add	lress	Oper	ator of device
Manufa	icturer na	ame and add	lress		
Manufa	icturer na	ame and add	lress	$\square_h$	ealth professional
Manufa	icturer na	ame and ado	lress	$\square_{h}$	ealth professional ser facility
Manufa	ncturer na	ame and add	lress	$\square_h$ $\square_u$ $\square_d$	ealth professional ser facility istributor
			lress	$\square_h$ $\square_u$ $\square_d$	ealth professional ser facility
model #	ŧ		lress	Expin	ealth professional ser facility istributor
model # catalog	ŧ #		lress	Expin	ealth professional ser facility istributor ration date
model # catalog serial #	ŧ		lress	Expin	ealth professional ser facility istributor ration date planted, give date
model # catalog serial #	ŧ #		lress	Expin	ealth professional ser facility istributor ration date
model # catalog serial # lot # other # Device	# #  av <u>ail</u> able	f <u>or</u> evaluat	 ion?	Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog serial # lot # other # Device : yes	# # available	for evaluat	ion?	Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog serial # lot # other # Device : yes	# # available	f <u>or</u> evaluat	ion?	Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog serial # lot # other # Device :  Ves Concon	# # available □_no nitant me	for evaluat	ion?	Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog serial # lot # other # Device : yes Concon <b>E. Rep</b> o	# # available □_no nitant me	for evaluat returned dical produ	ion? to m cts	Expin Lif imj	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog serial # lot # other # Device = yes Concon =. Repu	# # available □ no nitant me orter nd addre	for evaluat returned dical produ	ion? to m cts	Liff exp anufact	ealth professional ser facility istributor ration date planted, give date olanted, give date
model # catalog serial # lot # other # Device : yes Concon E. Repo Name a The Na	# # available  nitant me orter nd addre tional Pe	for evaluat returned dical produ ss	ion? to m cts	If explanation If explanation If explanation If explanation	ealth professional ser facility istributor ration date planted, give date olanted, give date
model # catalog serial # lot # other # Device · yes Concon E. Repu Name a The Na P.O. Bo	# # available  nitant me orter nd addre tional Pe	for evaluat returned dical produ ss diculosis A 9, Newton, N nal Occu	pi ion? cts pi assoc	hone #	ealth professional ser facility istributor ration date planted, give date olanted, give date
model # catalog serial # lot # other # Device :  yes Concon <u>=. Repu</u> Name a The Na P.O. Bo Health ☑ yes	# # available □ nitant me orter nd addre tional Pe tional Pe ox 610189 professio □	for evaluat returned dical produ ss diculosis A 9, Newton, N nal Occu	ion? to m cts sssoc 1/A. ( patio	hone #	ealth professional ser facility istributor ration date planted, give date planted, give date clanted, give date (781)449-6487

A. Patient Info				~	ļ		
Patient Identifi			rth	Sex	ľ	Weigh	ıt
1346		11/09/62		female		110	lbs
B. Adverse ev	ent						
		Advers					
Outcomes attri	bute			event			
☐ death			-				
☐ life-threaten	Ũ			anomaly			
hospitalizati	on		red in	terventi	on		
other:							
Date of event (	)8/04	4/	Date	of repo	ort	8/30	0/2004
Describe event	or p	roblem					
Relevant tests/l:	aboı	ratory da	ta				

Triage Unit Sequence #

#### C. Suspect medication(s)

Name:				
Rid Pure	Alternative	lice	and egg	remval system
Dose, frequency,	, route use	The	erapy d	ates
4 ounce bottle in l	kit. Used	8/10	)	to
about half the bot				to 8/10
Diagnosis for us			Event	abated after use
headlice, both nits	and live bug	(S	stoppe	d or dose reduced
found on my daug	hter.		no	
Lot #	Exp. date		Event	reappeared after
			reintro	oduction
			doesn	t apply
NDC # -	-			
Concomitant me	dical produ	cts		
none. Product was Demethicone.	s used one ti	ne o	only. Pr	oduct contained
D. Suspect med	lical device	9		
Brand name				
Type of device				
Manufacturer na	ame and add	lres	s Oper	ator of device
			$\square_{h}$	ealth professional
				ser facility
				istributor
			Ехріі	ration date
model #			p	
catalog #			- If im	planted, give date
serial #			-	
lot #			- If ext	planted, give date
other #			<b>I</b>	, g
Device available □ <sub>yes</sub> □ <sub>no</sub>				urer <u>/ /</u>
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	SS	р	hone #	(781)449-6487
The National Pe	diculosis A	.sso	ciation	
P.O. Box 610189	, Newton, N	IA.	02461	
Health professio		patio	)n	Also reported to manufacturer
If you do NOT wa	•	•		□user facility □distributor
disclosed to the ma	unufacturer, p	lace	an 🔲	uistributor

	ation				
Patient Identifier	Date of b	irth	Sex	Weigh	t
1342	12/94/		female	79	lbs
B. Adverse event	or produ	ict pr	oblem		
	Product	Prob	lem		
Outcomes attribut	ed to adv	erse e	event		
∐ death	∐disat				
☐ life-threatening	<u> </u>		anomaly		
hospitalization	□ requi	ired in	tervention		
other:		[			
Date of event 8/24 Describe event or		Date	e of report	8/27	7/2004
Relevant tests/labo	oratory da	ıta			

C. Suspect medica	ation(s)			
Name: Nix				
Dose, frequency, ro	ute use	Ther	apy d	ates
8/24/04_1_dose		8/24/		
0/24/04 1 0050		0/ 2-1/	-	to 9/2/04
				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Diagnosis for use				abated after use
Lice		S	toppe	d or dose reduced
			doesn'	t apply
Lot # Ex	p. date	1	Event	reappeared after
		1	eintro	duction
			doesn'	t apply
NDC # -	-			·
Concomitant medic	al produ	cts		
Ovide on 8/26/04				
D. Suspect medica	al device	•		
Brand name				
Type of device			T	
Manufacturer name	e and add	lress	Oper	ator of device
				ealth professional
				ser facility
				istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device available for				
yes no			inufact	urer _/_/
Concomitant medic	ai produ	cis		
E. Reporter				
Name and address		ph	one #	(781)449-6487
The National Pedic	ulosis A	ssoc	iation	
P.O. Box 610189, N	ewton, N	1A. 0	2461	
Health professional	Occup	patio	n	Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$				manufacturer
If you do NOT want y	our identi	ity		user facility
disclosed to the manuf	facturer, p	lace a	in 🔲	∐distributor

Patient Inform	ation			
tient Identifier	Date of bi	rth Sex	Weight	
1340	08/10/199	8 female	54	lbs
Adverse even			1	
	Product			
tcomes attribu				
death	∐ disab	-		
life-threatening		nital anomal	-	
hospitalization		red intervent	10 <b>n</b>	
other:				
te of event 08/		Date of rep	ort 8/23/2	2004
levant tests/lab	oratory da	a		

C. Suspect med	lication(s)			
Name: lindane				
Ovide				
Dose, frequency,	, route use	The	rapy d	ates
Lindane .05 once		08/1	2/04	
Ovide used once v	weekly for			to 08/23/04
o times Diagnosis for us	e		Event	abated after use
Lice Infestation	•			d or dose reduced
Liee intestation				
T . 4 #	E l-4-		no	
Lot #	Exp. date			reappeared after
			reintro	oduction
NDC # -			doesn'	t apply
Concomitant me	-	ote		
Conconntant me	uicai produ	cis		
D. Guerreet mee				
D. Suspect med				
Brand name				
<u>Type of device</u> Manufacturer na	mo and add	Inoce	Oner	ator of device
	inte and aut	11 655	L Â	
				ealth professional ser facility
				istributor
				ation date
			Схрп	ation date
model # catalog #			- If im	planted, give date
serial #				, <del>,</del> , ,
lot #			If ext	planted, give date
other #			-	, 8
Device available	for evaluat	ion?		
$\square_{\text{yes}} \square_{\text{no}}$	returned	to m	anufact	urer//
Concomitant me				
E. Reporter				
Name and addre	99	n	hone #	(781)449-6487
The National Pe		Ē		(781)449-0487
P.O. Box 610189				
Health professio $\mathbf{V}_{yes}$ $\mathbf{D}_{nc}$		patio	n	Also reported to
· · ·				manufacturer
If you do NOT was	•		🗖	⊔user facility □distributor
disclosed to the ma	inufacturer, p	lace	an 🔲	

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1338	01/01/63	female	120	lbs
3. Adverse event	t or product p	roblem		
	Adverse Eve			
Outcomes attribut		event		
death	☐ disability			
✓ life-threatening		-		
hospitalization other:	required in	ntervention		
Date of event 19/8	D4/ D-4	6	0 / <b>0</b> 0 /0	004
Date of event 19/8 Describe event or		e of report	8/20/2	2004
Relevant tests/labo	oratory data			
Other relevant his	story, includin <sub>t</sub>	g preexisti	ng condi	tion

C. Suspect med	lication(s)				
Name: lindane					
Dose, frequency,	route use	Ther	apy da	ates	
applied neck down		4/16/	1984		
on over night				to 4/17/11984	
Diagnosis for us		   T	Twont	abated after use	
_	e			d or dose reduced	
scabies					
			doesn'	t apply	
Lot #	Exp. date	F	Event 1	reappeared after	
		r	eintro	duction	
			doesn'	t apply	
NDC # -	-			IF J	
Concomitant me	dical produ	cts			
D. Suspect med	lical device	÷			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
			□di	istributor	
			Expir	ation date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
<b>Device available for evaluation?</b> $\square_{yes} \square_{no} \square_{returned to manufacturer/_/}$					
Concomitant medical products					
	-				
E. Reporter					
Name and addres	SS	ph	one #	(781)449-6487	
The National Pe					
P.O. Box 610189	, Newton, N	1A. 02	2461		
Health profession ✓ <sub>yes</sub> □ <sub>no</sub>		patior	n	Also reported to manufacturer	
le ves le inc					
¥yes □no If you do NOT war		ity		user facility	

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weigh	t
1332	02/14/19	95	female	50	lbs
B. Adverse event	or produ	lct p	roblem		
Advers	e Event &	Prod	luct Proble	em	
Outcomes attribut	ed to adv	erse e	event		
death	∐disat	oility			
☐ life-threatening			anomaly		
hospitalization	L requi	ired ir	itervention		
other:					
Date of event 8/11	/2004	Date	e of report	8/12	2/2004
Describe event or	problem				
On 8/10/04, I treated					
reatment, as directe			-		
woke up with a run today $\frac{8}{12}$					
today, 8/12/04, I fou the treatment did no		er nive	nce, an mo	lication	tnat
	n work				
Relevant tests/labo	oratory da	ita			
Other relevant his	tory, incl	uding	g preexisti	ng cono	lition
				-	

C. Suspect med	lication(s)			
Name: Nix				
Dose, frequency.	, route use	The	rapy d	ates
One bottle(2 oz)w	vas used.	8/10	/04	
one time, complet				to 8/10/04
coturating hair and	l onto cooln		<b>F</b> 4	
Diagnosis for us	e			abated after use d or dose reduced
Head lice		2	stoppe	u of uose feuticeu
	-		doesn	t apply
Lot #	Exp. date	]	Event	reappeared after
		1	reintro	oduction
			doesn	t apply
NDC # -	-		a00511	- "bbil
Concomitant me	dical produ	cts		
D. Suspect med	lical device	e		
Brand name				
Type of device				
Type of device Manufacturer na	me and add	lress	Oper	ator of device
	ame and add	lress	L Â	
	ame and add	lress	⊡ h	ealth professional
	ame and add	lress		
	nme and add	lress	$\square_h$ $\square_u$ $\square_d$	ealth professional ser facility istributor
Manufacturer na		lress	$\square_h$ $\square_u$ $\square_d$	ealth professional ser facility
Manufacturer na 		lress		ealth professional ser facility istributor
Manufacturer na model # catalog #		lress		ealth professional ser facility istributor ration date
Manufacturer na model # catalog # serial #		lress	Expin	ealth professional ser facility istributor ration date
Manufacturer na model #		lress	Expin	ealth professional ser facility istributor <b>ration date</b> planted, give date
Manufacturer na model # catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	f <u>or</u> evaluati	  ion?	Lif exp	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer na model # catalog # serial # lot # other # Device available U_Ves D_no	for evaluat	ion?	Lif exp	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer na model # catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	for evaluat	ion?	Lif exp	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer na model # catalog # serial # lot # other # Device available □_yes □_no	for evaluat	ion?	Lif exp	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer na model # catalog # serial # lot # other # Device available □_yes □_no	for evaluat	ion?	Lif exp	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer na model # catalog # serial # lot # other # Device available □yes □no Concomitant me	for evaluati returned dical produce	ion? cts	If explanation	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer na model # catalog # serial # other # Device available Uves Ino Concomitant me E. Reporter	for evaluati returned dical produce ss	ion? to ma cts	If im anufact	ealth professional ser facility istributor ration date planted, give date olanted, give date
Manufacturer na model # catalog # serial # lot # other # Device available Device available Device available Device available Concomitant me E. Reporter Name and addre	for evaluati returned dical produce ss diculosis A	ion? to ma cts	hone #	ealth professional ser facility istributor ration date planted, give date olanted, give date
Manufacturer na model # catalog # serial # other # Device available Uyes no Concomitant me E. Reporter Name and addre The National Pe	for evaluati returned dical produce ss diculosis A b, Newton, M nal Occup	ph ph sssoc 1A. 0	hone #	ealth professional ser facility istributor ration date planted, give date olanted, give date
Manufacturer na model # catalog # serial # other # Device available Uves Uno Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	for evaluati returned dical produce ss diculosis A b, Newton, N nal Occup	ion? to ma cts sssoc 1A. 0 patio	hone #	ealth professional ser facility istributor ration date planted, give date planted, give date urer _/_/ (781)449-6487 Also reported to

A. Patient Inform	ation				
Patient Identifier	Date of bir	th	Sex	Weigh	ıt
1328	01/26/95		male	80	lbs
B. Adverse event	or produc	ct pi	oblem	1	
	Adverse	Eve	ent		
Outcomes attribut	ed to adver	rse e	event		
death	🗹 disabi	lity			
□ life-threatening	$\Box_{\text{congen}}$	nital	anomaly		
hospitalization	$\Box_{\text{require}}$	ed in	terventior	ı	
other:					
Date of event 1/26	5/95 ]	Date	of repor	t 8/	7/2004
Child is developme REtardation and ser	asory integra	ation			ntal
Other relevant his	tory, inclu	dinş	g preexist	ing con	dition

-	ct mec	lication(s)			
Name: N	ix				
R	id also				
Dose, freq	uency,	route use	The	rapy da	ntes
Used on self 4 or 5 times, as 4/9		4/94	Ļ		
well as trea					to 5/94
fomilu mor Diagnosis		e		Event s	bated after use
head lice	ior us	C C			l or dose reduced
neau nee					
<b>T</b> 4 11		<b>F</b> 14		doesn't	
Lot #		Exp. date			eappeared after
				reintro	duction
NDC #	-	-		doesn't	apply
	ant me	dical produ	cts		
		-		rol voor	s ago. I would
		tion if others			
happen**	linoime		, ma ,	e nua si	unigs
D. Suspe	ct mec	lical device	÷		
Brand nan					
Type of de					
Manufact	urer na	me and add	lress	6 Opera	ator of device
				he	alth professional
					er facility
					stributor
				Expir	ation date
model #				Expir	ation date
model # catalog # _				_	ation date blanted, give date
catalog # _ serial #				_	
catalog # _ serial # lot #				_ If imp	
catalog # _ serial #				_ If imp	planted, give date
catalog # _ serial # lot # other # Device ava		for evaluat		If imp If exp	blanted, give date lanted, give date
catalog # _ serial # lot # other # Device ava □_yes	ailable	for evaluat	to m	If imp If exp	blanted, give date lanted, give date
catalog # _ serial # lot # other # Device ava □_yes	ailable	for evaluat	to m	If imp If exp	blanted, give date lanted, give date
catalog # _ serial # lot # other # Device ava □_yes	ailable no ant me	for evaluat	to m	If imp If exp	blanted, give date lanted, give date
catalog # _ serial # lot # other # Device ava □_yes [ Concomita	ailable no ant me	for evaluat returned dical produ	to m cts	If imp	blanted, give date lanted, give date
catalog # _ serial # lot # other # Device ava yes [ Concomita E. Report Name and	ailable no ant me er addre	for evaluat returned dical produ	to m cts p	If imp If exp	lanted, give date lanted, give date
catalog # _ serial # other # Device ava yes [ Concomita E. Report Name and The Natio	ailable no ant me er addre	for evaluat returned dical produ ss	to m cts p	If imp If exp	lanted, give date lanted, give date
catalog # _ serial # other # Device ava yes [ Concomita <b>E. Report</b> Name and The Natio P.O. Box ( Health pro	ailable no ant me er addre: onal Pe 510189	for evaluati returned dical produ ss diculosis A , Newton, M nal Occuj	to m cts P .ssoc 1A. (	If imp If exp anufactur hone # ciation	lanted, give date lanted, give date
catalog # _ serial # other # Device ava □_yes [ Concomita E. Report Name and The Natio P.O. Box ( Health pro yes	ailable no ant me er addre onal Pe 510189 ofession	for evaluati returned dical produ ss diculosis A , Newton, M nal Occuj	to m cts P .ssoo IA. ( patic	If imp If exp anufactur hone # ciation	blanted, give date lanted, give date urer/_/ (781)449-6487 Also reported to

Patient Identifier       Date of birth       Sex       Weight         1317       10/31/1969       male       185       lbs         B. Adverse event       report       Iss       lbs         Adverse Event       Adverse Event       Iss       lbs         Outcomes attributed to adverse event       death       disability       Iss       Iss         Iffe-threatening       congenital anomaly       Iss       Iss       Iss         Date of event 7/18/04       Date of report       7/20/2004         Describe event or problem       Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is issed.         Relevant tests/laboratory data       Adverse for the vehicle is used.	A. Patient Inform	ation			
B. Adverse event         Adverse Event         Outcomes attributed to adverse event         death       disability         life-threatening       congenital anomaly         hospitalization       required intervention         other:       mild reaction         Date of event 7/18/04       Date of report       7/20/2004         Describe event or problem       Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used.         Relevant tests/laboratory data	Patient Identifier	Date of birth	Sex	Weight	
Adverse Event         Outcomes attributed to adverse event         death       disability         life-threatening       congenital anomaly         hospitalization       required intervention         other:       mild reaction         Date of event 7/18/04       Date of report       7/20/2004         Describe event or problem       Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used.         Relevant tests/laboratory data	1317	10/31/1969	male	185 li	bs
Outcomes attributed to adverse event         death       disability         life-threatening       congenital anomaly         hospitalization       required intervention         other:       mild reaction         Date of event 7/18/04       Date of report       7/20/2004         Describe event or problem       Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used.         Relevant tests/laboratory data	B. Adverse event	or product p	roblem		
death       disability         life-threatening       congenital anomaly         hospitalization       required intervention         other:       mild reaction         Date of event 7/18/04       Date of report       7/20/2004         Describe event or problem       Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used.         Relevant tests/laboratory data         Other relevant history, including preexisting condition		Adverse Ev	ent		
life-threatening congenital anomaly   hospitalization required intervention   other: mild reaction   Date of event 7/18/04 Date of report 7/20/2004 Describe event or problem Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used. Relevant tests/laboratory data Other relevant history, including preexisting condition			event		
hospitalization required intervention other: mild reaction Date of event 7/18/04 Date of report 7/20/2004 Describe event or problem Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used. Relevant tests/laboratory data					
other:       mild reaction         Date of event 7/18/04       Date of report 7/20/2004         Describe event or problem       Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used.         Relevant tests/laboratory data					
Date of event 7/18/04       Date of report 7/20/2004         Describe event or problem       Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used.         Relevant tests/laboratory data		-	iter vention		
Describe event or problem Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used. Relevant tests/laboratory data Other relevant history, including preexisting condition			o of roport	7/20/200	74
Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 nours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several nours after leaving vehicle, but reappear each time vehicle is used. Relevant tests/laboratory data			e of report	7/20/200	<i>J</i> 4
Other relevant history, including preexisting condition					
	Kelevant tests/fab	iratory data			
ione		tory, includin	g preexisti	ing conditio	n
	none				

C. Suspect medication(s)		
Name: Pronto		
Dose, frequency, route use	The	rapy dates
$1/3 \sim 1/2$ of 6oz aerosol can.	7/18	
one application	// 10	to 7/18/04
	L ,	
Diagnosis for use		Event abated after use
headlice		stopped or dose reduced
		no
Lot # Exp. date	1	Event reappeared after
	]	reintroduction
		yes
NDC #		
Concomitant medical produ	icts	
D. Suspect medical device	е	
Brand name		
Type of device		
Manufacturer name and ad	dress	Operator of device
		health professional
		user facility
		user facility         distributor         Expiration date
model #		distributor
model # catalog #		distributor
catalog # serial #		distributor     Expiration date
catalog # serial # lot #		distributor     Expiration date
catalog # serial #		distributor         Expiration date         If implanted, give date
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able f <u>or</u> evaluat		<ul> <li>distributor</li> <li>Expiration date</li> <li>If implanted, give date</li> <li>If explanted, give date</li> </ul>
catalog # serial # lot # other # Device available for evaluat	to m	distributor         Expiration date         If implanted, give date
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able f <u>or</u> evaluat	to m	<ul> <li>distributor</li> <li>Expiration date</li> <li>If implanted, give date</li> <li>If explanted, give date</li> </ul>
catalog # serial # lot # other # Device available for evaluat  yesn	to m	<ul> <li>distributor</li> <li>Expiration date</li> <li>If implanted, give date</li> <li>If explanted, give date</li> </ul>
catalog # serial # lot # other # Device available for evaluat $\square_{yes}$ $\square_{no}$ $\square_{returned}$ Concomitant medical produ	to m	<ul> <li>distributor</li> <li>Expiration date</li> <li>If implanted, give date</li> <li>If explanted, give date</li> </ul>
catalog # serial # lot # other # Device available for evaluat yesnoreturned Concomitant medical produ E. Reporter	to ma icts	distributor Expiration date If implanted, give date If explanted, give date anufacturer/_ /
catalog # serial # lot # other # Device available for evaluat $\square_{yes}$ $\square_{no}$ $\square_{returned}$ Concomitant medical produ	to ma icts pl	distributor Expiration date If implanted, give date If explanted, give date anufacturer/_/
catalog # serial # lot # other # Device available for evaluat $\Box_{yes}$ $\Box_{no}$ $\Box_{returned}$ Concomitant medical produ E. Reporter Name and address	to ma acts pl	distributor     Expiration date     If implanted, give date     If explanted, give date anufacturer/_ /  hone # (781)449-6487 ciation
catalog #	to main to main to main to main to main to main to the second sec	distributor Expiration date If implanted, give date If explanted, give date anufacturer _/_/
catalog #	to maintende to ma	distributor Expiration date If implanted, give date If explanted, give date anufacturer/_/ hone # (781)449-6487 ciation 02461

A. Patient Inform Patient Identifier		Sou	Weisla	
1314	08/20/1982	Sex female	Weight	الم
B. Adverse event			100	lbs
B. Auverse even	Product Prob			
Outcomes attribut				
death	disability			
□ life-threatening	$\Box_{\text{congenital}}$	anomaly		
hospitalization	required in	-	n	
other: live lice f				
Date of event 07/0	04/ Dat	e of repoi	rt 7/19/	2004
Describe event or	problem			
washing everything in hot dryers, my da on her hair and head	ughter, Alicia E			
Relevant tests/labo	oratory data			
Relevant tests/labo Other relevant his My daughter has a s	tory, includin		-	ition

Triage Unit Sequence #

#### C. Suspect medication(s) Name: lindane Dose, frequency, route use Therapy dates 2 times in 2 weeks 07/05/04 to 07/18/04 Diagnosis for use Event abated after use stopped or dose reduced Head lice doesn't apply Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # **Concomitant medical products** My daughter has been treating herself for lice for two months with no success. D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date model # If implanted, give date catalog # serial # \_\_\_\_\_ lot # If explanted, give date other # Device available for evaluation? ves no returned to manufacturer Concomitant medical products E. Reporter Name and address **phone** # (781)449-6487 The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461 Health professional Occupation Also reported to ✓yes manufacturer $\square_{no}$ user facility If you do NOT want your identity distributor disclosed to the manufacturer, place an

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
1313	06/05/19	95	female	115	lbs
B. Adverse event	or produ	lct p	oblem		
	Product	Prob	lem		
Outcomes attribut	ed to adv	erse e	event		
death	□ disat	oility			
life-threatening	$\Box_{\rm cong}$	enital	anomaly		
hospitalization	L requi	ired ir	tervention		
other:					
Date of event 03/0	04-07/0	Date	e of report	7/18/	2004
the house. Ive also c long. Ive never seen has had the nits 3 th has had the nits 3 th <b>Relevant tests/labo</b>	a live bug me in the l	; in m ast si	y daughters	-	
Other relevant his	tory, incl	udinį	g preexisti	ng cond	ition

C. Suspect med	lication(s)		
Name:			
Our Fam	ily lice shan	ipoo,	Baby oil
Dose, frequency,	route use	The	rapy dates
once at finding the		03/0	10
days later	in then 7	05/0	to
-			2004
Diagnosis for us	е		Event abated after use
Head lice nits.		5	stopped or dose reduced
			doesn't apply
Lot #	Exp. date		Event reappeared after
		]	reintroduction
NDC# -	-		doesn't apply
Concomitant me	dical produ	cts	
Conconntant me	uicui produ	cus	
D. Suspect med	lical device	9	
Brand name			
Type of device			
Manufacturer na	me and add	lress	Operator of device
			health professional
			user facility
			distributor
			Expiration date
model #			
catalog #			If implanted, give date
serial #			
lot #			If explanted, give date
other #			in explainced, give dute
Device available	_		1
Uyes Uno	<u>Ireturned</u>	to ma	anufacturer//
Concomitant me	dical produ	cts	
E. Reporter			
E. Reporter Name and addres	ss	pł	hone # (781)449-6487
-		Ê	
Name and addres	diculosis A	ssoc	iation
Name and addres The National Pe P.O. Box 610189 Health profession	diculosis A , Newton, M nal Occuj	Issoc IA. 0	iation )2461 <b>n Also reported to</b>
Name and addres The National Pe P.O. Box 610189 Health profession	diculosis A , Newton, N nal Occuj	Assoc IA. 0 patio	iation 02461

A. Patient Inform	ation				
Patient Identifier	Date of bi	rth	Sex	Weight	
1306	04/22/194	14	female	220	lbs
B. Adverse event	or produ	ct pi	oblem		
Advers	e Event &	Prod	uct Proble	m	
Outcomes attribut	_		event		
∐ death	∐ disab	•			
☐ life-threatening			anomaly		
hospitalization		red in	tervention		
other:					
Date of event 07/0 Describe event or		Date	e of report	7/5	/2004
lice)!second doc. sa 7/4/04 after doing ha live lice. hair is very scratching and my n lymphnods i assume Relevant tests/labo	air removed 7 long,head leeck has big e. HELP!!!	l adu is fu g swo !!	lt live louse ll of open s	e. still ha ores fror	ve
Other relevant his			y preexisti	ng cond	ition

C. Suspect med	lication(s)			
Name: Nix				
permethi	rin 1%			
Dose, frequency,	, route use	The	rapy da	ntes
used 3 different tin	mes	6/25/		
				to 7/04/04
Diagnosis for us	e	h	Event s	abated after use
kill lice and nits	C			l or dose reduced
kin nee and mus				
<b>-</b>	-		doesn't	apply
Lot #	Exp. date			eappeared after
L312083 &		]	reintro	duction
1G2581(on nix)			doesn't	apply
NDC # -	-			
Concomitant me	dical produ	cts		
D. Suspect med	lical device	9		
Brand name				
Type of device			1	
Manufacturer na	ame and add	lress	Opera	ator of device
			$\square_{he}$	ealth professional
			$\square$ us	ser facility
			□di	stributor
			Expir	ation date
			Espi	
model # catalog #			Ifimr	planted, give date
catalog # serial #				, g. , e unie
lot #			TC	landad atma data
other #			II exp	lanted, give date
<b>Device available</b> uessian	_		anufacti	urer / /
Concomitant me				
	F			
E. Reporter				
Name and addre	SS	pł	none #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, N	<b>1</b> A. 0	2461	
Health professio ✓ <sub>yes</sub> □ <sub>nc</sub>		oatio	n	Also reported to manufacturer
If you do NOT wa	nt your identi	ity		user facility

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
1301	09/07/20	00	female	33	lbs
B. Adverse event	or produ	lct p	oblem		
Advers	e Event &	Prod	uct Proble	m	
Outcomes attribut	ed to adv	erse e	event		
death	disat	oility			
$\Box$ life-threatening	$\Box_{\rm cong}$	enital	anomaly		
hospitalization	□ requi	ired ir	tervention		
other:					
Date of event 06/0	07/2004	Date	of report	6/21/2	2004
Describe event or	problem	r			
Used nix. Irritated t later both live adult irritated scalp. skin bright red areas. Lie	louse four at top of l ce still a pr	nd. U nead c roblen	sed Rid day	y 10, furth	ner
Relevant tests/labo	oratory da	ita			
Other relevant his	story, incl	udinş	g preexisti	ng condit	tion

Triage Unit Sequence #

#### C. Suspect medication(s)

#### Name: Nix

also rid, using mayo and loive oil with combing no

	••••		e e
Dose, frequency	, route use	The	erapy dates
Nix used. failed. every other day ti	l day 10 Still uing	05/2	to 6/21
Diagnosis for us lice found on mon intense itching, eg	n and daught		Event abated after use stopped or dose reduced no
Lot #	Exp. date		Event reappeared after reintroduction
NDC # -	-		yes

#### Concomitant medical products

between treatments of pedilucides, used il and mayo and coconut shampoos. Car seats vaccummed daily after use and stem cleaned twice. Al bedding washed daily in 135

#### D. Suspect medical device

Brand name Type of device Monufacturer name and address Open

Manufacturer name and address Operator of device

	health professional user facility distributor
	Expiration date
model #	
catalog #	If implanted, give date
serial #	
lot #	If explanted, give date
other #	<b>F</b> , 8
Device available for evaluation?	
$\square_{\text{yes}}$ $\square_{\text{no}}$ $\square_{\text{returned to matrix}}$	anufacturer//
Concomitant medical products	

#### E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional ✓ <sub>yes</sub> □ <sub>no</sub>		Also reported to manufacturer
If you do NOT want you		user facility distributor
disclosed to the manufac	turer, place an 🔲	distributor

A. Patient Informa						
Patient Identifier			Sex	V	Veight	
1294	08/29/199		female		30	lbs
B. Adverse event						
	Product 1					
Outcomes attribut	_		vent			
☐ death	∐ disabi					
$\Box$ life-threatening			anomaly			
hospitalization	└ requir	red in	terventi	on		
other:						
Date of event 05/2		Date	of repo	ort	5/30/2	2004
is the one I can't get nit removal problem <b>Relevant tests/labo</b>	1.					. 13 u
Other relevant his			g preexi	istin	g condi	tion

Name	Ovide				
i (unic)					V T
		so used gen	-		
		, route use	Ther	apy d	ates
5-6 tim	es this yea	r alone	2000		to
					5/29/2004
Diagno	sis for us	e	ŀ	Event	abated after use
nits and	lice detec	ted in her ha	air s	toppe	d or dose reduced
				no	
Lot #		Exp. date	—		1.64
		Exp. dute			reappeared after oduction
			r	emtro	auction
NDC #	-	-		yes	
		dical produ	lete		
Concor	miani me	uicai pi ou	icis		
D. Sus	pect med	dical devic	e		
Brand	name				
Type of	f device				
	f device		Janaa	0	aton of donion
		ame and ad	dress	Oper	ator of device
		ame and ad	dress	Ê	
		ame and ad	dress	h	ealth professional
		ame and ad	dress		ealth professional ser facility
		ame and ad	dress	□h □u □d	ealth professional ser facility istributor
Manufa	acturer na		dress	□h □u □d	ealth professional ser facility
Manuf: model <del>;</del>	acturer na			□h □u □d Expin	ealth professional ser facility istributor ration date
Manuf model # catalog	acturer na 4 #			□h □u □d Expin	ealth professional ser facility istributor ration date
Manuf model # catalog serial #	acturer na #			Expin	ealth professional ser facility istributor ration date planted, give date
Manuf; model # catalog serial # lot #	#			Expin	ealth professional ser facility istributor ration date planted, give date
Manuf; model # catalog serial # lot #	acturer na #			Expin	ealth professional ser facility istributor ration date planted, give date
Manuf; model	#			Expin	ealth professional ser facility istributor <b>ration date</b> <b>planted, give date</b>
Manuf model # catalog serial # lot # other # Device	acturer na # # av <u>ail</u> able	f <u>or</u> evalua		Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
Manuf: model # catalog serial # lot # other # Device □_yes	acturer na # # available	for evalua	tion?	Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
Manuf: model # catalog serial # lot # other # Device □_yes	acturer na # # available	f <u>or</u> evalua	tion?	Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
Manuf: model # catalog serial # lot # other # Device □_yes	acturer na # # available	for evalua	tion?	Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
Manuf model # catalog serial # lot # other # Device Uges Concor	acturer na # # available □ no	for evalua	tion?	Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
Manuf model catalog serial # lot # other # Device yes Concor E. Rep	# # available  nitant me	for evalua returnec dical produ	tion? to ma icts	Expin If im	ealth professional ser facility istributor ration date planted, give date planted, give date
Manuf model # catalog serial # lot # other # Device Uyes Concor E. Rep Name a	acturer na	for evalua returnec dical produ ss	tion? i to ma icts ph	If exp nufact	ealth professional ser facility istributor ration date planted, give date planted, give date
Manuf model catalog serial # lot # other # Device Device Concor E. Rep Name a The Na	# # available  nitant me orter and addre	for evalua returnec dical produ ss ediculosis 4	tion? l to ma lcts ph Associ	If exp nufact	ealth professional ser facility istributor ration date planted, give date planted, give date
Manuf model # catalog serial # lot # other # Device Uyes Concor E. Rep Name a The Na P.O. Bo	acturer na # # available □ no nitant me orter and addre ational Pe ox 610189	for evalua □returnec dical produ ss ediculosis 4	tion? to ma icts ph Associ MA. 02	If im nufact	ealth professional ser facility istributor ration date planted, give date planted, give date turer/_/ (781)449-6487
Manuf model # catalog serial # lot # other # Device Uyes Concor E. Rep Name a The Na P.O. Bo Health	acturer na # # available □ no nitant me orter and addre ational Pe ox 610189 professio	for evalua □returnec dical produ ss ediculosis 4	tion? l to ma lcts ph Associ	If im nufact	ealth professional ser facility istributor ration date planted, give date planted, give date turer _/_/ (781)449-6487
Manuf model # catalog serial # lot # other # Device Uyes Concor E. Rep Name a The Na P.O. Bo	acturer na # # available □ no nitant me orter and addre ational Pe ox 610189 professio	for evalua returned dical produ ss sdiculosis 4 0, Newton, 1 nal Occu	tion? to ma icts ph Associ MA. 02	If im nufact	ealth professional ser facility istributor ration date planted, give date planted, give date turer/_/ (781)449-6487
Manufa model a catalog serial # lot # other # Device □yes Concor E. Rep Name a The Na P.O. Bo Health ☑yes	acturer na # # available □ nitant me orter ational Pe ational Pe bx 610189 professio □	for evalua returned dical produ ss sdiculosis 4 0, Newton, 1 nal Occu	tion? to ma icts ph Associ MA. 02 ipation	If im nufact	ealth professional ser facility istributor ration date planted, give date planted, give date turer _/_/ (781)449-6487

A. Patient Information	ation				
Patient Identifier	Date of bi	irth	Sex	Weigh	nt
1293	07/01/200	00	female	35	lbs
B. Adverse event	or produ	ict p	roblem		
	Product	Prob	lem		
Outcomes attribut	ed to advo	erse e	event		
death	∐disab	•			
☐ life-threatening	Γ ĭ		anomaly		
hospitalization	□requi	red ir	ntervention	1	
other:					
Date of event 05/1	10/2004	Date	e of repor	t 5/2	6/2004
daughter has it or I l 2-3 weeks later she l Pronto Plus, and the nit comb and follow loosing battle I'm al and my daughters he Fall and they have a	has them a be Dr. preserve instruction most to the ead. She was a nit free po	gain. ribed ns. I e poir vill be olicy.	I've tried ovide 0.5 am so tire at of shavi e starting s	Rid, Niz %. I us d of figh ng both chool in	x, e the nting a mine
Relevant tests/labo					
Other relevant his	story, incl	udin;	g preexis	ing con	dition

	dication(s)				
Name: Ovide					
nix					
Dose, frequency	, route use	The	erapy da	ates	
alternating brand	s 7-10 days	06/0	01/2003	to	
				10	05/25/2004
Diagnosis for u	se		Event a	abate	ed after use
left on 10 minute	s as directed	and	stopped	d or (	dose reduce
left ovide 0.5 on	for 8 hours		doesn'	t app	oly
Lot #	Exp. date		Event 1	eapp	peared after
			reintroduction		
			yes		
NDC # -	-		-		
Concomitant m		cts			
Pronto Plus, vase	line, Rid				
D. Suspect me	dical device	9			
Brand name					
Type of device					
Manufacturer n					
manufacturer n	ame and add	dress	s Opera	ator	of device
	ame and add	lres	h	ealth	professional
	ame and add	lres		ealth ser fa	professional acility
ivianulaciuref fi	ame and add	lress		ealth	professional acility
	ame and add	lress		ealth ser fa istrib	professional acility
model #	ame and add	lress	Expir	ealth ser fa istrib <b>atio</b>	professional acility outor n date
	ame and add	lress	Expir	ealth ser fa istrib <b>atio</b>	professional acility outor
model # catalog # serial #		lress	Expir	ealth ser fa istrib <b>atio</b>	professional acility outor n date
model # catalog # serial # lot #			Expir	ealth ser fa istrib ration	professional acility outor n date
model # catalog # serial #			Expir	ealth ser fa istrib ration	professional acility utor n date ted, give dat
model # catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	e f <u>or</u> evaluat	ion?	Expir If imp If exp	ealth ser fa istrib ation plant	professional acility outor <b>n date</b> ted, give dat ed, give dat
model # catalog # serial # lot # other # Device available □ yes □ no	e <b>for evaluat</b>	ion?	Expir If imp If exp	ealth ser fa istrib ation plant	professional acility outor <b>n date</b> ted, give dat ed, give dat
model # catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	e <b>for evaluat</b>	ion?	Expir If imp If exp	ealth ser fa istrib ation plant	professional acility outor <b>n date</b> ted, give dat ed, give dat
model # catalog # serial # lot # other # Device available □ yes □ no	e <b>for evaluat</b>	ion?	Expir If imp If exp	ealth ser fa istrib ation plant	professional acility outor <b>n date</b> ted, give dat ed, give dat
model # catalog # serial # lot # other # Device available uges uno Concomitant me	e for evaluat returned edical produ	ion? to m cts	Expir If imp If exp	ealth ser fa istrib ration plant	professional acility outor <b>n date</b> ted, give dat ed, give dat
model # catalog # serial # lot # other # Device available yesno Concomitant mo E. Reporter	e for evaluat returned edical produ ess	ion? to m cts	Expir Expir If imp If exp	ealth ser fa istrib ration plant	professional acility outor <b>n date</b> <b>ed, give dat</b> <b>ed, give dat</b>
model # catalog # serial # other # Device available yesno Concomitant mo E. Reporter Name and addro	e for evaluat returned edical produ ess ediculosis A	ion? to m cts	Expir Expir If imp If exp	ealth ser fa istrib ration plant	professional acility outor <b>n date</b> <b>ed, give dat</b> <b>ed, give dat</b>
model # catalog # serial # other # other # Device available yesno Concomitant me E. Reporter Name and addre The National Pe P.O. Box 61018 Health professio	e for evaluat returned edical produ ess ediculosis A 9, Newton, M onal Occuj	ion? to m cts p sssoo 1A. (		ealth ser fa istrib ation plant urer (781	professional acility outor <b>n date</b> <b>ied, give dat</b> <b>ed, give dat</b> 
model # catalog # serial # other # Device available yesno Concomitant me E. Reporter Name and addre The National Pe P.O. Box 61018	e for evaluat returned edical produ ess ediculosis A 9, Newton, N onal Occup	ion? to m cts sssoo 1A. ( patic		ealth ser fa istrib ation plant urer (78]	professional acility putor <b>n date</b> <b>ed, give dat</b> <b>ed, give dat</b> / /

A. Patient Inform			a			
Patient Identifier	Date of b	irth	Sex	We	eight	
1292	12/2/83		male	90		lbs
B. Adverse event	t or produ	lct p	roblem			
	Advers	se Eve	ent			
Outcomes attribut	ted to adv	erse e	event			
$\Box_{\text{death}}$	$\Box_{disat}$	oility				
□ life-threatening		•	anomaly	7		
$\square_{\text{hospitalization}}$			iterventi			
·	_			UII		
other: ADD/Pa	nic Anxiet	.y				
Date of event 31/7	71/992	Date	e of repo	ort	5/25/2	004
Describe event or	problem					
was treated betweer prescriptions we fill myself and daughte all over - due to the patient diagnosed - contaminated and it dangers of the drug Relevant tests/labo	ed 3/17 an r as well a fact that e myself and ched. I wa -	d aga s Dari ven th l daug as nev	in on 3/2 in by app nough D ghter alse	28. I tre plying arin wa o felt	eated the lot as the	ion
<b>Other relevant his</b> Now, some 10 year	s later - Da	arin c	ontinues	to be	on anie	ety
medication (paxil &						
cancer in 7/2001. N and just recently ha	• •			-		
reports. A tissue sa					•	u
5/25/04 - we are aw						cer
was estrogen positiv	-				-	
mastectomy in 12/0						ıe
looking into the fac	t that we c	an be	contami	inated a		
could actually be th	e cause of	our p	roblems	•		

Triage Unit Sequence #

### C. Suspect medication(s)

Name:	Kwell
ume.	11.00011

Dose, frequency	, route use	The	erapy dates
Couple of times a day		3/17	7/92 to
			3/31/92
Diagnosis for us	se		Event abated after use
scabies			stopped or dose reduced
			yes
Lot #	Exp. date		Event reappeared after reintroduction
NDC# -	·		doesn't apply

### Concomitant medical products

I would appreciate any comments that you may have relating to this situation and if I need to look into this further. Thanks. Donna Wells 202 Barden Drive,

### D. Suspect medical device

Brand name	
Type of device	
Manufacturer name and address	Operator of device health professional user facility distributor
model #	Expiration date
catalog # serial #	If implanted, give date
	If explanted, give date
<b>Device available for evaluation?</b> Use no returned to main the second	nufacturer//
Concomitant medical products	
E. Reporter	
Name and address ph	one # (781)449-6487
The National Pediculosis Associ	ation
P.O. Box 610189, Newton, MA. 02	2461
Health professionalOccupation	manufacturer
If you do NOT want your identity disclosed to the manufacturer, place a	n distributor

A. Patient Informa	ation				
Patient Identifier	Date of bi	rth S	ex	Weigh	t
1289	04/22/198	89 f	emale	45	lbs
B. Adverse event	or produ	ct pro	blem		
	Advers	e Even	t		
Outcomes attribut	ed to adve	erse evo	ent		
death	∐ disab	-			
☐ life-threatening	<u> </u>	enital ar	-		
hospitalization			rvention		
other: see "ever	-				
Date of event 12/1 Describe event or j		Date o	f report	5/1	8/2004
in parent spraying n		ta			
<b>Other relevant his</b> Asthma in parent	tory, inclu	ıding I	preexisti	ing con	dition

C. Suspect medication(s)		
Name:		
RID Spray		
Dose, frequency, route use	The	erapy dates
Sprayed mattresses	12/1	997
		to 01/1998
Diagnosis for use		Event abated after use
lice in aforementioned child		stopped or dose reduced
nee in aforementioned ennu		
T - 4 - 4		yes
Lot # Exp. date		Event reappeared after
		reintroduction
NDC #		yes
Concomitant medical produ	ete	
-		a reaction and lice serve
Eucalyptus oil mixed with way to DISLIKE	ter- n	o reaction, and nee seem
it a lot.		
D. Suspect medical devic	e	
Brand name		
Type of device		
Manufacturer name and ad	dress	s Operator of device
		health professional
		user facility
		distributor
		Expiration date
		Expiration date
model #		_
catalog #		If implanted, give date
catalog # serial #		If implanted, give date
catalog # serial # lot #		_
catalog # serial # lot # other #		- - - - - If explanted, give date
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able f <u>or</u> evaluat		If implanted, give date
catalog # serial # lot # other # Device available for evaluat	to m	If implanted, give date
catalog # serial # lot # other # Device available for evaluat	to m	If implanted, give date
catalog # serial # lot # other # Device available for evaluat	to m	If implanted, give date
catalog # serial # lot # other # Device available for evaluat $\Box_{yes}$ $\Box_{no}$ $\Box_{returned}$ Concomitant medical produ	to m	If implanted, give date
catalog #	to m icts p	If implanted, give date If explanted, give date If explanted, give date hanufacturer/_ / hone # (781)449-6487 ciation
catalog # serial # lot # other # Device available for evaluat $\Box_{\text{yes}}$ $\Box_{\text{no}}$ $\Box_{\text{returned}}$ Concomitant medical produ E. Reporter Name and address	to m icts p	If implanted, give date If explanted, give date If explanted, give date hanufacturer/_ / hone # (781)449-6487 ciation
catalog #	to m icts P Assoc	
catalog #	to m icts P Assoc AA. ( patic	If implanted, give date If explanted, give date If explanted, give date anufacturer/_/ hone # (781)449-6487 ciation 02461

	ation			
Patient Identifier	Date of birth	Sex	Weight	
1288	09/03/1981	female	155	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Pro	duct Proble	m	
Outcomes attribut		event		
death	∐ disability			
☐ life-threatening	$\Box_{\text{congenital}}$	-		
hospitalization	✓ required i	ntervention		
other: sever ras	h			
Date of event 05/0	03/2004 <b>Dat</b>	e of report	5/18/2	2004
had to shave her hea my hair 3 times used matter how much i o really bad rash from sores all over her he end with this it has l shaving my head to child and it makes m know that lice kits r you can before you	d lice kits, may do its just not e the lice kit i u ad and back. i f been about 2 w get rid of the lion ne feel so dirty nay harm your hurt them.	onasie, baby nough. my o sed on her, eel like i am eeks, i am o ce. i never g i just wan	y oil and n daughter y now she l n at my w n the very ad this as t everyone	no got a nas its g of a e to
Relevant tests/labo	natory uata			

C. Suspect med	lication(s)			
Name:				
equate lie	e kit			
Dose, frequency,	, route use	The	rapy d	ates
used twicwe on m	y head	05/0	3/2004	
	-			to 05/18/2004
Diagnosis for us	e	<u>ا</u>	Event	abated after use
to treat head lice			stoppe	d or dose reduced
			no	
Lot #	Exp. date	_	-	
2000.0	Linp: unit			reappeared after oduction
				Judenon
NDC # -	-		yes	
Concomitant me	dical produ	cts		
D. Suspect med	lical device	÷		
Brand name				
Type of device			-	
Manufacturer na	me and add	lress	Oper	ator of device
				ealth professional
				ser facility
				istributor
			Expi	ration date
model #			- T£ :	nlantad aire data
catalog #			· 11 m	planted, give date
serial # lot #			Ifor	planted, give date
other #				plaiteu, give uate
Device available	for evaluat	ion?		
$\square_{\text{yes}} \square_{\text{no}}$			anufact	turer _/_/
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	SS	p	hone #	(781)449-6487
The National Pe	diculosis A	ssoc	ciation	
P.O. Box 610189	, Newton, M	1A. (	02461	
Health professio		patio	n	Also reported to
$\mathbf{V}_{\text{yes}}$ $\mathbf{I}_{\text{normalized}}$				$\square$ manufacturer
If you do NOT was	•	•		user facility distributor
disclosed to the ma	nufacturer, p	lace	an 🔲	uisuidutor

A. Patient Information						
Patient Identifier	Date of b	irth	Sex	Weight		
1284	12/30/19	94	female	60	lbs	
B. Adverse event or product problem						
Adverse Event & Product Problem						
Outcomes attribut	ed to adv	erse e	event			
death	disat	oility				
□ life-threatening	$\Box_{\rm cong}$	enital	anomaly			
hospitalization	□ <sub>requi</sub>	red ir	itervention			
other: 3mm tun	nor on pitu	itary	gland			
Date of event 8/20	002	Date	e of report	5/6/2	2004	
Describe event or	problem					
my daughter got hea	dlice. we	used o	over the cou	inter lice		
treatments such as N	VIX and R	ID an	d also used	lindane.	We	
used them repeated	y over a 6	-9 mc	onth period	about one	ce a	
week to try to get ri	d of the lie	ce. the	e treatment	s were		
unsuccessful. My daughter started getting headaches around						
that time and she the	en began t	o deve	elop a breas	stbud (age	e 7).	
The dr performed a	MRI scan	whick	h determine	ed she had	l a	
3mm tumor on her	oituitary g	land.	I was too e	mbarrasse	ed to	
mention the lice trea	atments we	e had	been using	and didn'	t	
think they were rela	ted initial	vho	wever we s	topped us	sing	

think they were related initially..however we stopped usin the treatments and about 6 months later the tumor since disappeared. Two follow up MRI's have been performed and now there is no tumor. I believe the lice treatments caused the tumor.

### Relevant tests/laboratory data

Other rele	evant history,	including	preexisting	condition
none				

Triage Unit Sequence #

C.	Sus	pect	med	icatio	on(s	;)

Name:	Nix

Dose, frequency	, route use	The	erapy dates	
1 bottle approx or	ice a week	08/2	2001 to	
			to	08/2002
Diagnosis for us	e		Event abat	ed after use
headlice			stopped or	dose reduced
			yes	
Lot #	Exp. date		reintroduc	
NDC # -	-		doesn't app	oly

#### Concomitant medical products

RID..used both NIX and RID products.

### D. Suspect medical device

Brand name	
Type of device	
Manufacturer name and address	Operator of device health professional user facility distributor
model #	Expiration date
catalog # serial #	If implanted, give date
lot # other #	If explanted, give date
<b>Device available for evaluation?</b> Use no returned to main the second	nufacturer ///
Concomitant medical products	
E. Reporter	
Name and address ph	one # (781)449-6487
The National Pediculosis Associ	ation
P.O. Box 610189, Newton, MA. 02	2461
Health professional Occupation ✓ yes □ no If you do NOT want your identity	Also reported to manufacturer user facility
disclosed to the manufacturer, place a	

A. Patient Inform		a		
Patient Identifier		Sex	Weight	
1271	04-25-68	female	115	lbs
3. Adverse event				
	Adverse Ev			
Dutcomes attribut				
☐ death	□ disability			
$\Box$ life-threatening		l anomaly		
hospitalization	_	interventior	1	
other: extreme h	neadache			
Date of event 04-1	<b>Dat</b>	te of repor	t 4/13/	2004
complained of feelir			8 year old	
Relevant tests/labo	ng nauseus at sa			

C. Suspect med	lication(s)			
Name: Nix				
Lice-Fre	e Spray			
Dose, frequency	, route use	The	rapy d	ates
once			2-04	
				to 04-12-04
Diagnosis for us	e	<u> </u>	Event	abated after use
head lice				d or dose reduced
			no	
Lot #	Exp. date	_		1.0
	Exp. date			reappeared after oduction
NDC # -	-		doesn	t apply
Concomitant me	dical produ	cts		
D. Suspect med	lical device	è		
Brand name				
Type of device			-	
Manufacturer na	me and add	lress	-	ator of device
				ealth professional
				ser facility
				istributor
			Expi	ration date
model #			- If im	planted, give date
catalog # serial #			-	planteu, give uate
lot #			Ifov	planted, give date
other #				hanteu, give uate
Device available	for evaluat	ion?		
$\square_{\text{yes}} \square_{\text{no}}$	returned	to m		urer//
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	SS	n	hone #	(781)449-6487
The National Pe				(,,,,
P.O. Box 610189				
Health professio	nal Occuj			Also reported to
⊻ <sub>yes</sub> □ <sub>nc</sub>				manufacturer
If you do NOT was	-	-		user facility distributor
disclosed to the ma	inutacturer, p	lace	an 📖	-uisuibutoi

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1268	07/10/57	female	180	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Prod	luct Proble	em	
Outcomes attribut	ed to adverse o	event		
death	disability			
□ life-threatening	$\Box_{\text{congenital}}$	anomalv		
hospitalization	□ required in	-		
other: you tell 1	-	ner vention		
<u>-</u>	Ĩ	<b>0</b>	110	12004
Date of event 200		e of report	4/6/	/2004
Describe event or	-			
Can someone please		-		
something so dange				
they can be sold over				
hazards and I had no	Ũ	0		
never have used the		-		
my family while bei	-			
didn't have prior to		-	U	
which lasted into th				
from school in Octo				ly
after that I develope				
November 200 treat	ed in 2001. I gu	uess I will r	never kno	ow
huh? This is very fr	rightning. I will	never again	n purchas	se
these products. The	ey didn't work a	ny way. C	onstant	
combing and groom	ing and checking	g and mayo	naise and	l
olive oil. We would	l treat our hair g	et rid of the	em (we	
Relevant tests/labo	oratory data			
04		•		• • • • •
Other relevant his	story, including	g preexisti	ng cona	100n

C. Suspect med	lication(s)				
Name: Kwell					
Rid, Nix	, store brands	s, Clear oth	ers		
Dose, frequency,	, route use	Therapy of	lates		
each one once then follow up 10/2		10/2000			
in 7 to 10 days leave on ten			to 05/2001		
minutos Diagnosis for us	e	Event	abated after use		
			ed or dose reduced		
use to treat heading	use to treat headlice				
<b>T</b> (11	<b>F</b> 14		n't apply		
Lot #	Exp. date		reappeared after		
		reintr	oduction		
NDC # -		doesi	n't apply		
	-	ota			
Concomitant me	aicai produ	cis			
D. Suspect med	lical dovice				
-		;			
Brand name					
Type of device Manufacturer na	mo and add	Iross Ono	rator of device		
	une anu au	L Â			
			nealth professional user facility		
			distributor		
			iration date		
		Exp			
model # catalog #		If in	planted, give date		
serial #			<b>r</b> , <b>s</b>		
lot #		If ex	planted, give date		
other #		-	1		
<b>Device available</b>			turer / /		
	returned	to manufac	eturer _/_/		
$\square_{\text{yes}} \square_{\text{no}}$	returned	to manufac	turer <u>/ /</u>		
$\square_{\text{yes}} \square_{\text{no}}$	returned	to manufac	eturer/_/		
<b>□</b> <sub>yes</sub> <b>□</b> <sub>no</sub> Concomitant me	returned dical produc	to manufac cts	eturer <u>/ /</u>		
Concomitant me	returned dical produces ss	<u>to manufac</u> cts phone #	ŧ (781)449-6487		
Concomitant me E. Reporter Name and addre	returned dical production ss diculosis A	to manufac cts phone #	ŧ (781)449-6487		
<b>D</b> <sub>yes</sub> <b>D</b> <sub>no</sub> <b>Concomitant me</b> <b>E. Reporter</b> <b>Name and addre</b> The National Pe	returned dical production ss diculosis A b, Newton, M nal Occup	to manufac cts phone #	ŧ (781)449-6487		
Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	returned dical production ss diculosis A b, Newton, N nal Occup	to manufac cts phone # .ssociation 1A. 02461 pation	<ul> <li>(781)449-6487</li> <li>Also reported to</li> </ul>		

A. Patient Informa	ation			
Patient Identifier	Date of birth	Sex	Weight	
1267	06/26/1996	female	42	lbs
B. Adverse event	or product p	roblem		
	Adverse Eve	ent		
Outcomes attribut	ed to adverse o	event		
death	∐ disability			
$\Box$ life-threatening	_ ~			
hospitalization	required ir		1	
other: severe on				
Date of event 02/2	20/04 <b>Date</b>	e of report	t 4/5/2	.004
with the shampoos. 3 times, missed 26 c Pulmicort, Advair, S and she also uses Na like this before.	days of schools. Singulair, she wa	She is on as on Orap	Xopenex, red for a w	veek
Relevant tests/labo Other relevant his		g preexist	ing condit	ion

C. Suspec	t medication(s)	)		
Name: Ni	Х			
Ri	d, Pronto			
Dose, frequ	uency, route use	Ther	apy d	ates
every 7 days 01/2			004	
				to 02/2004
<b>Diagnosis</b>	for use	ŀ	Event	abated after use
lice		s	toppe	d or dose reduced
			doesn'	t apply
Lot #	Exp. date	I	Event	reappeared after
		r	eintro	oduction
NDC "			doesn'	t apply
NDC #				
Concomita	nt medical produ	ucts		
D. Suspec	t medical devic	e		
Brand nam	ie			
Type of dev			1	
Manufactu	rer name and ad	ldress	h u	ator of device ealth professional ser facility
				istributor
			Expi	ration date
model #			Tf im	planted, give date
catalog # _			11 1111	planteu, give uate
serial # lot #			Tf or	lanted aire data
other #			n exp	planted, give date
Device ava	ilable for evalua no returned nt medical produ	l to ma	unufact	urer _/_/
E. Reporte	er			
Name and	address	ph	one #	(781)449-6487
The Nation	nal Pediculosis A	Associ	iation	
P.O. Box 6	10189, Newton, I	MA. 0	2461	
Health pro ✓ yes	$\square_{no}$	ipation	n	Also reported to
•	OT want your iden	•		user facility
disclosed to	the manufacturer,	place a	in 🔲	□distributor

A. Patient Inform	ation				
Patient Identifier		h Sex		Weight	
1264	05/04/1997	fem	ale	60	lbs
B. Adverse event	or product	proble	em		
	Product Pr	oblem			
Outcomes attribut	ed to advers	e event	ţ		
death	disabili	y			
Life-threatening congenital anomaly					
hospitalization	<b>∠</b> required	linterve	ention		
other: Out of sc	chool				
Date of event 03/1	5/2004 <b>D</b>	ate of r	eport	3/31/	2004
anymore Relevant tests/labo	ratory data				

C. Suspect med	lication(s)			
Name: Nix				
Dose, frequency,	route use	Ther	apy d	ates
one bottle every o	ther week	10/01	1/2003	
2				to 03/31/2004
Diagnosis for us	<u>م</u>	F	Event	abated after use
Head lice	C .			d or dose reduced
neau lice				
	-		no	
Lot #	Exp. date			reappeared after
unkn		r	eintro	oduction
NDC# -			yes	
	-			
	uicai produ	cts		
rid 10/01/2003 nix 11/01/2003				
nix every month th	nere after			
D. Suspect med				
-		-		
Brand name Type of device				
Manufacturer na	me and add	lress		ator of device ealth professional ser facility istributor
			Expir	ation date
model #			-	
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
<b>Device available</b>			nufact	urer _/_/
Concomitant me				
E. Reporter				
Name and addres	SS	ph	one #	(781)449-6487
The National Pe	diculosis A	Ē.,		
P.O. Box 610189	, Newton, N	IA. 02	2461	
Health profession ✓ yes □ no	nal Occuj			Also reported to manufacturer
If you do NOT wai	nt your identi	ty	_	user facility
disclosed to the ma	nufacturer, p	lace a	ın 🔳	distributor

A. Patient Inform	ation				
Patient Identifier	Date of bir	th	Sex	Weight	
1262	06/24/1969	)	female	210	lbs
B. Adverse event	or produc	t pi	roblem		
	Adverse	Eve	ent		
Outcomes attribut	ed to adver	se e	event		
death	∐ disabil	•			
$\Box$ life-threatening $\Box$ congenital anomaly					
hospitalization	-		itervention		
other: intense s	ī				
Date of event 03/1		Date	e of report	3/21/	2004
Describe event or					
used a lice treatme	-			-	-
store ( it was their b			-	-	ne
reatment I have had				wollem	
oumps under my sk	in at the bas	e of	my skull.		
Relevant tests/labo	oratory data	1			
	·				
Other relevant his	story, inclu	ding	g preexisti	ng cond	ition

C. Suspect med	lication(s)				
C. Suspect medication(s) Name: generic lice shampoo					
sav-on osco by albertsons					
	-				
			capy dates		
maximum strength used once 03,			3/2004 to		
			03/13/2004		
Diagnosis for us	e		Event abated after use		
trreatment of head	lice	S	stopped or dose reduced		
			no		
Lot #	Exp. date	1	Event reappeared after		
3f19b			eintroduction		
NDC # -	-		doesn't apply		
Concomitant me	dical produ	cts			
	•				
D. Suspect med	lical device	<b>_</b>			
Brand name		,			
Type of device					
Manufacturer na	ime and add	iress	<u> </u>		
			health professional		
			user facility		
			distributor		
			Expiration date		
model #			If implanted, give date		
catalog #			II implanted, give dute		
serial # lot #			Te and a start of the		
ot # other #			If explanted, give date		
	D <u>ev</u> ice available f <u>or</u> evaluation?				
yes no returned to manufacturer _/_/					
		to ma	anufacturer _/_/		
Concomitant me		to ma	anufacturer/_/		
		to ma	nufacturer <u>/ /</u>		
Concomitant me		to ma	nufacturer <u>/ /</u>		
Concomitant me E. Reporter	dical produ	<u>to ma</u> c <b>ts</b>			
Concomitant me E. Reporter Name and addre	dical produc	to ma cts ph	none # (781)449-6487		
Concomitant me E. Reporter Name and addre The National Pe	<b>dical produ</b> ss diculosis A	to ma cts ph ssoc	<b>tone</b> # (781)449-6487 iation		
Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189	dical products ss diculosis A , Newton, N	to ma cts ph ssoc: IA. 0	oone # (781)449-6487 iation 2461		
Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	dical products ss diculosis A , Newton, N nal Occup	to ma cts ph ssoc: IA. 0	oone # (781)449-6487 iation 2461		
Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio ☑ yes □□nc	dical products ss diculosis A b, Newton, M nal Occup	to ma cts ph ssoc: IA. 0 pation	none # (781)449-6487 iation 2461 <b>Also reported to</b> manufacturer		
Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	dical products ss diculosis A b, Newton, M nal Occup ont your identi	to ma cts ph ssoc: IA. 0 pation	n       (781)449-6487         iation       2461         n       Also reported to manufacturer         user facility       user facility		

	ation			
Patient Identifier		th Sex	Weigh	t
1254	11/13/1999	male	31	lbs
B. Adverse event	or produc	t problem		
	Product P	roblem		
Outcomes attribut	_			
□ death	∐ disabili	2		
□ life-threatening		ital anomaly		
hospitalization other:	- require	d interventio	on	
			1 0/	2/2004
Date of event 2/26 Describe event or		Date of repo	rt 3/.	3/2004
Relevant tests/labo	ratory data			
Relevant tests/labo Other relevant his			ting cor	dition

C. Suspect medication(s)					
Name: Nix					
Rid					
Dose, frequency,	, route use	The	rapy d	ates	
Every week since	Every week since mid- 01/2		0/2004		
January				to 03/02/2004	
Diagnosis for use			Event abated after use		
head lice treatmen				d or dose reduced	
	c .		doesn'	t apply	
Lot #	Exp. date				
L0t #	Exp. uate			reappeared after	
			reintroduction		
NDC # -	-		doesn'	t apply	
Concomitant me	dical produ	cts			
Rite Aid Brand tre	-				
	Juliiont				
D. Suspect med	lical device	è			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			$\square_{h}$	ealth professional	
			$\square_{u}$	ser facility	
			$\square_d$	istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
Device available					
Uyes Ino Concomitant me	<u>Ireturned</u>		anufact	urer _/_/	
Conconntant me	uicai produ				
E. Reporter					
Name and addre		Ē.	none #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, N	1A. (	2461		
Health professio		oatio	n	Also reported to	
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$	)			manufacturer	
If you do NOT was				$\square$ user facility	
disclosed to the ma	nufacturer, p	lace	an 🔲	distributor	

A. Patient Informa	ation		
Patient Identifier	Date of birth	Sex	Weight
1253	8-14-69	female	110 lbs
B. Adverse event	or product	oroblem	
	Product Pro	blem	
Outcomes attribut	ed to adverse	event	
death	disability	7	
□ life-threatening		al anomaly	
hospitalization	required	intervention	
other:			
Date of event 200	1-2004 <b>Da</b>	te of report	3/3/2004
Describe event or p You really should ha	ave enough fo	r 2(two)trea	tments in the
Relevant tests/labo	oratory data		
Other relevant his In 1988, My daught mo.) When we retur diagnosed w/HEP B and is viral. Do lice in the grave and the on the victim when death is near? Mayb	er, husband ar rned to the US - or HEP non e, etc. know wh other on a bar their time is s	nd I moved t I was very s B. This is no nen someone nana peal? E	o India.(1yr.4 sick. I was ow HEP C., e has one foot Do they persist

C. Suspect medication(s)					
Name: Rid					
Dose, frequency,	route use	The	rapy d	ates	
1 bottle		10-0			
1 bottle		10 0	2	to 3-04	
<b>D:</b>			<b>F</b> 4		
Diagnosis for us	e			abated after use d or dose reduced	
n/a			stoppe	u of uose feutceu	
			no		
Lot #	Exp. date		Event	reappeared after	
			reintro	oduction	
			Ves		
NDC # -	-		yes		
Concomitant me	dical produ	ets			
n/a					
D. Suspect med	lical device	)			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			$\square_h$	ealth professional	
			🛄 u	ser facility	
			□d	istributor	
			Expir	ation date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #			1		
Device available	_			, ,	
	I returned		anufact	urer//	
Concomitant me	aicai produ	cts			
E. Reporter					
Name and addre	SS	p	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	IA. (	)2461		
Health professio	nal Occup	oatio	n	Also reported to	
$\mathbf{V}_{\text{yes}}$ $\square_{\text{nc}}$	)			manufacturer	
If you do NOT wa	nt your identi	ty		user facility	
disclosed to the ma	nufacturer, p	lace	an 🔲	distributor	

. Patient Inform		G	***	4
tient Identifier		h Sex female	Weigh	
_	03/03/01		35	lbs
Adverse event	Product Pr			
outcomes attribut				
$\Box_{\text{death}}$	disabilit			
□ life-threatening	_	y tal anomaly		
$\square$ hospitalization		l interventi		
other:	Tequilee			
Date of event 01-1	12-04 <b>D</b>	ate of repo	rt 3/*	1/2004
Describe event or		ate of Tepo	it 3/.	1/2004
elevant tests/labo	ratory data			
Other relevant his		ing preexi	sting cond	dition

C. Suspect med	lication(s)				
Name: lindane					
Nix					
Dose, frequency	route use	The	rapy d	ates	
am 25 125 lbs	augmer, r	01-1	01-12-04 to		
				02-29-04	
Diagnosis for us	e			abated after use	
no results			stoppe	d or dose reduced	
			no		
Lot #	Exp. date		Event	reappeared after	
	-			duction	
NDC # -	-		yes		
Concomitant me	dical produ	cts			
	· · · · ·				
D. Suspect med	lical device	<u>.</u>			
		,			
Brand name Type of device					
Manufacturer na	me and add	Irocc	Oper	ator of device	
	inc and aut	11 0.55	<u> </u>		
				ealth professional ser facility	
				istributor	
			-		
			Expi	ration date	
model #			Ifim	planted, give date	
catalog #				planteu, give uate	
serial # lot #			Tform	lanted sive date	
other #				planted, give date	
Device available	for avalue4	lon?			
$\square_{\text{yes}} \square_{\text{no}}$			anufact	urer / /	
Concomitant me			anuraci		
	arear produ				
E. Reporter					
Name and addre	SS	p	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	ciation		
P.O. Box 610189	, Newton, M	1A. (	)2461		
Health professio	nal Occuj	patio	n	Also reported to	
$\mathbf{V}_{\text{yes}}$ $\square_{\text{normalized}}$	)			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma	nufacturer n	lace	an 🔲	□ distributor	

A. Patient Informa	ation			
Patient Identifier	Date of birth	Sex	Weight	
1247	01/05/54	female	125	lbs
B. Adverse event	or product	problem		
	e Event & Pro		m	
Outcomes attribut				
∐ death	∐ disability			
L life-threatening		al anomaly		
▶ hospitalization	□ required	intervention		
other:				
Date of event 03/2	0/03 <b>Da</b>	te of report	2/19/2	2004
Relevant tests/labo	ratory data			

C. Suspect medication(s)					
Name: Nix					
Kwell,Rid, pest. spray,					
Dose, frequency,	, route use	The	rapy d	ates	
Shampooing and	spray	03/2	003		
treatments every 2				to 06/2003	
2noonlo and a doo Diagnosis for us		]	Event abated after use		
headlice			stopped or dose re		
neutrice			no		
Lot #	Exp. date	_	-		
Lot #	Exp. date			reappeared after	
		]	reintro	oduction	
NDC # -	-		yes		
Concomitant me	dical produ	cts			
	arear produ				
D. Suspect med	lical device	9			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			$\square_{h}$	ealth professional	
				ser facility	
			$\square_d$	istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
Device available					
Uyes Uno Concomitant me	returned		anufact	urer//	
Conconntant me	uicai produ	cis			
E. Reporter	E. Reporter				
Name and addre	SS	pł	none #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	<b>1</b> A. 0	2461		
Health professio	nal Occuj	patio	n	Also reported to	
$\mathbf{V}_{\text{yes}}$ $\square_{\text{normalized}}$	)			manufacturer	
If you do NOT was	nt your identi	ity	_	user facility	
disclosed to the ma	unufacturer, p	lace a	an 🔳	distributor	

A. Patient Inform	ation				
Patient Identifier	_	irth	Sex	Weight	
1246	07/15/197		female	145	lbs
B. Adverse event	or produ	ict pi	oblem		
	Advers	e Eve	ent		
Outcomes attribut	ted to adve	erse e	event		
death	disab	•			
✓ life-threatening			anomaly		
✓ hospitalization	<b>∠</b> requi	red in	tervention		
other:	-				
Date of event 08/2 Describe event or		Date	e of report	2/17/	2004
which caused me to time my baby was b took the drs. 17 min seizures and spent 1 childrens' hospital, I spent 11 days in th Relevant tests/labo	born, she d as. to revive l week in the then an add he hospital	id not e her. he NI d't 4 v as w	t have a he She suffer CU at an a veeks at the	artbeat. I ed with a rea's	t 1 few
Other relevant his	story, inclu	udinş	g preexisti	ng cond	ition

C. Suspect me	dication(s)			
Name: lindane				
<b>D</b>				
Dose, frequency			apy d	ates
Applied to infectory on head. Approx.		08/20	001	to
times in a pariod	of $1 \pm 4$		7	10/2001
Diagnosis for us				abated after use d or dose reduced
Headlice: treat all members.	Tamily			
Lot #	Evn data			t apply
L01 #	Exp. date			reappeared after oduction
NDC # -	-		doesn'	t apply
Concomitant me	edical produ	cts		
D. Suspect me	dical device	÷.		
Brand name				
<u>Type of device</u> Manufacturer n	ame and add	lress	Oper	ator of device
	une une une		<u> </u>	ealth professional
				ser facility
				istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial # lot #			7.0	
other #			If exp	planted, give date
Device available	e for evaluat	ion?		
			nufact	urer//
Concomitant me				
E. Reporter				
Name and addro	ess	ph	one #	(781)449-6487
The National Pe	ediculosis A			
P.O. Box 61018	9, Newton, N	1A. 0	2461	
Health profession ↓ yes □ n	onal Occu			Also reported to
If you do NOT wa		ity		user facility
disclosed to the m			in 🔲	distributor

Patient Iden 12 B. Adverse Outcomes at death life-threa hospitaliz other: re- Date of even my son had h week later i b it so the docto hair for 14 ho	241 event ttribut tening zation -treatm t 1/04 ent or p ead lic prought	03/06/19 or product Product ed to adv disat cong requi ent -2/04 problem e and was	94 m uct problem Problem erse even bility enital and ired inter Date of	ale lem n nt omaly vention	Weight 105 2/12/2	lbs
B. Adverse Outcomes at death life-threa hospitalit other: re- Date of even my son had h week later i b it so the doct	event ttribut tening zation -treatm at 1/04 ent or p aead lic prought	or product Product ed to adv disat cong requi ent -2/04 problem e and was	Ict prob Problem erse even bility enital and ired inter Date of	nt nt omaly vention		lbs
Outcomes at death life-threa hospitaliz other: re- Date of even Describe even my son had h week later i b it so the doctor	ttribut tening zation -treatm tt 1/04 ent or p aead lic prought	Product ed to adv disat cong requi ent -2/04 problem e and was	Problem erse even bility enital and ired inter Date of	n nt omaly vention	2/12/	
death life-threa hospitalin other: re- Date of even my son had h week later i b t so the doctor	tening zation treatm at 1/04 ent or p act lic prought	ed to adv disat cong requi ent -2/04 problem e and was	erse even bility enital and ired inter Date of	nt omaly vention	2/12/	
death life-threa hospitalin other: re- Date of even my son had h week later i b it so the doctor	tening zation treatm at 1/04 ent or p act lic prought	disat cong requi ent -2/04 problem e and was	bility enital and ired inter Date of	omaly vention	2/12/	
Date of even my son had h week later i b it so the docto	zation -treatm at 1/04 ent or p head lic prought	ent cong requi ent -2/04 problem e and was	enital and ired inter Date of	vention	2/12/2	
hospitaliz other: re- Date of even Describe even my son had h week later i b it so the docto	zation -treatm at 1/04 ent or p head lic prought	ent l-2/04 problem e and was	ired inter Date of	vention	2/12/2	
other: re- Date of even Describe even my son had h week later i b it so the docto	treatm t 1/04 ent or plead lic prought	ent I-2/04 problem e and was	Date of		2/12/2	
Date of even Describe even my son had h week later i b it so the docto	nt 1/04 ent or p lead lic prought	-2/04 problem e and was		report	2/12/2	
Describe even my son had h week later i b it so the docto	ent or j lead lic prought	<b>problem</b> e and was		report	2/12/2	
my son had h week later i b it so the docte	ead lic rought	e and was	treated v		2/12/2	2004
week later i b it so the doct	rought		treated v			
Lindane. All minutes and A worried abou and he said th I know if my should we use	Acticin t anyth nat Act kids ar e then t	for 14 hor ing?? I ca icin does r ad my self to get rid c	urs a wee alled my o not conta are going of the lice	ek later. doctor w in Linda g to be a	Should I with conce une. How	be erns do
Relevant tes	ts/labo	oratory da	ita			
<b>Other releva</b> My son has a		my daugh	nter becar		with a co	ugh,

Triage Unit Sequence #

#### C. Suspect medication(s) Name: Acticin and Nix Dose, frequency, route use Therapy dates Nix was used 10 minutes, 01302004 to one time use. (I used the Nix 02062004 Diagnosis for use Event abated after use stopped or dose reduced Head Lice doesn't apply Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # **Concomitant medical products** D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date model # If implanted, give date catalog # serial # \_\_\_\_\_ lot # If explanted, give date other # Device available for evaluation? ves no returned to manufacturer Concomitant medical products E. Reporter Name and address **phone** # (781)449-6487 The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461 Health professional Occupation Also reported to manufacturer ∕∠yes $\square_{\rm no}$ user facility If you do NOT want your identity distributor disclosed to the manufacturer, place an

	ation			
atient Identifier	Date of birt	h Sex	Weight	
1238	01-29-1998	female	50	lbs
Adverse event				
	Product P			
utcomes attribut				
death	∐ disabili			
life-threatening		ital anomaly	_	
hospitalization other:		d intervention	1	
			0/4/00	0.4
ate of event 11-2 escribe event or		ate of repor	t 2/4/20	04
elevant tests/labo	aratory data			
elevant tests/labo	oratory data			
			ing conditio	on
ther relevant his			ing conditio	on
her relevant his			ing conditio	on
ther relevant his			ing conditio	on
elevant tests/labo ther relevant his ne			ing conditio	on
her relevant his			ing conditio	on
her relevant his			ing conditio	on

C. Suspect med	lication(s	)		
Name: lindane				
Dose, frequency,	, route use	The	erapy d	ates
once every 7 days	5	11-2	20-2003	3
5 5				to 02-04-2004
Diagnosis for us	0		Event	abated after use
head lice	C			d or dose reduced
head lice				
			doesn	't apply
Lot #	Exp. date			reappeared after
			reintro	oduction
			yes	
NDC # -	-			
Concomitant me	dical prod	ucts		
lice be gone				
mayonaise treatme	ent			
safetek				
D. Suspect mec	lical devi	ce		
Brand name				
Type of device				
Manufacturer na	ame and ac	idres		ator of device
				ealth professional
				ser facility
				istributor
			Expi	ration date
model #			- Tf im	nlantad giva data
catalog #			- 11 1111	planted, give date
serial # lot #			- T£	lantad size data
other #				planted, give date
Device available		tion	·	
$\square_{\text{yes}} \square_{\text{no}}$				turer / /
Concomitant me			lanurae	
	1			
E. Reporter				
Name and addre	SS	p	hone #	(781)449-6487
The National Pe	diculosis	Asso	ciation	
P.O. Box 610189	, Newton,	MA.	02461	
Health profession		ipatio	on	Also reported to manufacturer
				user facility
If you do NOT was	-	-	an 🔲	
disclosed to the ma	mutacturer,	prace	an 📖	

A. Patient Inform	ation			
Patient Identifier		Sex	Weight	
1233	03/29/1993	female	125	lbs
3. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ed to adverse o	event		
death	∐ disability			
☐ life-threatening		-		
hospitalization	required in	ntervention		
other:				
Date of event 12/2 Describe event or		e of report	12/29/2	003
Relevant tests/labo	pratory data			
	story, includin			

C. Suspect med	ication(s)				
Name: Nix					
RID					
Dose, frequency,	route use	The	rapy d	ates	
As directed		12/0	12/05/2003		
				to 12/28/2003	
Diagnosis for use	e		Event	abated after use	
head lice			stoppe	d or dose reduced	
			doesn'	t apply	
Lot #	Exp. date			reappeared after	
unknown				oduction	
NDC # -	-		yes		
Concomitant mee	dical produ	cts			
Tried mayonaisse,	and reapply	ing	over the	e counter	
medications					
D. Suspect med	ical device	9			
Brand name					
Type of device			0		
Manufacturer na	me and add	lress	<u> </u>	ator of device	
				ealth professional	
				ser facility	
				istributor	
			Expir	ration date	
model #			- If im	planted, give date	
catalog #			-	planteu, give uate	
serial # lot #			Ifov	planted, give date	
other #				Janteu, give uate	
Device available	for evaluati	ion?			
	returned		anufact	urer _/_/	
Concomitant mee					
E. Reporter					
Name and addres	<b>5</b> 5	p	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	ciation		
P.O. Box 610189	, Newton, N	1A. (	)2461		
Health profession		oatio	n	Also reported to	
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$				manufacturer	
If you do NOT war		•		□user facility □distributor	
disclosed to the ma	nufacturer, p	lace	an 🔲	ulsuibutor	

A. Patient Information				
Patient Identifier Date of bi			Veight	
1230 07/04/199			45	lbs
B. Adverse event or produ				
Adverse Event &		roblen	1	
Outcomes attributed to adve				
⊔ <sub>death</sub> ⊔ <sub>disabi</sub>	•			
	nital anom	•		
hospitalization requir	red interve	ntion		
other: burning/itching rash	and hives			
Date of event 10/09/2003	Date of r	eport	12/16/2	2003
Describe event or problem				
I used, out of utter desperation	mind you	Kwel	ll. Her h	ead
starting burning and itching im				
numbness in her right foot. As	•		-	
head any part of her body it to				hd
	Jucifica cat	iscu bu	innig ai	iu
itening.				
acning.				
itching.				
licning.				
-				
Relevant tests/laboratory dat	ta			
-	ta			
Relevant tests/laboratory dat				
-		existin	g condi	tion
Relevant tests/laboratory dat		existin	g condi	tion
Relevant tests/laboratory dat		existin	g condi	tion
Relevant tests/laboratory dat		existin	g condi	tion
Relevant tests/laboratory dat		existin	g condi	tion
Relevant tests/laboratory dat		existin	g condi	tion
Relevant tests/laboratory dat		existin	g condi	tion
Relevant tests/laboratory dat		existin	g condi	tion
Relevant tests/laboratory dat		existin	g condi	tion
Relevant tests/laboratory dat		existin	g condi	tion

C. Suspect med	lication(s)			
Name: Kwell				
Dose, frequency,	route use	Ther	apy d	ates
loz one time		10/9/		
102 one time		10/9/.	2003	to
				10/9/2003
Diagnosis for us	e			abated after use
Licehead		S	toppe	d or dose reduced
			yes	
Lot #	Exp. date	F	vent	reappeared after
				duction
NDC # -	-		doesn	t apply
Concomitant me	dical produ	cts		
D. Suspect med	lical device	2		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oner	ator of device
			Ē	ealth professional
				ser facility
				istributor
			схрп	ration date
model #			If im	planted, give date
catalog #			11 111	planteu, give uate
serial # lot #			TE and	lantal stra data
other #			n exp	planted, give date
Device available	£			
$\square_{\text{yes}}$ $\square_{\text{no}}$			nufact	urer//
Concomitant me	dical produ	cts		
E. Reporter				
Name and addres	SS	ph	one #	(781)449-6487
The National Pe	diculosis A	ssoci	ation	
P.O. Box 610189	, Newton, N	1A. 02	2461	
Health profession	nal Occuj	patior	ı	Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$				manufacturer
If you do NOT wai	nt your identi	ity		user facility
	nufacturer, p			distributor

A. Patient Inform	ation					
Patient Identifier	Date of birth	Sex	Weight			
1223	6/25/97	female	50	lbs		
B. Adverse event	or product p	roblem				
	Product Prob	lem				
Outcomes attribut	ted to adverse o	event				
death	disability					
□ <sub>life-threatening</sub>		anomaly				
		•				
hospitalization required intervention						
other:						
Date of event 20/0	03/ <b>Date</b>	e of report	11/30/2	003		
Describe event or	problem					
I have been having	a lice problem w	ith my dau	ghter for tl	he		
whole year of 2003.	I have used eve	ry medicati	on on the			
shelf at pharmacies,	and been to the	Dr. and pre	escribed			
meds.She has misse						
still cannot control	the problem.The	e other fam	ily membe	rs		
have had no probler						
have it now also.I h	-	•				
used lice egg remov	-	-				
allow you to better				ed		
my home,thrown av	-		-			
unwashable items.U						
Dr.On 4 occasions		-		-		
me!! I am going to g		-				
going to fail.Not to		-				
and keeps a rash on		neck and b	ehind her e	ears		
Relevant tests/labo	oratory data					
Other relevant his						
	story, including	g preexisti	ng condit	ion		
N/A	story, including	g preexisti	ng condit	ion		
N/A	story, includin	g preexisti	ng condit	ion		
N/A	story, includin	g preexisti	ng condit	ion		
N/A	story, includin <sub>i</sub>	g preexisti	ng condit	ion		
N/A	story, including	g preexisti	ng condit	ion		
N/A	story, including	g preexisti	ng condit	ion		
N/A	story, including	g preexisti	ng condit	ion		
N/A	story, includin	g preexisti	ng condit	ion		
N/A	story, including	g preexisti	ng condit	ion		
√A	story, including	g preexisti	ng condit	ion		

Triage Unit Sequence #

### C. Suspect medication(s)

Name:			
lindane,r	id,nix ,clear		
Dose, frequency,	, route use	The	erapy dates
2 to 3 times a mor	nth	1/20	003 to 11/2003
Diagnosis for use			Event abated after use
head lice was seen,constant itching,rash			stopped or dose reduced doesn't apply
Lot #	Exp. date		Event reappeared after reintroduction
NDC # -	-		yes

#### Concomitant medical products

I have listed them all above.None of them are working.

### D. Suspect medical device

Brand name	
Type of device	
Manufacturer name and address	Operator of device health professional user facility distributor
model #	Expiration date
catalog # serial #	If implanted, give date
lot # other #	If explanted, give date
<b>Device available for evaluation?</b> Use no returned to main the second	nufacturer _/_/
Concomitant medical products	
E. Reporter	
Name and address ph	one # (781)449-6487
The National Pediculosis Associ	ation
P.O. Box 610189, Newton, MA. 02	2461
Health professionalOccupation	manufacturer
If you do NOT want your identity disclosed to the manufacturer, place a	n distributor

. Patient Inform			~		
atient Identifier			Sex	Weight	
1214	08/14/197		female	150	lbs
Adverse event					
· · · · · · ·	Advers				
I <b>tcomes attribut</b>			vent		
□ death ] life-threatening	∐ disab	•	1		
hospitalization	<u> </u>		anomaly terventio		
other:	- Tequi	ieu iii		11	
	1/2002	<b>D</b> (	0	4 11/11	2002
te of event 11/1 scribe event or		Date	of repo	rt 11/11/	2003
levant tests/labo her relevant his			preexis	ting cond	ition

C. Suspect med	lication(s)				
Name: Nix					
rid					
Dose, frequency,	, route use	The	rapy d	ates	
4 oz two seperate	e	11/0	2/2003		
applications				to 11/11/2003	
Diagnosis for us	e	ľ	Event	abated after use	
head lice		:	stoppe	d or dose reduced	
			no		
Lot#	Exp. date		-		
L01 #	Exp. uate			reappeared after	
		•	reintro	oduction	
NDC # -	-		yes		
Concomitant me	dical produ	cts			
	F				
D. Suspect med	lical device	)			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			$\square_{\rm h}$	ealth professional	
				ser facility	
			$\square_d$	istributor	
			Expir	ation date	
model #			_		
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
<b>Device available</b>	for evaluati		anufact	urer / /	
Concomitant me	dical produ	cts			
P. 0 44060					
E. Reporter					
Name and addre	SS	pl	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, N	1A. (	02461		
Health professio $\mathbf{V}_{yes}$ $\square_{nc}$		oatio	n	Also reported to manufacturer	
-				$\square$ user facility	
If you do NOT was disclosed to the ma	-	-	an 🔳	distributor	
anserosed to the life	maraciarci, p	iact	un 🔲		

A. Patient Inform	ation				
Patient Identifier	Date of bi	rth Se	ĸ	Weight	
1207	08/04/95	fei	nale	80	lbs
B. Adverse event	t or produ	ct prob	lem		
Advers	e Event &	Product	Proble	em	
Outcomes attribut	ted to adve	rse ever	ıt		
death	disabi	lity			
□ life-threatening	$\Box_{\text{conge}}$	nital ano	maly		
hospitalization	□ <sub>requin</sub>	ed interv	ention		
other: rested at	home				
Date of event 20/	01/	Date of	report	10/17/2	003
Describe event or	problem				
Treated with Lindar			-		
nauseaus, dizzy, he				g it on to	
long.I was sure I ha	d monitere	d proper	ly.		
Relevant tests/labo	oratory dat	a			
04		- 1 <sup>2</sup>			•
Other relevant his	story, inclu	ıding pr	eexisti	ng condit	ion
Other relevant his	story, inclu	ıding pr	eexisti	ng condit	ion
Other relevant his	story, inclu	ıding pr	eexisti	ng condit	ion
Other relevant his	story, inclu	iding pr	eexisti	ng condit	ion
Other relevant his	story, inclu	ıding pr	eexisti	ng condit	ion
Other relevant his	story, inclu	ding pr	eexisti	ng condit	ion
Other relevant his	story, inclu	iding pr	eexisti	ng condit	ion
Other relevant his	story, inclu	ıding pr	eexisti	ng condit	ion

C. Suspect me	dication(s)			
Name: lindane				
Dose, frequency	, route use	The	rapy d	ates
aprox 20 ml of so	lution, used	2000	)	to
twice only				2000
Diagnosis for us	se			abated after use
constant lice, larg	e and	5	stoppe	d or dose reduced
small,many nits &	k bites		yes	
Lot #	Exp. date	]	Event	reappeared after
		1	reintro	oduction
			doesn	t apply
NDC # -	-	- 1		
Concomitant me	-			.1
Nix R&C Kwel P				
2003 about 2 sha breaks in the sum				
			t0 g0 a	way. School
D. Suspect me	dical device	Ģ		
Brand name				
<u>Type of device</u> Manufacturer n	ama and add	Imagg	Oner	aton of dorigo
	ame and add	iress	Ĺ.	ator of device
				ealth professional ser facility
				istributor
			Expi	ration date
model # catalog #			If im	planted, give date
serial #				
lot #			If ext	planted, give date
other #				, , ,
<b>Device available</b>				
Concomitant me			anuraci	urer//
	produ			
E. Reporter				
Name and addre	ess	pł	none #	(781)449-6487
The National Pe	ediculosis A	ssoc	iation	
P.O. Box 610189	) Newton M	<b>1</b> A. 0	2461	
1.0. DOX 01010	, 1 10 11 1011, 11			
Health professio	onal Occuj		n	Also reported to
	onal Occuj	patio	n	Also reported to manufacturer user facility

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
1202	06/27/19	92	female	163	lbs
B. Adverse even	t or produ	lct pi	roblem		
Advers	se Event &	Prod	luct Proble	em	
Outcomes attribu	ted to adv	erse e	event		
death	□disat	oility			
□ <sub>life-threatening</sub>	$\Box_{\rm cong}$	enital	anomaly		
hospitalization	$\Box_{require$	ired in	itervention		
other: increased	l allergies/l	ifelon	g problems		
Date of event 07/	19/94	Date	e of report	10/14/2	2003
Describe event or	problem				
Rebecca (and her si	sters) was	treate	d no less th	nan 4 time	s in
a row using RID an	-	,	U	U	
spray, in the month	,	2	0		
believe that these re	-				
allergies and have c	ontributed	to sev	veral bouts	of bronch	1t1s.

#### Relevant tests/laboratory data

Other relevant history, including preexisting condition Rebecca was a toddler and then a two-year old in the day care program in which this occurred. We removed her and her sisters from the program when it became clear that the day care would not accept responsibility for cleaning up its own facilities and ending the exposure to the children onsite. They chose to blame the parents instead of take responsibility. Rebecca did not have allergies before this time, but developed them shortly thereafter (within the next two years). Triage Unit Sequence #

#### C. Suspect medication(s) Name: Nix Rid Dose, frequency, route use Therapy dates Shampoo and bedding spray 06/1994 to (sprayed on bedding, in car, 08/1994 Diagnosis for use Event abated after use stopped or dose reduced That she had head lice and needed to be treated with these no Lot # Exp. date Event reappeared after reintroduction unknown yes NDC # Concomitant medical products There were at least four other times in the next four years,

where she had to be treated for lice and we always used either Nix, or Rid, Shampoo and spray (with combing and

ח צ ר	enact	medi	cal d	avica
J. OU	Speci	IIIGui	cai u	

Brand name		
Type of device		
Manufacturer name and address	Operator of device health profession user facility distributor	nal
model #	Expiration date	
catalog # serial #	If implanted, give d	ate
lot # other #	If explanted, give d	ate
<b>Device available for evaluation?</b>	anufacturer _/_/	
Concomitant medical products		
E. Reporter		
Name and address ph	none # (781)449-648	7
The National Pediculosis Associ	iation	
P.O. Box 610189, Newton, MA. 02	2461	
Health professionalOccupation	manufactu	rer
If you do NOT want your identity disclosed to the manufacturer, place a	user facilit	

A. Patient Informa	ation			
A. Patient Identifier		Sex	Weight	
1196	02/20/98	female		•
B. Adverse event			45 II	os
	e Event & Prod		m	
Outcomes attribut				
	disability	event		
$\Box$ life-threatening		anomaly		
$\square$ hospitalization	$\Box$ required in	-		
other:				
	C/02	e 4	10/6/200	
Date of event 09/2 Describe event or		e of report	10/6/200	)3
weeks now, includir my children have be inbetween missing s lice over and over	en sick and mis	sing even n	nore school	
Relevant tests/labo	ratory data			
Other relevant his My daughtor Laney lice also has bites a case of flea bites? I d i can just incase it is do not have these m her happened around head liceIs it possil	whom is the or all over her body do have two dog flea bites? Alth arksIt does se d the same time	he that keep almost lik gs but have hough my o bem that the i started tr	e a really bac also done all ther children break out out	e d l n

c. Sus	pect med	dication(s)			
Name:	Rid				
	also NIX	I			
Dose, fr	equency	, route use	The	erapy d	ates
have dor	ne at least	six	09/2	23/03	
treatmer	nts that is a	meaning			to 10/06/03
double t	sis for us	trootmonto		Evont	abated after use
		C			d or dose reduced
Live lice	•				
				doesn	t apply
Lot #		Exp. date		Event	reappeared after
				reintro	oduction
NDC #				doesn	t apply
	-	- diaal	otc		
Concon	iitant me	dical produ	cts		
D. Sus	pect med	dical device	•		
Brand r					
Type of					
Manufa	cturer na	ame and add	lress	6 Oper	ator of device
					ealth professional
				□u	ser facility
				□u	
				$\square_{\rm u}$ $\square_{\rm d}$	ser facility
model #	£			$\square_{\rm u}$ $\square_{\rm d}$	ser facility istributor
	۰ ۲			Expin	ser facility istributor
catalog				Expin	ser facility istributor ration date
catalog serial # lot #	#			Expin	ser facility istributor ration date
catalog serial #	#			Expin	ser facility istributor ration date planted, give date
catalog serial # lot # other # Device :	# available	for evaluat		Expin If imp If exp	ser facility istributor ration date planted, give date planted, give date
catalog serial # lot # other # Device a yes	# available	returned	to m	Expin If imp If exp	ser facility istributor ration date planted, give date planted, give date
catalog serial # lot # other # Device a yes	# available		to m	Expin If imp If exp	ser facility istributor ration date planted, give date planted, give date
catalog serial # lot # other # Device a yes	# available D <sub>no</sub> nitant me	returned	to m	Expin If imp If exp	ser facility istributor ration date planted, give date planted, give date
catalog serial # lot # other # Device a yes Concon	# available D <sub>no</sub> nitant me	<b>dical produ</b>	to m cts	Lu Lu Lu Lu Lu Lu Lu Lu Lu Lu Lu Lu Lu L	ser facility istributor ration date planted, give date planted, give date
catalog serial # lot # other # Device : yes Concon E. Repo	# available no nitant me orter nd addre	<b>dical produ</b>	to m cts p	Lunch	ser facility istributor ration date planted, give date planted, give date urer _/_/
catalog serial # lot # other # Device a yes Concon E. Repo Name a The Na	#available	returned dical produces ss	to m cts p	Lunch Line Line Line Line Line Line Line Line	ser facility istributor ration date planted, give date planted, give date urer/_/
catalog serial # lot # other # Device : yes Concon E. Repo Name a The Na P.O. Bo Health	#available	returned      dical product      ss      sdiculosis A      p, Newton, M      nal Occup	to m cts p .ssoc 1A. (	Light for the second se	ser facility istributor ration date planted, give date planted, give date urer _/_/
catalog serial # lot # other # Device a yes Concon E. Repo Name a The Na P.O. Bo Health yes	# available no nitant me potter nd addre tional Pe x 610189 professio	returned      dical product      ss      sdiculosis A      p, Newton, M      nal Occup	to m cts p .ssoc IA. ( patic	Light for the second se	ser facility istributor ration date planted, give date olanted, give date urer _/_/ (781)449-6487 Also reported to

	ation			
Patient Identifier		Sex	Weight	
1194	11/28/1987	female	325	lbs
B. Adverse event	or product	problem		
Advers	e Event & Pr	oduct Proble	em	
Outcomes attribut	ed to adverse	event		
death	disabilit	1		
□ life-threatening	Congenit	al anomaly		
hospitalization	L required	intervention		
other:				
Date of event 199	9-2003 <b>D</b> a	te of report	10/3/2	2003
Relevant tests/labo	oratory data			
Relevant tests/labo Other relevant his asthma and excema		ng preexisti	ng condi	tion

C. Suspect medication(s)				
Name: Nix				
Dose, frequency,	route use	The	rapy d	ates
every 10 days		1999		
every 10 days		1777	•	to
				2003
Diagnosis for us	e			abated after use
head lice		5	stoppe	d or dose reduced
			no	
Lot #	Exp. date	1	Event	reappeared after
				oduction
NDC # -	-		yes	
Concomitant me	dical produ	ets		
D. Suspect med	lical device	<u>,</u>		
		•		
Brand name Type of device				
<u>I ype of device</u> Manufacturer na	mo and add	ross	Oper	ator of device
	une anu auu	11 055	1 Â	
				ealth professional ser facility
				istributor
			Expu	ration date
model #			Ifim	planted, give date
catalog #			II III	planteu, give uate
serial #			Te	
lot # other #			If exp	planted, give date
<b>Device available</b>				
Concomitant me			anulaci	urer//
Conconntant me	uicai pi ouu			
E. Reporter				
Name and addre	SS	pł	10ne #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	<b>IA</b> . 0	2461	
Health professio ✓ <sub>yes</sub> □ <sub>nc</sub>	-	oatio	n	Also reported to
				$\square$ user facility
If you do NOT was		•		
disclosed to the ma	inutacturer, p	lace a	an 🔲	-uisu ibutor

. Patient Inform	ation			
tient Identifier	Date of birth	Sex	Weight	
1189	6-22-95	female	60	lbs
Adverse even	t or product p			
	Product Prob			
	ted to adverse o	event		
death	□ disability			
☐ life-threatening		-		
hospitalization	□ required ir	ntervention		
other:				
te of event 8-1	2-03 Date	e of report	9/17/2	003
elevant tests/lab	oratory data			
ther relevant hi	story, includin;	g preexisti	ng condit	ion

C. Suspect medi	cation(s)		
Name: Kwell			
Dose, frequency, 1	oute use	Therap	y dates
wash hair 2times		8-12-03	-
wash han 2thics		0 12 00	to 9-12-03
		5	
Diagnosis for use			ent abated after use
headlice		sto	pped or dose reduced
		no	
Lot # E	xp. date	Ev	ent reappeared after
			ntroduction
NDC # -	-	ye	S
Concomitant med	ical produc	cts	
nix,rid still had lie	-		
-, Suit 1144 II			
D. Suspect medi	cal device		
Brand name			
Type of device			
Manufacturer nan	ne and add	lress 0	perator of device
			health professional
			user facility
			distributor
		E	xpiration date
model #			-
catalog #		If	implanted, give date
serial #			
lot #		If	explanted, give date
other #		[	
Device available f			
$\square_{\text{yes}} \square_{\text{no}}$			ıfacturer//
Concomitant med	ical produo	ets	
E. Reporter			
Name and address	,	nhor	ne # (781)449-6487
The National Ped		_	
P.O. Box 610189,	Newton, M	IA. 024	61
Health profession			Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$	Joccup	<i>au011</i>	manufacturer
If you do NOT want	vour identi	tv	user facility

A. Patient Inform	ation				
Patient Identifier	Date of bi	rth	Sex	Weight	
1184	03/26/196	8	female	155	lbs
B. Adverse event	or produ	ct pr	roblem		
	Product				
Outcomes attribut	ed to adve	rse e	event		
death	□disabi	litv			
□ life-threatening		•	anomaly		
$\square$ hospitalization			itervention		
· · · · · · · · · · · · · · · · · · ·		eu II			
other: shaved h	ead				
Date of event 08-2	24-2003	Date	e of report	9/12/	2003
Describe event or	problem				
am still battling wi	ith head lice	e. It	will be thre	e weeks	
Sunday. I have was					ver
the counter product	s such as: 1	RID,	NIX, and	Permethr	rin.
After these failed I					
These too were BIC	-				
completely!) The lid					each
product was rinsed			-		
them scurrying arou			•	•	
dangerous products					
they DON'T WORI	-		• •	•	men
-		-			
mayonnaise on my					ers
on, I have combed w					
combed with dry ha			•	•	
husband shave my b		-			
quarter inch to aid i	n getting rid	l of t	hese horrib	oly resilie	ent
Relevant tests/labo	oratory dat	a			
<b></b>				_	
Other relevant his	story, inclu	iding	g preexisti	ng condi	ition
None known					

C. Suspect med	dication(s)			
Name: lindane				
malathio	n			
Dose, frequency	, route use	The	rapy d	ates
1% and 0.5% both	1% and 0.5% both were 08-2		4-2003	to
applied twice.				09-12-2003
Diagnosis for us	e		Event	abated after use
head lice			stoppe	d or dose reduced
			doesn'	t apply
Lot #	Exp. date		Event	reappeared after
unknown				duction
			doesn'	t apply
NDC # -	-			· ···r·r-J
Concomitant me NIX, RID, Permit				
,,				
D. Suspect med	dical device	÷		
Brand name				
Type of device				
Manufacturer na				ealth professional ser facility istributor
			Expir	ation date
model # catalog #			If im	planted, give date
catalog # serial #				p
lot #			If ext	planted, give date
other #				
<b>Device available</b>			anufact	urer / /
Concomitant me				·····
	-			
E. Reporter				
Name and addre	SS	p	hone #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	1A. (	)2461	
Health professio ✓ <sub>yes</sub> □ <sub>nc</sub>	)		n	Also reported to
If you do NOT wa	-	-		User facility
disclosed to the ma	nufacturer, n	lace	an 📘	□distributor

	ation			
atient Identifier	Date of birth	Sex	Weight	
1180	01/18/1999	female	40	lbs
8. Adverse event	or product p	roblem		
	Product Prob			
Outcomes attribut		event		
∐ death	∐ disability			
☐ life-threatening				
hospitalization		ntervention		1
other: still has b	-			
Date of event 9/02	1-9/03 <b>Dat</b>	e of report	9/9/	2003
have used mayona		il. HELP!		

	dication(s)			
Name:				
all on the	e list except k	well a	and lin	dane
Dose, frequency	, route use	Ther	apy da	ates
recommended on	package	9-200	01	
	, U			to 9-2003
Diagnosis for us	e	l F	Event a	abated after use
live lice	-			d or dose reduced
iive nee			no	
Lot #	Exp. date			
L01 #	Exp. date			reappeared after
		r	eintro	duction
NDC # -	-		yes	
Concomitant me	dical produ	cts		
conconntant int	uicui prouu	<b>C U</b> 5		
D. Suspect med	dical device	e		
Brand name				
Type of device				
Manufacturer na	ame and add	lress	Oner	ator of device
	anie and aut	11 000	oper	ator of actice
			Π.	1.1 6
				ealth professional
				ser facility
				ser facility stributor
				ser facility
			Expir	ser facility istributor ation date
catalog #			Expir	ser facility stributor
catalog # serial #			Expir	ser facility istributor ation date
catalog # serial # lot #			Expir	ser facility istributor ation date
catalog # serial # lot #			Expir	ser facility istributor ation date planted, give date
catalog # serial # lot # other # Device available	for evaluat	ion?	Expir If imp	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available	for evaluat	ion? to ma	Expir If imp	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available	for evaluat	ion? to ma	Expir If imp	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available	for evaluat	ion? to ma	Expir If imp	ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available yesno Concomitant me	for evaluat	ion? to ma	Expir If imp	ser facility istributor ration date planted, give date planted, give date
catalog # serial # other # Device available U yesno Concomitant me	for evaluat	ion? to ma cts	Expir Expir If imj If exp	ser facility istributor ration date planted, give date planted, give date
catalog # serial # other # Device available Uges Uno Concomitant me E. Reporter Name and addre	for evaluat returned dical produ	ion? to ma cts ph	If imp If exp	ser facility istributor ation date planted, give date lanted, give date
	for evaluat returned dical produ ess ediculosis A	ion? to ma cts ph	If imp If exp nufact	ser facility istributor ation date planted, give date lanted, give date
catalog # serial # other # Device available $\Box_{yes}$ $\Box_{no}$ Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189	for evaluat returned dical produ ss ediculosis A 9, Newton, N	ion? to ma cts ph sssoci 1A. 02	If imp If exp inufact	ser facility istributor ation date planted, give date planted, give date urer/_/ (781)449-6487
catalog # serial # other # Device available Uges Uno Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	for evaluat returned dical produ ss ediculosis A 0, Newton, M nal Occuj	ion? to ma cts ph sssoci 1A. 02	If imp If exp inufact	ser facility istributor ation date planted, give date lanted, give date
catalog # serial # other # Device available Uyes no Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	for evaluat returned dical produ ess ediculosis A 0, Newton, N onal Occup	ion? to ma cts ph sssoci 1A. 02 patior	If imp If exp inufact	ser facility istributor ation date planted, give date planted, give date urer/_/ (781)449-6487 Also reported to

A. Patient Inform	ation				
Patient Identifier	Date of bir	th	Sex	Weight	
1179	07/02/1961	1	female	218	lbs
B. Adverse event	or produc	ct p	roblem		
	Product P	rob	lem		
Outcomes attribut	ed to adver	rse e	event		
death	disabil	lity			
□ life-threatening	$\Box_{\text{conger}}$	nital	anomaly		
hospitalization	$\Box_{\text{require}}$	ed ir	tervention		
other: missing	work				
Date of event 8/06	5/03	Date	e of report	9/7/2	2003
Describe event or	problem				
Scabies, was gotten					om a
mothers friend and			-		
treated by dr. twice				did	
everything that the	Dr. said to c	lo			
Dalamant ta sta/la ha		~			
Relevant tests/labo	oratory data	a			
Other relevant his	story, inclu	ding	g preexisti	ng condi	tion
Has high Blood Pres				2	
Ũ					

C. Suspect med	dication(s)				
Name: lindane					
Dose, frequency	ose, frequency, route use Therapy dates				
the Lindane lotior		8/06/			
time and the Actic	ine cream			to 8/24/03	
5% use 1 time Diagnosis for us	e	۱ را	Event	abated after use	
Scabies	-			d or dose reduced	
Seables			yes		
Lot #	Exp. date				
Lot #	Exp. date			reappeared after oduction	
				Junction	
NDC # -	-		yes		
Concomitant me	dical produ	cts			
Acticine (permeth	rin) cream 5	%			
8/12/03 and 8/18	/03				
D. Suspect med	dical device	÷			
Brand name					
Type of device					
Manufacturer na	ame and add	iress	Ē		
				ealth professional ser facility	
				istributor	
				ration date	
model #			Expi	ation date	
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
Device available					
□ <sub>yes</sub> □ <sub>no</sub> Concomitant me			anufact	urer/_/	
Conconntant me	uicai produ	cis			
E. Reporter					
Name and addre		Ē		(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	<b>1</b> A. 0	2461		
Health professio ✓ <sub>yes</sub> □ <sub>nc</sub>		patio	n	Also reported to manufacturer	
If you do NOT wa	nt your ident	ity		user facility	
disclosed to the ma	•	•	an 🔳	distributor	

A. Patient Inform	ation					
Patient Identifier	Date of b	irth	Sex	Weight	,	
1178	09/25/95		female	60	lbs	
B. Adverse event	or produ	ict p	oblem			
	Advers	se Eve	ent			
Outcomes attribut			event			
$\Box_{\text{death}}$ $\Box_{\text{disability}}$						
$\Box$ life-threatening $\Box$ congenital anomaly $\Box$ hospitalization $\Box$ required intervention						
hospitalization		red ir	tervention		1	
Date of event 5/20	-	D-4		0/2	/2002	
Date of event 5/20 Describe event or		Date	of report	9/3	/2003	
Relevant tests/labo	nratory da	ta				
Other relevant his none	tory, incl	udinş	g preexisti	ng cond	lition	

C. Suspect medication(s)						
Name: Nix						
you name the brand we tried it						
Dose, frequency, route use Therapy dates				ates		
as directed		05/03	3	to		
				to 09/03		
Diagnosis for us	e	I	Event	abated after use		
head lice		s	toppe	d or dose reduced		
			no			
Lot #	Exp. date		-	1 0/		
L0t #	Exp. uaic			reappeared after oduction		
		ľ	eintro	auction		
NDC # -	-		doesn'	t apply		
Concomitant me	dical produ	cts				
we have tried ever	-		ble fro	om ones		
containing pesticio	-					
results				_		
D. Suspect med	lical devic	e				
Brand name						
Type of device						
Manufacturer na	me and ad	dress	Oper	ator of device		
				ealth professional		
			user facility			
				istributor		
			Expir	ration date		
model #			70.1			
catalog #			If im	planted, give date		
serial #			7.0			
lot # other #			If exp	planted, give date		
Device available			I			
$\square_{\text{yes}} \square_{\text{no}}$			nufact	urer / /		
Concomitant me			inunuot			
concontaint medical products						
E. Reporter	E. Reporter					
Name and addre	SS	ph	one #	(781)449-6487		
The National Pe	diculosis A	ssoci	iation			
P.O. Box 610189	, Newton, N	/IA. 0	2461			
Health profession ↓ yes □ nc		patio	1	Also reported to manufacturer		
If you do NOT war		ity		$\square$ user facility		
II YOU GO NOT WA	at your fuellt	10.1				

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1171	04/26/1990	female	100	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Proc	luct Proble	m	
Outcomes attribut	ed to adverse	event		
death	∐ disability			
Life-threatening		anomaly		
hospitalization	□ required in	ntervention		
other:				
Date of event 199	6-1998 <b>Dat</b>	e of report	8/7/2	2003
<b>Describe event or</b> My daughter, Rebel	-			
turned out to be a ba Stacey never contrac attract them by the l shampooing with ev all the natural ways cause so much dama never would die. I l sprayed day in and of finally had to move. surely did Rebekah <b>Relevant tests/labo</b>	ted head lice, F nundreds even a very product on of getting rid o age. The more iterally washed lay out for a ye Once I finally get released fro	Rebekah see after numbe the market f these little I tried, it see and shamp ar and a hal moved, the	med to crous . I even t bugs tha emed they ooed and If before I en slowly	ried t ⁄ [ but
<b>Other relevant his</b> Heart Disease (Puln			ng condi	tion

Triage Unit Sequence #

### C. Suspect medication(s)

Name:	Rid

Dose, frequency	Dose, frequency, route use The		herapy dates		
Dosage: every 2 v year and a half. I	also	199	6 to 1998		
	Diagnosis for use		Event abated after use		
shampoo every 10 days			stopped or dose reduce		
			doesn't apply		
Lot #	Exp. date		Event reappeared after reintroduction		
NDC #			doesn't apply		

#### Concomitant medical products

Nix, Maynaise, Clear, Vaseline, Tee Tree Oil, Olive Oil, Vinegar, mixture of conditioner and a small amount of bleach (I was desperate).

#### D. Suspect medical device

Brand name

Type of device Manufacturer name and address Operator of device

	health professional user facility distributor
model # catalog #	Expiration date
serial # lot # other #	-
Device available for evaluation Uses no returned to 1 Concomitant medical products	
E. Reporter	
Name and address	phone # (781)449-6487
The National Pediculosis Asso	ociation

P.O. Box 610189, Newton, MA. 02461

Health professional ✓ yes □ no		Also reported to manufacturer
If you do NOT want you	2	user facility
disclosed to the manufac	turer, place an 🔲	distributor

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1157	08/08/1998	female	50	lbs
B. Adverse event	or product p	roblem		
	Product Prob			
Outcomes attribut		event		
□ death	$\Box$ disability			
□ life-threatening		•		
hospitalization	required in	ntervention		1
other:				
Date of event 07/1		e of report	7/11/2	2003
Describe event or				
after treating with b				
prescription shampo	o nve nce retu	medin 5 we	eks	
Dalamant taata/laha	matanı Jata			
Relevant tests/labo	oratory data			
Other relevant his	tory, includin	g nreevicti	ng condi	tion
Guier reievant IIIs	, includin	s preexisti	ng conui	
none				
				_

	lication(s)				
Name: Rid					
lindane					
Dose, frequency,	, route use	The	nerapy dates		
twice with the rid/	/ twice	6/20/2003			
with lindane over a 3 week			to 7/11/2003		
noried Diagnosis for use	e		Event aba	ted after use	
head lice			stopped or	dose reduced	
neud nee			no		
Lot #	Erm data				
LOI #	Exp. date			opeared after	
		]	reintrodu	ction	
NDC # -			yes		
Concomitant me	dical produ	ete			
	uicai produ	.15			
D. Suspect med	lical device	<u>.</u>			
Brand name		, 			
Type of device					
Manufacturer na	me and add	lress	Operato	r of device	
			L Ê	h professional	
			user	racility	
			distri	butor	
model #				butor	
 model # catalog #			distri Expiration	butor	
catalog # serial #			distri Expiration	butor on date	
catalog # serial # lot #			distri Expiratio	butor on date	
catalog # serial #			distri Expiratio	butor on date nted, give date	
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	f <u>or</u> evaluati		distri Expiration If implan	butor on date nted, give date nted, give date	
catalog # serial # lot # other #	for evaluat	to m	distri Expiration If implan	butor on date nted, give date nted, give date	
catalog # serial # lot # other # Device available	for evaluat	to m	distri Expiration If implan	butor on date nted, give date nted, give date	
catalog # serial # lot # other # Device available	for evaluat	to m	distri Expiration If implan	butor on date nted, give date nted, give date	
catalog # serial # lot # other # Device available Device available Orconcomitant met	for evaluati returned dical produce	<u>to m</u> cts	distri Expiration If implan If explant	butor on date nted, give date nted, give date	
catalog # serial # lot # other # Device available $\square_{yes}$ $\square_{no}$ Concomitant means E. Reporter	for evaluati returned dical produce ss	to ma cts pl	distri Expiration If implant If explant anufacture	butor on date nted, give date nted, give date	
catalog # serial # lot # other # Device available UVES UND Concomitant met E. Reporter Name and addre	for evaluati returned dical produce ss diculosis A	to ma cts pl	distri Expiration	butor on date nted, give date nted, give date	
catalog # serial # lot # other # Device available Urres Urres Ves Urres Concomitant means E. Reporter Name and addres The National Pe P.O. Box 610189 Health profession	for evaluati returned dical produce ss diculosis A b, Newton, M nal Occup	to ma cts pl .ssoc 1A. (	distri Expiration If implant If explant anufacture none # (7) iation 2461	butor on date nted, give date ited, give date r _/_/ 81)449-6487 so reported to	
catalog # serial # lot # other # Device available $\Box_{yes}$ $\Box_{no}$ Concomitant means E. Reporter Name and address The National Pe P.O. Box 610189	for evaluati returned dical product ss diculosis A Newton, N nal Occup	to ma cts pl .ssoc 1A. () patio	distri Expiration If implant If explant anufacture none # (7) iation 2461	butor on date nted, give date nted, give date r/_/	

	aun			
A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1153	4-4-1967	female	112	lbs
B. Adverse event	or product p	oroblem		
Advers	e Event & Pro	duct Probl	em	
Outcomes attribut	ed to adverse	event		
death	🗹 disability			
□ life-threatening	✓ congenita	l anomaly		
hospitalization	required i		l	
other: depressio				/age
Date of event 10/5	5/01 <b>D</b> at	te of report	t 7/7/2	2003
Describe event or		-		
Treated for scabies	-	hampoo. N	ligrane the	ree
days later so bad I v		-	-	
Still had bumps and	itching but roo	omate and h	er son did	
not. Hairlike fuzz, l	U U			
see migration when	I stretch skin,	-		
Reoccurring now fo				
12 doctors in two ye		0		
cloearly visible para menestration blood,				
with no air. Dog aff	-	-		
contamination like				
house gets it !!! Reg		-		
what I have and I pa				
cured before I lose e		ve worked s	so hard for	•
Relevant tests/labo	ratory data			
Other relevant his			ing condi	tion
I have no spleen (ca	r accidnet at ag	ge 16)		
My friand who has	this as well is t	rom Torra	Unuto Ind	one
My friend who has t and	uns as wen 18 1	10111 1 erre	naute Indi	ana
had an apendictimy	at age 7 or 8			
······································				

Triage Unit Sequence #

### C. Suspect medication(s)

Name: K	well
---------	------

Dose, frequency, route use		Therapy dates			
5 minutes then shower.		10/	75/01	to	
I re-trated a co	ouple times the			to	10/7/01
Diagnosis for			Event	abate	ed after use
Scabies			stoppe	d or (	dose reduced
			no		
Lot #	Exp. date		Event 1 reintro		peared after ion
NDC #			yes		

#### **Concomitant medical products**

antibiotics, keflex, metrodiazadol (three times), 15 types of cortizone creams, prednisone, difluxican, Herpes zoster med zovirox for 5 month,

#### D. Suspect medical device

Brand name			
Type of device			
Manufacturer name and address	Operator of device health professional user facility distributor		
model #	Expiration date		
catalog # serial #	If implanted, give date		
	If explanted, give date		
<b>Device available for evaluation?</b>	nufacturer//		
Concomitant medical products			
E. Reporter			
Name and address ph	one # (781)449-6487		
The National Pediculosis Associ	ation		
P.O. Box 610189, Newton, MA. 02	2461		
Health professionalOccupation	manufacturer		
If you do NOT want your identity disclosed to the manufacturer, place a	n distributor		

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
1143	03/07/19	56	female	110	lbs
B. Adverse event	or produ	ict p	roblem		
Advers	e Event &	Prod	luct Proble	em	
Outcomes attribut	ed to adv	erse e	event		
death	∐disat	oility			
Life-threatening		enital	anomaly		
hospitalization	L requi	red ir	tervention		
other:					
Date of event 04/1	15/2003	Date	e of report	6/22/	2003
Describe event or					
Still have not gotter					
Shampoo use 5 time					
Elimite 3 times - see	condary in	tectio	n and mass	ive hair le	DSS.
Relevant tests/labo	ratory da	ta			
	natory da	u			
Other relevant his	story, incl	uding	g preexisti	ng condi	tion
	•	,	<b>3</b>	8	

C. Suspect	medicat	ion(s)			
Name: Rid					
nix,	generic ar	nd elinir	nite		
Dose, frequ	ency, rou	te use	The	rapy d	ates
shampoo 5 times elinimite 3 04/			04/1	5/2003	
times					to 06/22/2003
Diagnosis fo	or use				abated after use
head lice alth	ough Dr's	have		stoppe	d or dose reduced
never found	any nits			no	
Lot #	Exp.	date		Event	reappeared after
					oduction
NDC #	-	-		yes	
Concomitan	t medical	produ	cts		
antibiotic for	secondary	- doxi	oen f	or aller	gic reaction,
	-	-			ay and they just
don't go away	y				
D. Suspect	medical	device	e		
Brand name					
Type of devi					
Manufactur	er name a	and add	dress	o Oper	ator of device
				h	ealth professional
					ser facility
					istributor
					ration date
model #				Expi	ation date
catalog #				- If im	planted, give date
serial #					,0
lot #				If ext	planted, give date
other #					, grie unie
Device avail					
				anufact	turer//
Concomitan	i meaical	proau	cts		
E. Reporter					
Name and a			p	hone #	(781)449-6487
The Nationa		losis A	Ê		
P.O. Box 61	0189, Nev	vton, N	1A. (	02461	
Health prof V <sub>yes</sub>	essional	Occu			Also reported to
•	□no				manufacturer
If you do NO	-		-		User facility
disclosed to the	he manufac	cturer, p	lace	an 🔲	□distributor

A. Patient Ir	nform	ation				
Patient Iden	tifier	Date of b	irth	Sex	Weight	t
11	142	06/22/54		female	160	lbs
B. Adverse	event					
		Product				
Outcomes at	tribut			event		
$\Box_{\text{death}}$		∐ disat	•			
$\Box$ life-threat	Ũ			anomaly		
hospitaliz	zation	└─ requi	irea ir	itervention	1	
	4 4/02	0. (/02	D-4		(/01	/2002
Date of even Describe eve			Date	e of report	6/21	/2003
day for a wee comb all faile prescription p instructions.	d over produc OVerr	3 month t ts used str night olive	oil so	ent period	. OTC a to	ind
	.5/1404		ita			
Other releva			udin	g preexist	ing cond	lition
patient is a he	ealth p	hysician				

C. Suspect med	dication(s)				
Name: Ovide					
Dose, frequency	, route use	The	Therapy dates		
One bottle worn o		4/03			
dry each week for	-	1,00	to 6/03		
Diagnosis for us			Fvont	abated after use	
head lice	C			d or dose reduced	
nead fice					
			doesn	t apply	
Lot #	Exp. date			reappeared after	
		]	reintro	oduction	
NDC # -			yes		
	-	- 4			
Concomitant me	dical produ	cts			
D. Suspect med	dical device	÷.			
Brand name					
Type of device					
Manufacturer na	ame and add	iress		ator of device	
				ealth professional	
				ser facility	
				istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
<b>Device available</b>			anufact	uror / /	
Concomitant me	dical produ	cts	anuraci		
	E E				
E. Reporter					
Name and addre	SS	pl	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, N	1A. (	02461		
Health professio ↓ yes □ nc	-	patio	n	Also reported to manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
	anufacturer, p	-		distributor	

A. Patient Inform	ation		
Patient Identifier	Date of birt	h Sex	Weight
1139	04-08-52	female	150 lbs
B. Adverse event	or product	problem	
	Adverse 1	Event	
Outcomes attribut	ed to advers	se event	
$\Box_{\text{death}}$	□ disabili	ty	
□ life-threatening		ital anomaly	
hospitalization		d intervention	
other: Called E	R for help		
Date of event 06-0	06-03 <b>D</b>	ate of report	6/13/2003
Rapid heart rate, dr burning scalp <b>Relevant tests/lab</b> c			te, weakness,
Other relevant his Had what we thoug didn't work and the	<b>story, includ</b> ht were head	<b>ling preexist</b> ilice and used	RID which

C. Suspect medication(s)					
Name: lindane					
Dose, frequency,	, route use	Ther	Therapy dates		
Used only once		06-06	5-03		
, j				to 06-06-03	
Diagnosis for us		<u></u> т	Tront	abated after use	
Diagnosis for us	e			d or dose reduced	
? body lice					
		'	doesn'	t apply	
Lot #	Exp. date	F	Event	reappeared after	
		r	eintro	oduction	
			doesn'	t apply	
NDC # -	-				
Concomitant me	dical produ	cts			
Bayer Alternative	RID for con	nbing			
D. Suspect med	lical device	9			
Brand name					
Type of device		_	-		
Manufacturer na	ame and add	iress	Ē	ator of device	
				ealth professional	
				ser facility istributor	
			Expir	ration date	
model #			Ifim	planted, give date	
catalog #			11 1111	planteu, give uate	
serial # lot #			If ove	alantad give data	
other #			If explanted, give date		
Device available		ion?			
$\square_{\text{yes}} \square_{\text{no}}$			nufact	urer / /	
Concomitant me			inunuo		
	<b>.</b>				
E. Reporter					
Name and addre		Ē	one #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189	, Newton, N	1A. 02	2461		
Health professio				Also reported to	
		patior	1		
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$	)		1	manufacturer	
yes no If you do NOT was disclosed to the ma	nt your identi	ity			

A. Patient Inform	ation				
Patient Identifier	Date of bi	rth	Sex	Weigh	t
1138	10/17/199	96	female	53	lbs
B. Adverse event	or produ	ct p	roblem	1	
	Product	Prob	lem		
Outcomes attribut	ed to adve	erse e	event		
death	$\Box_{disab}$	ility			
□ life-threatening			anomaly		
$\square$ hospitalization			tervention		
other:	— Tequi	icu ii	ner vention		
Date of event 06/0	02/03	Date	e of report	6/12	2/2003
Describe event or	_				
have been fighting	head lice f	or 18	months. V	Ve'll go	for 5-
10 days w/out a pro	blem, then	all o	f a sudden	she is	
scratching & I will c	heck & the	ere ar	e live lice i	n her ha	ir. I
don't do things half	way. I hav	ve sp	ent many r	nights, 4	hours
at a time going throu	ugh her hai	r to r	nake sure t	hat the 1	nits &
ive lice are gone &	still, to no a	avail.	I have use	ed Nix, l	Rid &
Lindane (3 times in	the last 18	mos.	& after re	ading w	hat I
have read tonight, th	nat scares n	ne) al	13. After	we rinse	e it all
out, they are still cra	wling & al	ive.	I am metic	ulous in	going
hrough her hair to r	emove the	lice &	& nits, was	hing & d	drying
everuything for at le	east 30 min	utes,	(most time	es 50 m	ins),
vacuumming, mopp	ing, to mak	e su	e they're g	one. I e	ven
blow dry her hair, fo	or the pure	heat	of it all for	a solid	week
after the fact. Still,					
ell me how to stop		•			
Relevant tests/labo		ta			
	lavor j uu				
Other relevant his	story, inclu	ıdinş	g preexisti	ing con	dition
N/A					

C. Suspect med	lication(s)	
Name: lindane		
Dose, frequency,	, route use	Therapy dates
Once every 7-10	days	06-02-03
		to 06-12-03
Diagnosis for us	e	Event abated after use
Consistant head L		stopped or dose reduced
		no
Lot #	Even data	
L01 #	Exp. date	Event reappeared after
		reintroduction
NDC # -	_	yes
Concomitant me	dical produ	cts
Nix & Rid	r	
D. Suspect med	lical device	2
Brand name		
Type of device		
	me and add	Iress Operator of device
		health professional
		$\square$ user facility
		Expiration date
		Expiration date
model # catalog #		If implanted, give date
serial #		I
lot #		If explanted, give date
other #		II esplanteu, give udit
 Device available	for evaluati	ion?
		to manufacturer//
Concomitant me		
	-	
E. Reporter		
L. Reporter		
-	SS	<b>phone</b> # (781)449-6487
-		
Name and addre	diculosis A	ssociation
Name and addre The National Pe P.O. Box 610189 Health professio	diculosis A , Newton, N	A. 02461
Name and addre The National Pe P.O. Box 610189	diculosis A , Newton, M nal Occuj	A. 02461
Name and addre The National Pe P.O. Box 610189 Health professio	diculosis A , Newton, M nal Occuj	Also reported to

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1136	10/28/96	female	47	lbs
B. Adverse event	or product p	roblem		
	Product Prob			
Outcomes attribut		event		
□ death	$\Box$ disability			
□ life-threatening		•		
hospitalization	required in	ntervention		
other:				
Date of event 12/2 Describe event or		e of report	6/9/2	2003
when i think i have reatments i still find <b>Relevant tests/labo</b>	l live crawling t			80 
Other relevant his	tory, includin	g preexisti	ng condi	iion

	cation(s)			
Name: lindane				
nix,generi	c,mayonaise	e,baby	y oil,rio	1,
Dose, frequency,	route use	The	rapy d	ates
periodically		12/2002		
-				to 6/2002
Diagnosis for use		]]	Event	abated after use
no help		s	stoppe	d or dose reduced
<u>`</u>			no	
Lot #	Exp. date		Fvent	reappeared after
	•			duction
NDC # -	-		yes	
Concomitant med	ical produ	cts		
D. Suspect medi	cal device	<u> </u>		
D. Suspect medi		÷		
Brand name				
<u>Type of device</u> Manufacturer naı	ne and add	Irese	Oner	ator of device
	ne unu uut	11 055	Ē	ealth professional
				ser facility
				istributor
			Ехріі	ation date
model #			1	
catalog #				
			If im	planted, give date
serial #				
serial # lot #				
serial # lot # other #				
serial # lot # other # D <u>ev</u> ice av <u>ail</u> able f	or evaluati		If exp	planted, give date
serial # lot # other # Device available f	or evaluat	to ma	If exp	planted, give date
serial # lot # other # Device available f	or evaluat	to ma	If exp	planted, give date
serial # lot # other # Device available f Dyes no f Concomitant med	or evaluat	to ma	If exp	planted, give date
serial # lot # other # Device available f Dyes no f Concomitant med	or evaluat	to ma cts	If exp	blanted, give date
serial # lot # other # Device available f Device available f Orcomitant med Concomitant med E. Reporter Name and address	or evaluati returned ical products	to ma cts ph	If exp anufact	olanted, give date
serial # lot # other # Device available f Dyes Dno 1 Concomitant med E. Reporter Name and address	or evaluati returned ical products	to ma cts ph	If exp anufact	olanted, give date
serial # lot # other # Device available f yesno Concomitant med E. Reporter Name and address The National Ped	or evaluati returned ical products s	to ma cts ph	If exp anufact none # iation	
serial # lot # other # D <u>ev</u> ice av <u>ail</u> able f	or evaluati returned ical product s liculosis A Newton, N	to ma cts ph .ssoc: 1A. 0	If exp anufact none # iation 2461	olanted, give date
serial #	ical products s liculosis A Newton, M al Occuj	to ma cts ph ssoc: 1A. 0 pation	If exp anufact none # iation 2461	olanted, give date urer _/_/ (781)449-6487 Also reported to

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1133	08/12/74	female	125	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Pro	duct Proble	em	
Advers Outcomes attribut death life-threatening other: Date of event 05/0 Describe event or I noticed red marks friends house who h arm that appeared to clinic . They prescri she said it looked lift neck down but the r my body starting fro know what I should	ed to adverse disability congenital required i 08/03 Dat 08/03 Dat problem on my neck aft as a ferret. Th be a bite marking bed me a crean ke I had scabies ed marks are st om my neck to	event anomaly ntervention e of report er staying o ere was a m c so I went i n called actions. I put it or arting to ap	5/18/2 over at a nark on m into a wal cin becau n from the pear all o	y k in se e ver
Relevant tests/labo Other relevant his I have allergies to m would have happene	<b>tory, includin</b> any things but 1	believe the	allergies	

C. Suspect med	dication(s)			
Name:				
acticin				
Dose, frequency	, route use	The	erapy d	ates
once all over body			2/03	
down.				to 05/12/03
Diagnosis for us	e		Event	abated after use
scabies			stoppe	d or dose reduced
			no	
Lot #	Exp. date		Event	reappeared after
	-			duction
			Vac	
NDC # -	-		yes	
Concomitant me	dical produ	cts		
D. Suspect med	dical device			
Brand name				
Type of device	1 1			
Manufacturer na	ame and add	iress	Ē	ator of device
				ealth professional
				ser facility istributor
			Expi	ration date
model # catalog #			- If im	planted, give date
serial #			-	,0
lot #			If exp	planted, give date
other #				
<b>Device available</b>				urer / /
Concomitant me				
E. Reporter				
Name and addre	SS	р	hone #	(781)449-6487
The National Pe	diculosis A	sso	ciation	
P.O. Box 610189	, Newton, M	1A. (	02461	
Health professio ✓ <sub>yes</sub> □ <sub>nc</sub>		patio	on	Also reported to manufacturer
If you do NOT wa	nt your identi	ity		user facility
disclosed to the ma	•	•	an 🔲	distributor

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
1130	02/18/98	female	4 lbs
3. Adverse event	or product p	oroblem	
	Adverse Ev		
Dutcomes attribut			
death	☐ disability		
<ul><li>✓ life-threatening</li><li>✓ hospitalization</li></ul>		l anomaly ntervention	
other:		inter vention	
Date of event 11/3	2/2000 <b>D</b> et	e of report	5/12/2003
Describe event or		e of report	J/12/2003
reatment, intubatio failure.			
Relevant tests/labo	oratory data		
Other relevant his	tory, includir	g preexisti	ing condition

C. Suspect me	edication(s)			
Name:				
OSCO	Lice Treatme	nt Sh	ampoo	
Dose, frequenc	y, route use	The	rapy d	ates
1 application		11/3	/2000	
				to 11/3/200
Diagnosis for ı	ise	- 1	Event	abated after use
lice			stoppe	d or dose reduced
lice			yes	
Lot #	Even data		•	
LOI #	Exp. date			reappeared after oduction
			reintro	auction
NDC # -	-		doesn	t apply
Concomitant m	edical produ	icts		
	icuicai prout	1013		
D. Suspect me	adical devic	0		
		C		
Brand name				
Type of device		_		
Manufacturer	name and ad	dress	Oper	ator of device
			$\square_h$	ealth professional
			$\square_{u}$	ser facility
			$\square_d$	istributor
			Expi	ration date
model #			<b>r</b>	
catalog #			- If im	planted, give date
serial #			-	
lot #			Ifex	planted, give date
other #				function, give dute
Device availab	le for evaluat	tion?		
			anufact	urer / /
<u>Concomitant n</u>			anurae	
	iculcal prout	1015		
E. Reporter				
Name and add	ress	p	hone #	(781)449-6487
The National I	Pediculosis A	Assoc	ciation	~ /
P.O. Box 61018				
Health profess				Also reported to
	no	Paulo	11	manufacturer
-				user facility
If you do NOT w	•	•		
disclosed to the 1	nanutacturer,	place	an 🔳	

# MadWatah

	atch					
A. Patient Information						
Patient Identifier	Date of birth	Sex	Weight			
1129	12/07/76	female	158	lbs		
B. Adverse event	or product pr	oblem				
Advers	e Event & Prod	uct Proble	m			
Outcomes attribut	ed to adverse e	event				
death	disability					
□ life-threatening	$\Box_{\text{congenital}}$	anomaly				
hospitalization	$\Box$ required in	tervention				
other:	-					
Date of event 10/2	20/01 <b>Date</b>	of report	5/12/2	2003		
Describe event or			2, 12,			
worse. Relevant tests/labo	pratory data					
Other relevant his				tion		
It seemed that the s Although my doctor				hed		
all over and it got su						
to loose sleep. My						
determined that I pr						
hives. From there to	o a hives specia	list who sai	id I didn't			

have hives. Back to the derm. who said I was depressed.

Back to my family doc. who perscribed an antidepressant

and suggested I go see a counselor. 9 months later I have

finished with therapy and discontinued taking

Triage Unit Sequence #

#### C. Suspect medication(s) Name: none of these have seemed to work for me and I ha Dose, frequency, route use Therapy dates I spent over \$3000 dollars 10/2001 to last year on perscriptions 04/2003 Diagnosis for use Event abated after use stopped or dose reduced Scabies, parasite, unknown skin condition. hives no Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # **Concomitant medical products** D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date model # If implanted, give date catalog # serial # \_\_\_\_\_ lot # If explanted, give date other # Device available for evaluation? $\square_{\text{ves}}$ $\square_{\text{no}}$ $\square_{\text{returned to manufacturer}}$ **Concomitant medical products** E. Reporter Name and address **phone** # (781)449-6487 The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461 Health professional Occupation Also reported to manufacturer ∕∠ves $\square_{\rm no}$ user facility If you do NOT want your identity distributor disclosed to the manufacturer, place an

A. Patient Informa Patient Identifier		rth	Sex	Weight	
1127	05/02/199		female	41	lbs
B. Adverse event	or produ	ct pi	oblem		
	Product	Prob	lem		
Outcomes attribut	ed to adve	erse e	event		
death	disab	ility			
□ life-threatening			anomaly		
hospitalization		red in	tervention	1	
other:					
Date of event 05/0		Date	of report	t 5/10/	/2003
Relevant tests/labo Other relevant his					

C. Suspect med	ication(s)				
Name: Nix					
Dose, frequency,	route use	Ther	apy da	tes	
as recommended		05/03/2003			
		to 05/10/2003			
D'		 	7		
Diagnosis for use				bated after use	
from doctor, in the	case of	s	toppea	or dose reduced	
Lindane			doesn't	apply	
Lot #	Exp. date	I	Event r	eappeared after	
				luction	
NDC # -	-		yes		
Concomitant mee	lical produ	cts			
in comments above	e				
D. Suspect med	ical device	•			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Opera	tor of device	
			□ <sub>he</sub>	alth professional	
				er facility	
			$\Box_{dis}$	stributor	
			Expira	ation date	
model #					
catalog #			If imp	lanted, give date	
serial #					
lot #			If expl	anted, give date	
other #					
<b>Device available</b>			nufactu	irer / /	
Concomitant med					
	-				
E. Reporter					
Name and addres	s	ph	one #	(781)449-6487	
The National Peo	diculosis A	ssoci	ation		
P.O. Box 610189,	Newton, N	1A. 0	2461		
Health profession ↓ yes □ no		pation	1	Also reported to manufacturer	
If you do NOT war	nt vour identi	itv		user facility	
- jou do mon war		· · J		distributor	

A. Patient Informa	ation				
Patient Identifier	Date of birtl	n Sex		Weight	;
1126	07-14-03	fem	ale	160	lbs
B. Adverse event	or product	proble	em		
	Adverse <b>F</b>	vent			
Outcomes attribut	ed to advers	e event			
death	∐ disabilit	-			
☐ life-threatening			•		
hospitalization					
other: missing s					
Date of event 20/0 Describe event or		ate of r	eport	5/4	/2003
the bugs and nits on cry when anyone ev youngest grandaugh hot, so the lice bugs year and we just car Relevant tests/labo	ren mentions tter has thick i love her. She i't get rid of th	the lice nair and has had	comb l her s l lice	o. My scalp is v for over a	ery
<b>Other relevant his</b> Can't get rid of lice.		ng pre	existi	ing cond	lition

C. Suspect med	dication(s)			
Name: Rid				
Dose, frequency	, route use	Thera	npy d	ates
4 or 5 times a yea	r	1999		
				to 2003
Diagnosis for us	e	E	vent	abated after use
head lice boo coo		st	oppe	d or dose reduced
		d	loesn'	t apply
Lot #	Exp. date			reappeared after
n/a	-			duction
NDC # -	-	У	es	
Concomitant me	dical produ	cts		
achol and oil				
D. Suspect med	dical device	2		
Brand name				
<u>Type of device</u> Manufacturer na	mo and add	moor	Onor	ator of device
	int and aut	11 055	Ē	
				ealth professional ser facility
				istributor
				ration date
model #			p	
catalog #		]	If im <sub>]</sub>	planted, give date
serial #				
lot #		]	If exp	planted, give date
other #				
Device available			<b>c</b>	, ,
Understand Series Series Concomitant me			nufact	urer _/_/
Conconntant inc	uicai prouu	<b>CU</b> 5		
E. Reporter		_		
Name and addre				(781)449-6487
The National Pe				
P.O. Box 610189	, Newton, N	1A. 02	461	
Health professio		oation		Also reported to
⊻ <sub>yes</sub> □ <sub>nc</sub>				manufacturer
If you do NOT wa	-			user facility distributor
disclosed to the ma	mutacturer, p	race an	L 🔲	- 41511104101

A. Patient Inform	ation				
Patient Identifier		h Sex		Weigh	ıt
1121	11/15/1995	fem	ale	45	lbs
B. Adverse event	or product	proble	em		
	Product Pr	oblem			
Outcomes attribut	ed to advers	se event			
death	□disabili	ty			
□ life-threatening		tal anon	naly		
hospitalization		l interve	ention		
other: don't wo	rk				
Date of event 20/0	)1/ <b>D</b>	ate of r	eport	4/2	6/2003
Describe event or	-				
I have three kids we					
now. I have done ev	very thing(ov	er count	er,kwo	ell,ovid	e,you
name it)					
Relevant tests/labo	oratory data				
Other relevant his	tom indud	ina nro	ovict	nacor	dition
none	story, menua	ing pre	CAISU	ng con	uluoli
none					

	lication(s)			
Name:				
all				
Dose, frequency,	, route use	The	erapy dates	
every two weeks a	and have	200		
given up			to 2003	
Diagnosis for us	e		Event abated after	use
?	•		stopped or dose red	
<i>'</i>				
	<b>_</b>		no	
Lot #	Exp. date		Event reappeared a	fter
?			reintroduction	
NDC # -			no	
	-			
Concomitant me	dical produ	cts		
all				
D. Suspect med	lical device	9		
Brand name				
Type of device				
Manufacturer na	ame and add	iress	1 <u>-</u>	
			health profession	omo1
				onai
			user facility	Jilai
			user facility distributor	JIIAI
			user facility	JIIAI
model #			user facility distributor Expiration date	
catalog #			user facility distributor	
catalog # serial #			Expiration date	date
catalog # serial # lot #			user facility distributor Expiration date	date
catalog # serial # lot # other #			user facility         distributor         Expiration date         If implanted, give         If explanted, give	date
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	f <u>or</u> evaluati		User facility distributor Expiration date If implanted, give If explanted, give	date
catalog # serial # lot # other # Device available	for evaluat	to m	user facility distributor Expiration date If implanted, give If explanted, give	date
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	for evaluat	to m	user facility distributor Expiration date If implanted, give If explanted, give	date
catalog # serial # lot # other # Device available	for evaluat	to m	user facility distributor Expiration date If implanted, give If explanted, give	date
catalog # serial # lot # other # Device available Uves 0 no Concomitant me	for evaluati returned dical produce	to m cts	user facility distributor Expiration date If implanted, give If explanted, give	date date
catalog # serial # lot # other # Device available Uyes Ino Concomitant me E. Reporter	for evaluati returned dical produce ss	to m cts	user facility distributor Expiration date If implanted, give If explanted, give If explanted, give hone # (781)449-64	date date
catalog # serial # lot # other # Device available Uyes Uno Concomitant med E. Reporter Name and addre	for evaluati returned dical produce ss diculosis A	to m cts p	user facility distributor Expiration date If implanted, give If explanted, give If explanted, give hone # (781)449-64 ciation	date date
catalog # serial # lot # other # Device available UVES UND Concomitant med E. Reporter Name and addres The National Pe P.O. Box 610189 Health profession	for evaluati returned dical produce ss diculosis A b, Newton, M nal Occup	to m ets p .ssoc 1A. (	user facility distributor Expiration date If implanted, give If explanted, give anufacturer/_/ hone # (781)449-64 ciation 02461 Also report	date date 87 ed to
catalog # serial # lot # other # Device available Device available Device available Device available Device available Device available Device available The vallable E. Reporter Name and addres The National Pe P.O. Box 610189	for evaluati returned dical product ss diculosis A Newton, N nal Occup	to m cts p .ssoc IA. ( patic	user facility distributor Expiration date If implanted, give If explanted, give If explanted, give hone # (781)449-64 ciation 02461	date date 87 ed to urer

A. Patient Inform Patient Identifier		.41	C .	XX7 • 3 ·	
		rth	Sex	Weight	
1120	5-6-92		female	170	lbs
B. Adverse event					
	Adverse				
Outcomes attribut			event		
⊔death	∐ disabi	lity			
□ life-threatening		nital	anomaly		
hospitalization	L requir	ed in	terventio	n	
other: doctors p	prescribing of	extra	medicati	ion for the	asth
Date of event 4-03	3-03	Date	of repo	rt 4/25	/2003
Describe event or	problem				
Have treated my da	-	ral ti	mes with	NIX and	it has
caused terrible asth	-				
the lice and the retre			-		
asthma.					
Relevant tests/labo	oratory dat	a			
Othon volament 1.1		d:		ting and 1	:+:
Other relevant his					nuon
She has had asthma					
anticipate that the li	-				
Nix does not work a	and is hurtir	ng m	y child.	l do not kr	low
what to use to get ri					

D			
	ency, route use		rapy dates
3 times		4-03	-03 to 4-24-03
Diagnosis fo	or use	]	Event abated after use
head lice		2	stopped or dose reduced
			yes
Lot #	Exp. date		Event reappeared after reintroduction
NDC #		yes	
	t medical produ	icts	
D. Suspect	medical devic	е	
Brand name			
Di una nuni			
Type of devi	ice	dress	Operator of device
Type of devi	ice	dress	Operator of device
Type of devi	ice	dress	health professional
Type of devi	ice	dress	health professional
Type of devi	ice	dress	health professional user facility distributor
Type of devi	ice	dress	health professional
Type of devi Manufactur model #	ice rer name and ad		<ul> <li>health professional</li> <li>user facility</li> <li>distributor</li> </ul> Expiration date
Type of devi Manufactur model # catalog #	ice Per name and ad		<ul> <li>health professional</li> <li>user facility</li> <li>distributor</li> </ul> Expiration date
Type of devi Manufactur model # catalog # serial #	ice er name and ad		<ul> <li>health professional</li> <li>user facility</li> <li>distributor</li> <li>Expiration date</li> <li>If implanted, give date</li> </ul>
Type of devi Manufactur model # catalog # serial # lot #	ice Per name and ad		<ul> <li>health professional</li> <li>user facility</li> <li>distributor</li> <li>Expiration date</li> <li>If implanted, give date</li> </ul>
Type of devi Manufactur model # catalog # serial # lot # other #	ice er name and ad		<ul> <li>health professional</li> <li>user facility</li> <li>distributor</li> <li>Expiration date</li> <li>If implanted, give date</li> </ul>
Type of devi Manufactur model # catalog # serial # lot # other # Device avail	ice er name and ad		<ul> <li>health professional</li> <li>user facility</li> <li>distributor</li> </ul> Expiration date If implanted, give date If explanted, give date
Type of devi Manufactur model # catalog # serial # lot # other # Device avail	ice er name and ad lable for evaluat no □returned	tion?	health professional user facility distributor Expiration date If implanted, give date anufacturer/_ /
Type of devi Manufactur Manufactur catalog # catalog # serial # lot # other # Device avail Ovice avail Concomitan	ice rer name and ad able for evaluat no returned t medical produ	tion?	health professional user facility distributor Expiration date If implanted, give date anufacturer/_ /
Type of devi Manufactur Manufactur catalog # catalog # serial # lot # other # Device avail Ovice avail Concomitan	ice rer name and ad able for evaluat no returned t medical produ	to ma ccts	<ul> <li>health professional</li> <li>user facility</li> <li>distributor</li> </ul> Expiration date If implanted, give date anufacturer/_/
Type of devi Manufactur Manufactur catalog # catalog # catalog # catalog # dot # other # Device avail yes Concomitan E. Reporter Name and a	ice er name and ad lable for evaluat no returned it medical produ ddress	tion? to ma acts	health professional user facility distributor Expiration date If implanted, give date anufacturer/_ / hone # (781)449-6487
Type of devi Manufactur Manufactur catalog # catalog # catalog # catalog # dot # other # Device avail yes Concomitan E. Reporter Name and a	ice rer name and ad able for evaluat no returned t medical produ	tion? to ma acts	health professional user facility distributor Expiration date If implanted, give date anufacturer/_ / hone # (781)449-6487
Type of devi Manufactur Manufactur catalog # serial # lot # other # Device avail yes Concomitan E. Reporter Name and a The Nation	ice er name and ad lable for evaluat no returned it medical produ ddress	iion? to ma ccts	health professional user facility distributor Expiration date If implanted, give date If explanted, give date anufacturer/_/ hone # (781)449-6487
Type of devi Manufactur Manufactur catalog # serial # lot # other # Device avail yes Concomitan E. Reporter Name and a The Nation	ice er name and ad lable for evaluat lable for evaluat lno □returned t medical produ ddress al Pediculosis A 0189, Newton, N	tion? to ma icts pl Assoc	health professional user facility distributor Expiration date If implanted, give date anufacturer/_ / hone # (781)449-6487 iation
Type of devi Manufactur Manufactur catalog # serial # other # Device avail Usyss Device avail Usyss Concomitan E. Reporter Name and a The Nation P.O. Box 61 Health prof	ice rer name and ad able for evaluat no returned it medical produ ddress al Pediculosis A 0189, Newton, N essional Occu	ion? to ma icts pl Assoc MA. 0 patio	health professional user facility distributor Expiration date If implanted, give date If explanted, give date anufacturer/_ / none # (781)449-6487 iation 2461 n Also reported to

. Patient Inform	ation			
tient Identifier	Date of birth	Sex	Weight	
1118	33/10/0	female	34	lbs
Adverse even	t or product p	oroblem		
	Product Pro	blem		
utcomes attribu	ted to adverse	event		
death	∐ disability			
☐ life-threatening		-		
hospitalization	required i	ntervention		
other:				
ate of event 35/	02/ Dat	e of report	4/20/2	2003
escribe event or	=			
ant get rid of lice H	IELP			
elevant tests/lab	oratory data			
ther relevant his	story includin	a nreevisti	ng condi	tion
ther relevant m	, in y, menuum	g precaisti	ng conu	tion

C. Suspect med	ication(s)			
Name: Rid				
Dose, frequency,	route use	The	rapy d	ates
	Toute use	4200		ates
everyweek		4200	JZ	to
				41803
Diagnosis for use	e			abated after use
all			stoppe	d or dose reduced
			no	
Lot #	.ot # Exp. date		Event	reappeared after
	- I			duction
		I CIIII I	Juiction	
NDC # -			yes	
Concomitant me	lical produc	ote		
Conconntant med	lical produ	cis		
D. Suspect med	ical device	9		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
				ealth professional
				ser facility
			□d	istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
<b>Device available</b>	for evaluat		anufact	urer / /
Concomitant me			anuraet	
	p			
E. Reporter				
Name and addres	SS	p	hone #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, N	1A. (	02461	
Health profession	nal Occuj	patio	n	Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$				manufacturer
If you do NOT war	nt your identi	ity		user facility
disclosed to the ma	nufacturer, p	lace	an 🔲	distributor

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
1117	02/13/1998	female	50 lbs
B. Adverse event	or product p	roblem	
	Adverse Ev		
Outcomes attribut		event	
death	$\Box$ disability		
□ life-threatening		-	
hospitalization	_	ntervention	
other: Dry scal			
Date of event 11/2 Describe event or		e of report	4/17/2003
house. I quit using t complained about h extremely dry scalp yet, so I can't imagin always combed her with those products has calmed down no other day. If I find I metal comb, but I ju afford to use it. Any appreciated. Thank Relevant tests/labo	er head still itch and a red rash. ne where she's g hair thoroughly i I listed, but the ow, and I check ice or nits, I stil ust can't use that y information w you for your th	ing, and I f She's not e etting them after I sha problem c her head at I remove th t shampoo ill be great	ound ven in school i. I have mpooed it continued. I cout every tem with the anymore. Or, y
Other relevant his	story, includin	g preexisti	ng condition

C. Suspect med	lication(s)			
Name: Nix				
Dose, frequency,	route use	The	rapy d	ates
Approximately ev	very 2	11/2	002	
weeks.				to 01/2003
Diagnosis for us	e	]	Event	abated after use
Head lice		5	stoppe	d or dose reduced
			yes	
Lot #	Exp. date		•	reappeared after
	-			duction
NDC # -	-		yes	
Concomitant me	dical produ	cts		
D. Suspect med	lical device	e		
Brand name				
Type of device Manufacturer na		1	0	aton of dontos
Manufacturer na	ime and add	iress	- i	ator of device
				ealth professional ser facility
				istributor
				ration date
			схрп	ration date
model # catalog #			If im	planted, give date
serial #				, , ,
lot #			If exp	planted, give date
other #			-	
D <u>ev</u> ice av <u>ail</u> able				
$\square_{\text{yes}} \square_{\text{no}}$	returned	to ma	anufact	urer//
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	SS	pł	10ne #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, N	<b>1</b> A. 0	2461	
Health professio $\mathbf{V}_{yes}$ $\square_{nc}$	nal Occuj			Also reported to manufacturer
If you do NOT wa	nt your ident	ity		user facility
disclosed to the ma	•	•	an 🔳	distributor

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
1114	01/06/1996	female	50 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Prod	luct Proble	em
Outcomes attribut		event	
death	☐ disability		
☐ life-threatening		•	
hospitalization	required ir		
other: it burns r			
Date of event 04/1		e of report	4/15/2003
Describe event or	-		
the medcine for the	treatment of hea	ad lice burr	ns my 7 year
old daughters head			
Relevant tests/labo	oratory data		
Other relevant his	story, including	g preexisti	ng condition
none			
1			

C. Suspect medication(s)			
Name: Ovide			
Dose, frequency, route use	The	erapy d	ates
0.5% i am using at least	6/10	)/02	
every 6 weeks			to 04/14/03
Diagnosis for use		Event	abated after use
head lice			d or dose reduced
nead nee			
		no	
Lot # Exp. date			reappeared after
not known	r		oduction
	`#		
NDC #			
Concomitant medical produ			
rid 12/02/2002 lindane 03/31/	/03 m	ayo 12/	30/02 vinegar
every other day just about			
D. Success modical device	_		
D. Suspect medical devic	e		
Brand name Type of device			
i vde of device			
	drose	Oper	ator of device
Manufacturer name and ad	dress		ator of device
	dress	h	ealth professional
	dress		
	dress		ealth professional ser facility istributor
Manufacturer name and ad	dress		ealth professional ser facility
Manufacturer name and ad	dress		ealth professional ser facility istributor
Manufacturer name and ad model # catalog #	dress		ealth professional ser facility istributor ration date
Manufacturer name and ad model # catalog # serial # lot #	dress	Expin	ealth professional ser facility istributor ration date
Manufacturer name and ad model # catalog # serial #	dress	Expin	ealth professional ser facility istributor <b>ration date</b> <b>planted, give date</b>
Manufacturer name and ad model # catalog # serial # lot # other # Device available for evalua	tion?	□ h □ u □ d □ Expin □ If im	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer name and ad model # catalog # serial # lot # other # Device available for evalua □ yes □ no □ returned	tion?	□ h □ u □ d □ Expin □ If im	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer name and ad model # catalog # serial # lot # other # Device available for evalua	tion?	□ h □ u □ d □ Expin □ If im	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer name and ad model # catalog # serial # lot # other # Device available for evalua □ yes □ no □ returned	tion?	□ h □ u □ d □ Expin □ If im	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer name and ad model # catalog # serial # lot # other # Device available for evalua □ yes □ no □ returned	tion?	□ h □ u □ d □ Expin □ If im	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer name and ad model # catalog # serial # lot # other # Device available for evalua $\Box_{yes} \Box_{no} \Box_{returnec}$ Concomitant medical produ	tion? l to m acts	Expin	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer name and ad model # catalog # serial # other # Device available for evalua  yesno returned Concomitant medical produ	tion? 1 to m acts	If explanation	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer name and ad model # catalog # serial # lot # other # Device available for evalua $u_{yes}$ $u_{no}$ $u_{returnec}$ Concomitant medical produ E. Reporter Name and address	tion? l to m lcts P Assoc	If im If im If explanation If explanation If explanation	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer name and ad model #	tion? 1 to m ncts P Assoo MA. 0	<pre>h h u u d d Expin F If im If exp If exp</pre>	ealth professional ser facility istributor ration date planted, give date planted, give date
Manufacturer name and ad model #	tion? l to m ncts P Assoo MA. ( patio	<pre>h h u u d d Expin F If im If exp If exp</pre>	ealth professional ser facility istributor ration date planted, give date planted, give date planted, give date (781)449-6487

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1113	10/12/1968	female	135	lbs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut  death  life-threatening  hospitalization other: lots of sc  Date of event 8/1/  Describe event or Iworked at a compa later I was all broke weeks figured out it birdlice when appro saying I need to con to work with new le because other memb	ted to adverse of disability congenital disability congenital disability congenital disability congenital disability congenital disability congenital disability required in tars 02 Date problem any one of the st with my young tass scabies. St ached managem sult a lawyer be sions and asking	event anomaly ntervention e of report aff had a ra children at aff kept tel nent I was fi cause she k g if I had m	4/12/2 ash 8 week fter about ling me it ired for kept comin ore medic	ks 2-3 was ng
Relevant tests/labo		g preexisti	ng condi	tion

C. Suspect med	lication(s)			
Name: lindane				
Permithi	n			
Dose, frequency,	, route use	The	rapy d	ates
breakouts 7 days	after	7/1/0	)2	
				to 4/12/03
Diagnosis for us	e	l]	Event	abated after use
scabies				d or dose reduced
seables			no	
Lot#	Even data		-	
2001	Exp. date			reappeared after
Lindane		1	reintro	oduction
NDC # -	-		yes	
Concomitant me	dical produ	cts		
throughout this ye				
D. Suspect med	lical device	÷		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			$\square_{h}$	ealth professional
				ser facility
			$\square_d$	istributor
			Expir	ation date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device available	_			
Uyes uno Concomitant me			anutact	urer//
Conconntant me	uicai produ	<b>CIS</b>		
E. Reporter				
Name and addre	SS	pł	none #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	1A. 0	2461	
Health professio		patio	n	Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{normalized}}$	)			
If you do NOT was		-		user facility
disclosed to the ma	unufacturer, p	lace a	an 🔲	distributor

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
1112	08/02/1994	female	80 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Pro	duct Proble	em
Outcomes attribut	ed to adverse	event	
death	disability		
☐ life-threatening		anomaly	
hospitalization	required in	ntervention	
other: seizures			
Date of event 11/0	04/2002 <b>Dat</b>	e of report	4/12/2003
Describe event or	_		
Child has suffered f		-	
treatment. Also, pro our problem.	escription Elim	ite has done	e nothing for
our problem.			
Relevant tests/labo	ratory data		
	natory uata		
Other relevant his		g preexisti	ng condition
No preexisting med	ical contitions		

C. Suspect med	lication(s	s)		
Name: Nix				
Rid				
Dose, frequency	route us	e The	erapy d	ates
once every three r	nonths	11/2	2001	
				to 11/2003
Diagnosis for us	e		Event	abated after use
head lice	-			d or dose reduced
nead nee			no	
Lot #	E-m data			
Lot #	Exp. date			reappeared after
			reintro	oduction
NDC # -			doesn	't apply
Concomitant me	- dical pred	nete		
	-		ah at:11	a hair
nightly combing a	na picking	throug	gn child	s nair
D. Suspect med	lical devi	<u></u>		
		66		
Brand name Type of device				
Manufacturer na	me and a	ddres	s Oner	ator of device
	une une u	uures	_	ealth professional
				ser facility
				istributor
				ration date
model #			p	
catalog #			- If im	planted, give date
serial #			_	
lot #			_ If exp	planted, give date
other #				
Device available		ation?		
$\square_{\text{yes}} \square_{\text{no}}$	returne	ed to n	nanufact	turer//
Concomitant me	dical prod	lucts		
E. Reporter				
Name and addre	SS	n	hone #	(781)449-6487
The National Pe		Ê		((01)))) 0107
P.O. Box 610189	, Newton,	MA.	02461	
Health professio		upati		Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$		1		manufacturer
If you do NOT wa	nt your ide	ntity		user facility
disclosed to the ma			an 🔲	distributor

Patient Informa		-		
tient Identifier		Sex	Weight	
1107	05-01-1984	female	165	lbs
Adverse event				
	Product Prob			
comes attribut	_	event		
death	disability			
life-threatening hospitalization	$\Box$ congenital	ntervention		
other:		nei vention		
te of event 03-0	1 02 Det	of non-out	4/1/2	002
cribe event or		e of report	4/1/2	.005
evant tests/labo	ratory data			

C. Suspect med	ication(s)			
Name: lindane				
Dose, frequency,	route use	The	apy d	ates
twice		03-0		
twice		05-0	1-05	to
			_	03-31-03
Diagnosis for use				abated after use
lice		5	stoppe	d or dose reduced
			no	
Lot #	Exp. date	1	Event	reappeared after
n/a				oduction
NDC # -	-		yes	
Concomitant med	lical produ	cts		
none other than usi	-			
	5			
D. Suspect med	ical device	•		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			$\square_{h}$	ealth professional
				ser facility
			$\square_d$	istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device available f				
$\square_{\text{yes}} \square_{\text{no}}$			nufact	urer _/_/
Concomitant med	lical produ	ets		
E. Reporter				
Name and addres	S	pł	none #	(781)449-6487
The National Peo		Ē.		. /
P.O. Box 610189,	Newton, M	IA. 0	2461	
Health profession	al Occup	oatio	n	Also reported to
<b>⊻</b> <sub>yes</sub> <b>□</b> <sub>no</sub>				manufacturer
If you do NOT wan	-	-		User facility
disclosed to the man	nufacturer, p	lace a	ın 🔲	□distributor

A. Patient Inform				
Patient Identifier			Weight	
1100	02/11/1982	female	140	lbs
3. Adverse even				
	Product Pro			
Outcomes attribut	_			
death	∐ disability			
$\Box$ life-threatening		•		
hospitalization	1	nterventic	n	
other: resistant				
Date of event 00/	00/0000 <b>Dat</b>	e of repo	rt 3/23/	2003
for about 6 months to get rid of them. H				
Relevant tests/labo	oratory data			
Relevant tests/labo Other relevant his I have no preexistin	oratory data story, includin			ition

C Sucro	t modication(c)			
	t medication(s)			
Name: lin	idane			
Dose, freq	uency, route use	The	rapy d	ates
1% lindane	shampoo	02/0	6/03	to
				00/00/0000
Diagnosis	for use	1	Event	abated after use
Head Lice		s	stoppe	d or dose reduced
			no	
Lot #	Exp. date			
LUI #	Exp. date			reappeared after
		1	reintro	oduction
NDC #			doesn'	t apply
	nt medical produ	ote		
Conconnta	int metrical produ	icis		
	t medical device			
-		e		
Brand nan				
<u>Type of de</u> Monufactu	vice irer name and add	dross	Oper	ator of device
		ui ess	-	
				ealth professional ser facility
				istributor
				ation date
			стри	auon uate
model # catalog # _			If im	planted, give date
serial #				, , ,
lot #			If exr	planted, give date
other #				
Device ava	ilable for evaluat	ion?	I	
	no returned		anufact	urer//
	nt medical produ			
E. Reporte	or.			
		. 1		(791)440(497)
Name and		-	none #	(781)449-6487
	nal Pediculosis A			
P.O. Box 6	10189, Newton, N	/IA. 0	2461	
Health pro		patio	n	Also reported to
⊻yes	lono			
•	OT want your ident	•		User facility
disclosed to	the manufacturer, p	place a	an 🔲	distributor

A. Patient Informa	ation				
Patient Identifier	Date of bi	rth	Sex	Weight	t
1098	08/01/199	6	female	60	lbs
3. Adverse event	or produ	ct pr	oblem		
Adverse	e Event & I	Prod	uct Prob	lem	
Outcomes attribut	ed to adve	rse e	vent		
$\Box_{\text{death}}$	□disabi	lity			
$\Box$ life-threatening	$\Box_{\text{congen}}$	nital a	anomaly		
hospitalization	$\Box_{requir}$	ed in	tervention	n	
other:					
Date of event 03/2	0/03	Date	of repor	t 3/21	/2003
Describe event or <b>j</b>	problem				
she keeps giving it t don't understand wh hat they can not go	y. The ma	in pr	oblem no	w is the	fact
Relevant tests/labo	ratory dat	a			
Other relevant his	tory, inclu	ding	preexist	ting cond	lition

C. Suspect med	dication(s)			
Name: Nix				
rid all of	them			
Dose, frequency,	, route use	Ther	apy d	ates
once every 10 day	ys	01/20	003	
				to 03/2003
Diagnosis for us	e	ŀ	Event	abated after use
head lice		s	toppe	d or dose reduced
			doesn'	t apply
Lot #	Exp. date	I	Event	reappeared after
		r	eintro	oduction
			doesn'	t apply
NDC # -	-			
Concomitant me	dical produ	cts		
D. Suspect med	dical device	÷		
Brand name				
Type of device				
Manufacturer na	ame and add	lress	Oper	ator of device
			$\square_{\rm h}$	ealth professional
				ser facility
				istributor
				ration date
model #			Елри	ation date
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #			-	, 0
Device available	for evaluat	ion?		
$\square_{\text{yes}} \square_{\text{no}}$	returned	to ma	nufact	urer _/_/
Concomitant me				
E. Reporter				
Name and addre	SS	ph	one #	(781)449-6487
The National Pe	diculosis A	ssoci	iation	
P.O. Box 610189	, Newton, N	1A. 0	2461	
Health professio		pation	n	Also reported to manufacturer
-				
If you do NOT was			. 🗖	
disclosed to the ma	inutacturer, p	nace a	in 🔲	-uisuituutoi

A. Patient Information Patient Identifier 1095 03/30/1994 male 45 lbs B. Adverse event or product problem  Product Problem Outcomes attributed to adverse event death disability life-threatening congenital anomaly hospitalization required intervention other: Date of event 10/30/02 Date of report 3/19/2003 Describe event or problem This is our 4th outbreak in the last 6mo. Is there any end to this madness?  Relevant tests/laboratory data Other relevant history, including preexisting condition he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on my daughters. Is there a home remedy to treat head lice?						
1095 03/30/1994 male 45 lbs   B. Adverse event or product problem   Product Problem   Outcomes attributed to adverse event   death disability   life-threatening congenital anomaly   hospitalization required intervention   other:					_	
B. Adverse event or product problem         Product Problem         Outcomes attributed to adverse event         death       disability         life-threatening       congenital anomaly         hospitalization       required intervention         other:						
Product Problem         Outcomes attributed to adverse event         death       disability         life-threatening       congenital anomaly         hospitalization       required intervention         other:					45	lbs
Outcomes attributed to adverse event         death       disability         life-threatening       congenital anomaly         hospitalization       required intervention         other:	B. Adverse event					
death disability   life-threatening congenital anomaly   hospitalization required intervention   other:						
life-threatening congenital anomaly   hospitalization required intervention   other:	Outcomes attribut	ed to adv	erse e	vent		
hospitalization       required intervention         other:	$\Box$ death	∐ disat	oility			
other:	Life-threatening		enital	anomaly		
Date of event       10/30/02       Date of report       3/19/2003         Describe event or problem       This is our 4th outbreak in the last 6mo. Is there any end to this madness?         Relevant tests/laboratory data         Relevant tests/laboratory data         Other relevant history, including preexisting condition he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on	hospitalization	□ <sub>requi</sub>	red in	terventio	on	
Describe event or problem         This is our 4th outbreak in the last 6mo. Is there any end to this madness?         Relevant tests/laboratory data         Other relevant history, including preexisting condition he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on	other:					
Describe event or problem         This is our 4th outbreak in the last 6mo. Is there any end to this madness?         Relevant tests/laboratory data         Other relevant history, including preexisting condition he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on	Date of event 10/3	30/02	Date	of repo	rt 3/1	19/2003
This is our 4th outbreak in the last 6mo. Is there any end to this madness? Relevant tests/laboratory data Other relevant history, including preexisting condition he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on	Describe event or	problem	<u> </u>	-		
this madness? Relevant tests/laboratory data Other relevant history, including preexisting condition he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on		_	e last (	6mo. Is	there any	end to
<b>Other relevant history, including preexisting condition</b> he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on						
<b>Other relevant history, including preexisting condition</b> he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on						
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he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on	Relevant tests/labo	oratory da	ita			
he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on						
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he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on						
he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on	Other relevant his	tory, incl	uding	g preexis	sting coi	ndition
my daughters. Is there a home remedy to treat head lice?						
	my daughters. Is th	ere a home	e reme	edy to tre	eat head l	ice?

Name:       Pronto Nix, Rid, Kwell         Dose, frequency, route use every 7-10 days       Therapy dates 10/30/02 to 12/31/02         Diagnosis for use Tried all the above and Lindane.       Event abated after use stopped or dose reduced doesn't apply         Lot #       Exp. date       Event reappeared after reintroduction yes         NDC #       -       yes         Concomitant medical products       yes         I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)       D. Suspect medical device         Brand name
Dose, frequency, route use every 7-10 days       Therapy dates 10/30/02 to 12/31/02         Diagnosis for use Tried all the above and Lindane.       Event abated after use stopped or dose reduced doesn't apply         Lot #       Exp. date       Event reappeared after reintroduction yes         NDC #       -         Concomitant medical products       yes         I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)       I heard of a home treatment of the ingredients and amounts (olive oil, rosemary)         D. Suspect medical device       Event reappeared of device         Brand name       Upperator of device         Manufacturer name and address       Operator of device
every 7-10 days       10/30/02 to         Diagnosis for use Tried all the above and Lindane.       Event abated after use stopped or dose reduced doesn't apply         Lot #       Exp. date       Event reappeared after reintroduction yes         NDC #       -       Vent reappeared after reintroduction         I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)       I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)         D. Suspect medical device       Event reappeared of device         Brand name       Upperator of device         Manufacturer name and address       Operator of device
to 12/31/02 Diagnosis for use Tried all the above and Lindane. Event abated after use stopped or dose reduced doesn't apply Lot # Exp. date Exp. date NDC # Concomitant medical products I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary) D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device
12/31/02         Diagnosis for use         Tried all the above and Lindane.       Event abated after use stopped or dose reduced doesn't apply         Lot #       Exp. date       Event reappeared after reintroduction yes         NDC #       -         Concomitant medical products       I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)         D. Suspect medical device       Brand name         Type of device       Manufacturer name and address       Operator of device
Tried all the above and Lindane. Stopped or dose reduced doesn't apply Lot # Exp. date Exp. date Event reappeared after reintroduction yes Concomitant medical products I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary) D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device
Tried all the above and Lindane. Stopped or dose reduced doesn't apply Lot # Exp. date Exp. date Event reappeared after reintroduction yes Concomitant medical products I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary) D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device
Lot #       Exp. date       Event reappeared after reintroduction         NDC #       -       yes         Concomitant medical products       yes         I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)       I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)         D. Suspect medical device       Brand name         Type of device       Operator of device
Lot #       Exp. date       Event reappeared after reintroduction         NDC #       -       yes         Concomitant medical products       yes         I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)       D. Suspect medical device         Brand name       Type of device         Manufacturer name and address       Operator of device
NDC #       -       -         Concomitant medical products       yes         I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)       D. Suspect medical device         Brand name
NDC #       -       yes         Concomitant medical products       -       -         I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)       -       -         D. Suspect medical device       -       -       -         Brand name       -       -       -         Type of device       -       -       -         Manufacturer name and address       Operator of device       -
NDC #       -         Concomitant medical products         I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)         D. Suspect medical device         Brand name         Type of device         Manufacturer name and address         Operator of device
Concomitant medical products         I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary)         D. Suspect medical device         Brand name         Type of device         Manufacturer name and address         Operator of device
I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary) D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device
home treatment but do not know all the ingredients and amounts (olive oil, rosemary) D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device
amounts (olive oil, rosemary) D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device
D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device
Brand name Type of device Manufacturer name and address Operator of device
Type of device Manufacturer name and address Operator of device
Manufacturer name and address Operator of device
· · · · · · · · · · · · · · · · · · ·
haalth mof1
user facility
distributor
Expiration date
model #
catalog # If implanted, give date
serial #
lot # If explanted, give date
other #
<b>Device available for evaluation?</b> $\square_{yes} \square_{no} \square_{returned to manufacturer _/_/}$
Concomitant medical products
E. Reporter
E. Reporter Name and address phone # (781)449-6487
Name and address phone # (781)449-6487
Name and addressphone # (781)449-6487The National Pediculosis AssociationP.O. Box 610189, Newton, MA. 02461Health professionalOccupationAlso reported to
Name and addressphone # (781)449-6487The National Pediculosis AssociationP.O. Box 610189, Newton, MA. 02461

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
1088	03/06/19	96	female	75	lbs
B. Adverse event	or produ	ict pr	oblem		
Advers	e Event &	Prod	uct Proble	m	
Outcomes attribut	ed to adv	erse e	event		
Death	□disat	oility			
□ <sub>life-threatening</sub>	$\Box_{\rm cong}$	enital	anomaly		
$\Box_{hospitalization}$	$\Box_{\text{requi}}$	red in	tervention		
other: Allergic/	Intolerant	React	ion to Pyre	thrins	
Date of event 19/9	99/2000	Date	e of report	3/8/2	2003

#### Describe event or problem

My daughter Heather has had intermittent problems with Head Lice ever since entering daycare. Initially, I tried a standard lice-killing shampoo, Licetrol, which did not have any marked effect on the lice. One week later, as instructed, I did a follow-up treatment on my daughters head and within an hour she had fallen to vomiting. At the time we didn't make the connection, but the next time we did because, sure enough, within half an hour of the second treatment she had fallen to vomiting again.

Needless to say I sought out medical information with regards to this from both our doctor and pharmacist, and was informed that in all likelyhood my daughter was either allergic/intolerant to pyrethrins, and was advised to seek and alternative treatment until she was old enough to use

Relevant tests/laboratory data

Other relevant history, including preexisting condition
Now we're right back at the problems again. 18 months
clean and then yesterday it turned up on my oldest daughter
again. She seems to be particularly susceptible, and I
suspect that that is a result of her having the same skin
sensitivity that is passed on my father's side of the family.
We are all allergic to perfumes and are unable to use skin
creams, lotions, etc. Even soap is a difficulty.

C. Suspect med	lication(s)			
Name: generic li				
Dose, frequency,	, route use	The	rapy dat	tes
Just enough to lath		199	9	to
with, twice at a or				2000
Diagnosis for us			Event al	bated after use
Unclear what this	field is askin	g	stopped	or dose reduced
for.			yes	
Lot #	Exp. date		Event re	appeared after
			reintrod	
			yes	
NDC# -	-		<i>y</i> <b>c</b> 5	
Concomitant me	dical produ	cts		
D. Suspect med	lical device	9		
Brand name				
<u>Type of device</u> Manufacturer na	bhe hre am	roce	Operat	tor of device
	une anu aut	11 055	-	alth professional
				er facility
			$\square_{dis}$	tributor
				tion date
model #			<b>r</b>	
catalog #			If impl	anted, give date
serial #				
lot #			If expla	anted, give date
other #				
Device available			2	
U <sub>yes</sub> no Concomitant me			anufactu	rer//
Conconntant me	uicai produ	cis		
E. Reporter				
Name and addre	SS	р	hone # (	(781)449-6487
The National Pe	diculosis A	ssoc	ciation	
P.O. Box 610189	, Newton, M	IA. (	)2461	
Health professio	nal Occup	oatio	n A	Also reported to
⊻ <sub>yes</sub> □ <sub>nc</sub>	)			
If you do NOT was	-	-		Uuser facility
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor

A. Patient Information	ation		
Patient Identifier	Date of birth	Sex	Weight
1085	11/19/63	female	180 lbs
B. Adverse event	or product p	roblem	
	Product Prob	olem	
Outcomes attribut	ed to adverse	event	
death	disability		
□ life-threatening	$\Box_{\text{congenital}}$	anomaly	
$\Box_{hospitalization}$	required in	ntervention	
other:			
Date of event 12-0	)2 <b>Dat</b>	e of report	2/28/2003
Describe event or		-	
i have went to the pu giving me NIX whic FIGHTING THIS L DECEMBER. I AN BUGS ARE RUINI CLOTHING. LINI LOSING IT, I AM I TIME, THESE NIT OF ME. THE LICE HAVE O SERIOUSLY. NO SERIOUS!!!	The DOES NOT LICE PROBLEM M DAMN NEA NG MY LIFE, DANE DOES N NERVOUS AN 'S ARE JUST ( GOT INTO MY DOCTOR BEL	WORK!!!! M SINCE R SUICID MY HAIR NOT WOR ND CRYIN GETTING	I'VE BEEN AL, THESE , MY K. I AM G ALL THE THE BEST DO,
Relevant tests/labo Other relevant his		g preexisti	ng condition

C. Suspect med	lication(s)			
Name: Nix				
LINDAN	NE, ELIMIT	Έ		
Dose, frequency	, route use	Ther	apy d	ates
EVERY OTHER DAY, I'M 1-25-03			4.5	
DESPERATE, Al	ND			to 3-1-03
CRVING Diagnosis for us	e	I	Event	abated after use
LINDANE, NIX,		s	toppe	d or dose reduced
, , ,			no	
Lot#	Exp. date		-	
	Lap. auto			reappeared after oduction
				Judenon
NDC # -	-		yes	
Concomitant me	dical produ	cts		
****				
D. Suspect med	lical device	÷		
Brand name				
Type of device		1		
Manufacturer na	ime and add	iress	L Â	ator of device
				ealth professional ser facility
			Expi	ration date
model #			Espi	ation date
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
<b>Device available</b>				
Concomitant me	returned dical produ	to ma cts	inulaci	urer/_/
conconneant me	arear produ	~~		
E. Reporter				
Name and addre		Ê.		(781)449-6487
The National Pe				
P.O. Box 610189	· ·			
Health professio		patio	n	Also reported to
<b>⊻</b> <sub>yes</sub> <b>□</b> <sub>nc</sub>				manufacturer
If you do NOT wa	2	2		user facility distributor
disclosed to the ma	inutacturer, p	nace a	in 🔲	

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
1082	1/14/97	female	38 lbs
B. Adverse event	or product p	roblem	
	e Event & Proc		em
Outcomes attribut		event	
$\Box_{\text{death}}$	$\Box$ disability		
$\Box$ life-threatening		•	
hospitalization	required in	ntervention	
other:			
Date of event 10/0 Describe event or		e of report	2/23/2003
prescribed Ovide fo and irritated as were	e the scalps of h	-	-
Relevant tests/labo Other relevant his	-	g preexisti	ng condition
Head Lice have beer for over a year and h keeps sending her he	n a recurring pro nothing seems t	oblem for th o work. Th	nese children ne school

C. Suspect med	lication(s)			
Name: Ovide				
		1		
Dose, frequency,	, route use	Ther	apy d	ates
as needed		10/02	1/02	to
				10/14/02
Diagnosis for us	e	l	Event	abated after use
head lice		S	toppe	d or dose reduced
			no	
Lot #	Exp. date	ī	Event	reappeared after
				duction
NDC # -	-	_ ]	yes	
Concomitant me	dical produ	cts		
NIX, Lice AWAy	, Eckerds bra	and li	ce sha	mpoos and too
many others to rec	call since 20	01		
D. Suspect med	lical device	e		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			Ĺ.	ealth professional
				ser facility
				istributor
			Expi	ration date
model # catalog #			If im	planted, give date
catalog # serial #				plantea, give aute
lot #			Ifov	planted, give date
other #			псл	Janeu, give uate
Device available	for evaluat	ion?		
			nufact	urer / /
Concomitant me				
	•			
E. Reporter				
Name and addre	SS	ph	one #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	1A. 0	2461	
Health professio	nal Occuj	patio	n	Also reported to
$\mathbf{V}_{\text{yes}}$ $\mathbf{U}_{\text{normalized}}$	1			manufacturer
	)			
If you do NOT wa		ity		

	ation			
Patient Identifier	Date of birth	Sex	Weight	
1081	01/26/1973	female	175	lbs
B. Adverse event	or product p	oblem		
Advers	e Event & Prod	uct Proble	m	
Outcomes attribut	ed to adverse e	event		
death	∐ disability			
□ life-threatening		-		
hospitalization	_	tervention		
other: loss of ha	air			
Date of event 02/2	20/03 <b>Date</b>	of report	2/22/2	2003
<b>Describe event or</b> My son came home	_			
son with multiple pr and not one of them result, I have notice breaks off. My hair to the point that it le about an inch from comb now on all of Fortunately, I have what if it continues Relevant tests/labo	a work like they d that I have sta comes out in he ooks as if I have my head. I just us. My hair is really thick hair ?	say they w rted losing andfulls and taken scis continually now so dry	ill. As a hair and i d breaks o sors to it use the and brittl	t off .e.

C. Suspect med	lication(s)			
Name: Clear				
Rid, Wa	l-Mart's Equ	ate		
Dose, frequency	, route use	Ther	apy d	ates
According to direct	ctions on	11/20	002	
bottle every 10 da				to 2/10/03
Diagnosis for us	e	I I	ent	abated after use
Head Lice	•			d or dose reduced
riedd Llee			no	
Lot#	From data			
LOI #	Exp. date			reappeared after
		r	eintro	oduction
NDC # -	-		yes	
Concomitant me	dical produ	cts		
none	<b>F</b>			
liono				
D. Suspect med	lical device	•		
Brand name				
Type of device			-	
Manufacturer na	me and add	lress	Oper	ator of device
			$\square_{h}$	ealth professional
user facility				
distributor				
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device available			<b>c</b> .	, ,
U <sub>yes</sub> U <sub>no</sub> Concomitant me			nuraci	urer _/_/
Conconntant Inc	arear produ			
E. Reporter				
Name and addre		-	one #	(781)449-6487
The National Pe	diculosis A	ssoci	ation	
P.O. Box 610189	, Newton, M	1A. 02	2461	
Health professio		patior	ı	Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{normalized}}$	)			
If you do NOT wa		-		$\Box$ user facility
disclosed to the ma				distributor

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
1073	01/04/1990	female	70 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Proo	luct Proble	em
Outcomes attribut	ed to adverse	event	
death	disability		
□ life-threatening	$\Box_{\text{congenital}}$	anomaly	
hospitalization	$\Box$ required in	ntervention	
other:			
Date of event 02-2	2003 <b>Dat</b>	e of report	2/6/2003
Describe event or	problem		
MY DAUGHTER I	-	S. OLD. W	VE HAVE
BEEN BATTLING	WITH LICE S	INCE SHE	WAS IN
KINDERGARTEN			
STILL BATTLINC			
THE LICE WILL N			
ALONE. I HAVE			
FROM RID TO PR THE DOC. THAT			
AND SHAVING H			
WITH PLASTIC C			
OUR BELONGING	GS PLACED IN	PLASTIC	BAGS.
Relevant tests/labo	oratory data		
	futory dutu		
Other relevant his			
TO ADD HEARTE			
HOUSEHOLD CO			
CAT AND A DOG			
EXTREMLY LON PERSON TO CON			
DAUGHTER. NO			
DITE OIT LIC. NO			

C. Suspect medication(s)		
Name: Clear		
Dose, frequency, route use	Therapy d	ates
AS DIRECTED AND	09-1994	
THEN SOME		to 02-2003
Diagnosis for use	Event	abated after use
DID NOT WORK		d or dose reduced
DID NOT WORK		
	no	
Lot # Exp. date		reappeared after
	reintro	oduction
NDC #	yes	
	- 4 -	
Concomitant medical produ		
RID, NIX, PET LICE KILLIN		
BEER, HAIR BLEACH, PEA DRIER, VEGTABLE OIL, SI		
D. Suspect medical device		ill fill/ill,
	-	
Brand name Type of device		
Manufacturer name and add	ress Oner	ator of device
	-	ealth professional
		ser facility
		istributor
		ation date
model #	Espi	ution dute
catalog #	If im	planted, give date
serial #		
lot #	If exp	planted, give date
other #		
Device available for evaluat		
yes no returned		urer _/_/
Concomitant medical produ	ets	
E. Reporter		
Name and address	phone #	(781)449-6487
The National Pediculosis A	<u>^</u>	. /
P.O. Box 610189, Newton, M	IA. 02461	
Health professional Occuj	oation	Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$		manufacturer
If you do NOT want your ident	ty	user facility
disclosed to the manufacturer, p	lace an	distributor

-	Weight 180 2/3/2 em. Have hair twice urs!	
ent ent nomaly ervention of report ave proble mbed my	2/3/2 em. Have hair twice	003
ent ent nomaly ervention of report ave proble mbed my	em. Have hair twice	
ent nomaly ervention of report ave proble mbed my	em. Have hair twice	
nomaly ervention of report ave proble mbed my	em. Have hair twice	
of report ave proble mbed my	em. Have hair twice	
of report ave proble mbed my	em. Have hair twice	
o <b>f report</b> ave proble mbed my	em. Have hair twice	
ave proble mbed my	em. Have hair twice	
ave proble mbed my	em. Have hair twice	
mbed my	hair twice	:_
preexisti	ng condit	ion
]	preexisti	preexisting condit

C. Suspect medication(s)			
Name: lindane			
Dose, frequency, route use	The	rapy d	ates
2 oz for 4 minutes	1/19	/2003	
On 1/19 and 1/29			to 1/28/2003
Diagnosis for use	1	Event	abated after use
lice		stoppe	d or dose reduced
		no	
Lot # Exp. date		-	1.0
Lot "			reappeared after oduction
		remut	ouuction
NDC #		yes	
Concomitant medical produ	cts		
Ĩ			
D. Suspect medical device	е		
Brand name			
Type of device			
Manufacturer name and add	dress	Oper	ator of device
		$\square_{h}$	ealth professional
			ser facility
			istributor
		Expir	ration date
model #			
catalog #		If im	planted, give date
serial #			
lot #		- If exp	planted, give date
other #			
Device available for evaluat			
Upper no returned Concomitant medical produ		anufact	urer//
Concomitant metical produ	cts		
E. Reporter			
Name and address	p	hone #	(781)449-6487
The National Pediculosis A	ssoc	ciation	
P.O. Box 610189, Newton, N	/IA. (	02461	
Health professional Occu	patio	n	Also reported to
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$			manufacturer
If you do NOT want your ident	ity		user facility
disclosed to the manufacturer, p	blace	an 🔲	□distributor

	ation			
Patient Identifier	Date of birth	Sex	Weight	
1068	05/15/95	female	41	lbs
B. Adverse event	or product p	oblem		
Advers	e Event & Prod	uct Proble	m	
Outcomes attribut	ed to adverse e	event		
∐ death	∐ disability			
☐ life-threatening	$\Box$ congenital	-		
hospitalization	$\Box$ required in	tervention		
other:				
Date of event 07/2	20/01 <b>Date</b>	e of report	1/30/2	003
a half and everything and nits out of the h coming back. We have tried all the using olive oil. we e to pull them out as y	hair by hand. Ha e treatments and even use the cor	has gone ends with th	ed they ke ven as far	ep as
Relevant tests/labo	oratory data			

Triage Unit Sequence #

#### 

C. Suspect med	lication(S)		
Name: Nix			
we have	tried them al	1	
Dose, frequency,	, route use	The	erapy dates
We use these treat once a week and	when we	7-20	001 to 1-30-2003
Diagnosis for us Doctors prescripti that over the cour	ion and after		Event abated after use stopped or dose reduced doesn't apply
Lot # Don't know the lot #	Exp. date		Event reappeared after reintroduction
NDC # -	-		yes

#### **Concomitant medical products**

We have used all the medications and tried all the natural treatments

#### D. Suspect medical device

Brand name						
Type of device						
Manufacturer name and address	Operator of device health professional user facility distributor					
	Expiration date					
model # catalog # serial #	If implanted, give date					
	If explanted, give date					
<b>Device available for evaluation?</b> $\square_{\text{yes}} \square_{\text{no}} \square_{\text{returned to manufacturer } _/_/}$						
Concomitant medical products						
E. Reporter						
Name and address ph	none # (781)449-6487					
The National Pediculosis Associ	iation					
P.O. Box 610189, Newton, MA. 02	2461					
Health professional Occupation ✓ yes □ no Occupation	n Also reported to manufacturer user facility					
If you do NOT want your identity disclosed to the manufacturer, place a						

A. Patient Inform	ation		
Patient Identifier		Sex	Weight
1062	02/05/1999	female	45 lbs
B. Adverse event	or product p	roblem	
	e Event & Prod		em
Outcomes attribut	ted to adverse of	event	
death	disability		
□ life-threatening		anomaly	
hospitalization	required in	-	
other: Complai			
Date of event 1/01	1/03 <b>Date</b>	e of report	1/22/2003
Describe event or		-	
While I am not certa the treatment, she h and her eyes. I will checked	as been complai	ining that h	er head hurts
Relevant tests/labo	oratory data		
Other relevant his	story, includin	g preexisti	ng condition

C. Suspect medication(s)						
Name: Nix						
RID Xta strength						
Dose, frequency,	, route use	Ther	apy d	ates		
One bottle 3 to 4	different	11-29	9-02			
times				to 01-01-03		
Diagnosis for us	e	I	Event	abated after use		
Lice			stopped or dose reduced			
2.00			no			
Lot #	Exp. date		-			
L0t #	Exp. uate			reappeared after duction		
		r	eintro	duction		
NDC # -	-		doesn'	t apply		
Concomitant me	dical produ	cts				
	uicui prouu	eus				
D. Suspect med	lical device	9				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
				ealth professional		
			user facility			
	distributor			istributor		
			Expir	ration date		
model #			TC	1		
catalog #			11 im]	planted, give date		
serial # lot #			TE and	lantal ains data		
other #			n exp	planted, give date		
Device available		ion?	I			
			nufact	urer / /		
	yes no returned to manufacturer ///					
-						
E. Reporter						
Name and address phone # (781)449-6487						
The National Pe	The National Pediculosis Association					
P.O. Box 610189	P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to						
				manufacturer		
If you do NOT want your identity user facility disclosed to the manufacturer, place an distributor						
and to the life	maraoraror, p	u				

A. Patient Inform	ation				
Patient Identifier	Date of b	oirth	Sex	Weigh	t
1060	09/12/96	5	female	50	lbs
B. Adverse event	or prod	uct p	roblem		
	Product	t Prob	lem		
Outcomes attribut	ted to adv	erse (	event		
death	$\Box_{disal}$	bility			
□ life-threatening		•	anomaly		
$\square$ hospitalization	_ ĭ		itervention		
1	_	neu n			
other: total rein	ifestation	1			
Date of event 10/0	02-1/03	Date	e of report	1/18	8/2003
Describe event or	problem				
My children moved	from Atla	anta,G	A to Lobe	lville,TN	N in
October. They got h	ead lice w	/ithin	2 weeks.W	e began	
treating it immediat	ely with o	over th	e counter p	oroducts	. We
cleaned everything	in our hon	ne. W	e spent hou	irs on en	d
picking nits and clip					
of this worked we the					
through the headlice					and
we are still dealing	-				
instructions right do	-				
have even gone as fa				-	
beds out in the snov	-		-		-
				0	
combs.We have trie					ed the
salt water.We have					
products.Our family	-				-
working.I am in a pa			going to g	et their p	pants
Relevant tests/labo	oratory da	ata			
<u></u>			•		
Other relevant his	story, inc	luding	g preexisti	ing con	lition
none					

-			
	medication(s)		
Name: lind	ane		
Nix	, Rid, Clear, Robio	comb,gene	rics,peppermint extr
Dose, freque	ency, route use	Therapy	dates
-	with follow up	10/02	to
treatments ev	very 10 days		01/03
Diagnosis fo	or use	Event	abated after use
Mature lice a	nd nits every tim	e stopp	ed or dose reduced
we retreat.		no	
Lot #	Exp. date	Event	reappeared after
n/a		reinti	oduction
NDC #		yes	
	t medical produ	ote	
0011001110	· incurent produ		
		_	
D. Suspect	medical device	e	
Brand name			
Type of devi			
	er name and add	dress Ope	rator of device
	cr nume und ud		
			health professional
			user facility
			distributor
		Exp	iration date
model #			
		If in	nplanted, give date
serial #			
lot #			xplanted, give date
other #			
	able for evaluat		
	no returned		cturer/_/
Concomitan	t medical produ	cts	
E. Reporter			
Name and a	ddress	phone	# (781)449-6487
The Nationa	al Pediculosis A	ssociation	n
P.O. Box 61	0189, Newton, N	1A. 02461	
Health prof		pation	Also reported to
⊻yes	no		manufacturer
•	Γ want your ident	· _	$\Box$ user facility
disclosed to th	ne manufacturer, p	olace an	distributor

Patient Inform tient Identifier		Sex	Weight	
1058	12/22/1993	male	50	lbs
Adverse event	t or product p	roblem		
	Product Prob			
tcomes attribut	ted to adverse o	event		
death	disability			
life-threatening	$\Box_{\text{congenital}}$	anomaly		
hospitalization	$\Box$ required in	ntervention		
other: still findi	ng lice			
ate of event 1/9/	'2002 <b>Date</b>	e of report	1/10/2	003
elevant tests/labo				
ther relevant his		g preexisti	ng condit	ion

C. Suspect medication(s)					
Name: lindane					
Dose, frequency,	route use	The	rapy d	ates	
?		1/6/0	)3		
			to 1/6/03		
Diagnosis for us	0	<u> </u>	Front	abated after use	
_	C			d or dose reduced	
head lice				a of abbe feateeu	
			no		
Lot #	Exp. date	]	Event	reappeared after	
		1	reintro	oduction	
			yes		
NDC # -	-		5		
Concomitant me	dical produ	icts			
D. Suspect med	lical devic	е			
Brand name					
Type of device					
Manufacturer na	me and ad	dress	Oper	ator of device	
				ealth professional	
			user facility		
			$\square_d$	istributor	
			Expii	ration date	
model #					
catalog #			_ If implanted, give date		
serial #					
lot #			If exp	planted, give date	
other #					
Device available					
yes no			anufact	urer _/_/	
Concomitant me	dical produ	icts			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189, Newton, MA. 02461					
Health profession	nal Occu	patio	n	Also reported to	
⊻ <sub>yes</sub> □ <sub>nc</sub>	)			manufacturer	
If you do NOT want your identity					
disclosed to the ma	nufacturer, j	place a	an 🔳	∐distributor	