	ation			
atient Identifier	Date of birth	Sex	Weight	
709	9-13-90	female	80	lbs
3. Adverse even				
	e Event & Pro		em	
Outcomes attribut	_	event		
∐ death	∐ disability			
\Box life-threatening		•		
hospitalization	-	ntervention		
other: diarhea/h				
Date of event 10- Describe event or		e of report	10/10/20	01
Relevant tests/labo	oratory data			

C. Suspect medication(s)						
Name: Nix						
Dose, frequency,	, route use	Ther	apy d	ates		
		9-20-	-2001			
days apart		to 10-01-2001				
			Event abated after use			
Diagnosis for use			stopped or dose reduce			
headlice		stopped of dose reduce				
	-		no			
Lot #	Exp. date	F	Event	reappeared after		
			reintroduction			
			doesn't apply			
NDC # -	-		uoesn	t appiy		
Concomitant me	dical produ	cts				
	-					
D. Suspect med	lical device	2				
Brand name Type of device						
Manufacturer na	me and add	Irocc	Oner	ator of device		
	inc and au	11 055	Ē			
			health professional			
			Expir	ation date		
model #			Tf im	alantad give data		
catalog #			11 1111	planted, give date		
serial # lot #			TC	1 / 1 + 1 :		
lot # other #			If explanted, give dat			
Device available	for evaluat		unufact	urer / /		
Concomitant me	dical produ	cts				
E. Reporter						
Name and addre	SS	ph	one #	(781)449-6487		
The National Pe	diculosis A	ssoci	iation			
P.O. Box 610189	, Newton, M	1A. 0	2461			
Health professio	_	patio	1	Also reported to		
⊻ _{yes} ⊔ _{nc}						
If you do NOT want your identity						
disclosed to the ma	anufacturer, p	lace a	in 🔲	distributor		

Adverse event or	D-22-91 roduct product product Prob to adverse a disability congenital required in 01 Data Dblem not rid or ni	event anomaly ntervention e of report x not even l		
Adverse event or P tcomes attributed death life-threatening other: te of event 10-06-0 cribe event or pro- ning is killing them	product product Prob roduct Prob to adverse of disability congenital required in 01 Date oblem not rid or nit	roblem olem event anomaly ntervention e of report x not even 1	10/6/20 indane1%	0001
Participation Pa	roduct Prob to adverse of disability congenital required in 01 Date oblem not rid or nit	event anomaly ntervention e of report x not even l	indane1%	
tcomes attributed death [life-threatening [hospitalization [other: [te of event 10-06-0 scribe event or pro- ning is killing them	to adverse of disability congenital required in 01 Date oblem	event anomaly ntervention e of report x not even l	indane1%	
death [life-threatening] hospitalization [other: [te of event 10-06-0 scribe event or pro- ning is killing them	disability congenital required in 01 Date oblem not rid or ni	anomaly ntervention e of report x not even l	indane1%	
life-threatening hospitalization to hospitalization	congenital required ir 01 Date oblem not rid or ni	e of report	indane1%	
hospitalization conter:	required in 01 Date oblem not rid or nit	e of report	indane1%	
other: te of event 10-06-0 scribe event or pro- ning is killing them	01 Date oblem not rid or ni	e of report x not even l	indane1%	
te of event 10-06-0 scribe event or pro- ning is killing them	oblem not rid or ni	x not even l	indane1%	
scribe event or pro	oblem not rid or ni	x not even l	indane1%	
ning is killing them	not rid or ni			
evant tests/laborat	tory data			
ner relevant histor	ry, including	g preexisti	ng condit	ion
	·			

C. Suspect med	C. Suspect medication(s)						
Name: lindane							
rid and nix							
Dose, frequency,	, route use	The	rapy d	ates			
reg dose 7-10 day	s	09-0	01-01				
· ·				to 10-06-01			
Diagnosis for us	e	ŀ	Event	abated after use			
head lice	-		stopped or dose redu				
neud nee			doesn't apply				
Lot #	Exp. date						
LOI #	Exp. date		Event reappeared after				
		•	reintroduction				
NDC # -	_		doesn't apply				
Concomitant me	dical produ	rte					
conconntant inc	uicai prouu	<i>c</i> 15					
D. Suspect med	lical device	2					
Brand name							
Type of device							
Manufacturer na	me and add	lress	Oper	ator of device			
			Ĺ.	ealth professional			
				ser facility			
			distributor				
			Expir	ration date			
model #							
catalog #			If im	planted, give date			
serial #							
lot #			If exp	planted, give date			
other #							
Device available Update the second			anufact	urer / /			
Concomitant me							
E. Reporter	E. Reporter						
Name and addre	SS	pl	hone #	(781)449-6487			
The National Pe	diculosis A	ssoc	iation				
P.O. Box 610189	, Newton, M	1A. ()2461				
Health professio ✓ _{yes} □ _{nc}		patio	n	Also reported to			
	▶ yes □no □manufacturer If you do NOT want your identity □user facility						
If you do NOT was disclosed to the ma	•		an 🔲				
anserosed to the life	maracturer, p	ince					

	ation		
Patient Identifier	Date of birth	Sex	Weight
702	05/12/95	female	35 lbs
B. Adverse event	or product p	oroblem	
	Product Pro		
Outcomes attribut			
∐ death	□ disability		
		-	
hospitalization other:		ntervention	
Date of event 06/2	0/01 D -4	6	10/5/2001
Date of event 06/2 Describe event or		e of report	10/5/2001
THINGS.			
Relevant tests/labo Other relevant his		a provicti	ng condition

C. Suspect medication(s)					
Name: Nix					
Kwell als	50				
Dose, frequency,	route use	The	rapy d	ates	
every seven days if live lice 6,		6/20	6/2001		
are found		to 10/2001			
Diagnosis for use			Event abated after use		
live brownish lice found as well		stopped or dose reduce			
as nits.	s nits.		doesn't apply		
Lot #	Exp. date		Event reappeared aft		
			reintroduction		
			yes		
NDC # -	-		J		
Concomitant me	dical produ	icts			
pronto, nix , and k	well used.	also t	tea tree	treatments.	
D. O					
D. Suspect med	lical devic	е			
Brand name					
<u>Type of device</u> Manufacturer na	mo and ad	droce	Oper	ator of dovice	
	une and au	urcs			
				ealth professional ser facility	
			istributor		
				ration date	
model #			Expi	ation date	
catalog #			- If im	planted, give date	
serial #			-		
lot #					
other #					
Device available					
\square_{yes} \square_{no}			anufact	urer _/_/	
Concomitant me	dical produ	icts			
E. Reporter					
Name and addre	ss	р	hone #	(781)449-6487	
The National Pe	diculosis A	Assoc	ciation		
P.O. Box 610189	, Newton, I	MA. (02461		
Health profession		patio	on	Also reported to	
⊻ _{yes} □ _{nc}					
If you do NOT was		•		\Box user facility	
disclosed to the ma	nufacturer,	place	an 🔲	distributor	

C. Suspect med	lication(s)				
Name: lindane					
Dose, frequency,	route use	Thera	apy d	ates	
One time for 4 minutes. $9/2$)1		
				to 9/27/01	
Diagnosis for use	a	F	vent	abated after use	
-				d or dose reduced	
crabs					
		r	10		
Lot #	Exp. date		vent	reappeared after	
		r	reintroduction		
			doesn't apply		
NDC $\#$ -	-				
Concomitant me	dical produ	cts			
none					
D. Suspect med	ical device	9			
Brand name					
Type of device			0		
Manufacturer na	me and add	iress	Ē	ator of device	
				ealth professional	
				ser facility istributor	
			Expir	ration date	
model #			TC •	1	
catalog #			II Imj	planted, give date	
serial #			70		
lot # other #			If exp	planted, give date	
Device available \square_{yes} \square_{no}	_		aufoot		
Concomitant me				uiei//	
	incur prouu	cus			
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	461		
Health profession ▼ _{yes} □ _{no}		pation		Also reported to manufacturer	
If you do NOT war	nt vour identi	itv		user facility	
disclosed to the ma	•	•	n 🔲	distributor	

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
697	2/12/99	female	26 lbs
B. Adverse event	or product p	roblem	
	e Event & Proo		em
Outcomes attribut	ed to adverse	event	
∐ death	☐ disability		
□ life-threatening			
hospitalization	required in	ntervention	
other:			
Date of event 9/20		e of report	9/28/2001
Describe event or			
tried nix twice, wa			
matresses & couche			
comb after every ba rash on the back of 1			
ash on the back of	ner neek/upper		used onve on.
Dalaman4 4aa4a/laha			
Relevant tests/labo	fatory uata		
Other relevant his	story, includin	g preexisti	ng condition

C. Suspect med	lication(s)					
Name: Nix						
olive oil						
Dose, frequency,	, route use	The	rapy d	ates		
twice with nix within 4 days, 9/20		9/20	/01	4-		
then olive oil				to 9/29/01		
Diagnosis for us	e]	Event	abated after use		
treat lice		2	stopped or dose redu			
			doesn't apply			
Lot #	Exp. date		Event reappeared aft			
9J1989				oduction		
			Vac			
NDC # -	-		yes			
Concomitant me	dical produ	cts				
D. Suspect med	lical device	9				
Brand name						
Type of device			1			
Manufacturer na	ame and add	lress	-	ator of device		
				ealth professional		
				ser facility		
				istributor		
			Expi	ration date		
model #			Tf im	nlantad <i>a</i> iva data		
catalog #			II IM	planted, give date		
serial # lot #			TE and	Janta Jata		
other #			n exp	planted, give date		
Device available	for avaluat	ion?				
$\square_{\text{yes}} \square_{\text{no}}$			anufact	urer / /		
Concomitant me						
E. Reporter						
Name and addre	SS	pł	10ne #	(781)449-6487		
The National Pe	diculosis A	.ssoc	iation	· · /		
P.O. Box 610189	, Newton, M	1 A. 0	2461			
Health professio	nal Occu	patio	n	Also reported to		
\mathbf{V}_{yes} \square_{no}				manufacturer		
If you do NOT wa	nt your ident	ity		user facility		
disclosed to the ma	unufacturer, p	lace a	an 🔳	□distributor		

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
696	10/10/1996	male	35 lbs
B. Adverse event	or product p	roblem	
	Product Prob	lem	
Outcomes attribut	_	event	
death	∐ disability		
\Box life-threatening		•	
hospitalization	required ir	ntervention	
other:			
Date of event 08/0		e of report	9/27/2001
Describe event or			
my daughter got hea failed my doctor has	-		
acticin	s presented eve	ryuning noi	
Relevant tests/labo	oratory data		
			74.4
Other relevant his	story, including	g preexisti	ng condition
asthma			

C. Suspect me	dication(s)			
Name: Rid				
Dose, frequency, route use Therapy dates				
		08/0	8/2001	
overy o days		0/2001	to 09/27/2001	
		<u> </u>	E	
Diagnosis for u				abated after use
reaply after 10 days		stopped or dose reduce		
			no	
Lot #	Exp. date		Event reappeared afte	
				oduction
NDC # -	-		yes	
Concomitant me	edical produ	cts		
this is a constant	battle i have	used	probab	ly every lice
product out there			1	5 5
*				
D. Suspect me	dical device)		
Brand name				
Type of device				
Manufacturer n	ame and add	lress	Oper	ator of device
			Ē	ealth professional
				ser facility
			\square_d	istributor
				ration date
			Laph	auton unc
model # catalog #			- If im	planted, give date
catalog # serial #			-	
lot #			If ext	planted, give date
other #				sinited, give dute
Device available	e for evaluat	ion?		
□ _{yes} □ _{no}	Ireturned		anufact	turer//
Concomitant me	edical produ	cts		
E. Reporter				
Name and addro	ess	p	hone #	(781)449-6487
The National P	ediculosis A	ssoc	ciation	
P.O. Box 61018	9, Newton, M	1A. ()2461	
Health professio ↓ yes □ n		patio	n	Also reported to
	-			manufacturer
If you do NOT wa	-	-		User facility
disclosed to the m	anufacturer, p	lace	an 🔲	distributor

A. Patient Information	ation				
Patient Identifier	Date of birt	h So	ex	Weight	
694	5-2-95	fe	emale	40	lbs
B. Adverse event	or product	pro	blem		
	Product Pr	oble	n		
Outcomes attribut			ent		
☐ death	∐ disabili	•			
\Box life-threatening					
☐ hospitalization ☐ required intervention					
other:		<u> </u>		0.00.0	
Date of event 7-2- Describe event or		ate o	f report	9/24/	2001
physician have faile scoured house. Now Relevant tests/labo	/ showing up	on o			-

C. Suspect medication(s)					
Name: Rid					
NIX, Pre	scription of	Lind	ane		
Dose, frequency	route use	The	rapy d	ates	
Every week since		7-2-			
2001		,	to 9-24-01		
			F 4		
Diagnosis for us	e			abated after use d or dose reduced	
Failed			stoppe	u or uose reduced	
			no		
Lot #	Exp. date]	Event	reappeared after	
]	reintro	oduction	
			yes		
NDC # -	-		- ·		
Concomitant me	dical produ	cts			
D. Suspect med	lical device	,			
Brand name					
Type of device					
Manufacturer na	ime and add	iress	L È	ator of device	
				ealth professional ser facility	
				istributor	
			Expi	ration date	
model #			If im	planted, give date	
catalog # serial #				planteu, give unte	
lot #			Ifev	planted, give date	
other #				Juniceu, give unic	
Device available	for evaluati	ion?			
			anufact	urer / /	
Concomitant me					
E Bonortor					
E. Reporter				(701) 440 (407	
Name and addre		Ē.	hone #	(781)449-6487	
The National Pe					
P.O. Box 610189	, Newton, N	1A. ()2461		
Health professio	nal Occuj	patio	n	Also reported to	
\mathbf{V}_{yes} $\square_{\text{normalized}}$)			manufacturer	
If you do NOT wa	•	•		\Box user facility	
disclosed to the ma	unufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform	ation				
Patient Identifier	Date of birth	Sex	Weight		
689	7/27/94	male	55	lbs	
B. Adverse event	or product p	roblem			
Product Problem					
Outcomes attribut	ed to adverse e	event			
∐ death	∐ disability				
\Box life-threatening \Box congenital anomaly					
hospitalization	\Box required in	tervention			
other:					
Date of event 6/20 Describe event or		e of report	9/13/2	2001	
DAYS LATER TH EVERYTHING IN BEDDING MATT THE CARPET FLO Relevant tests/labo	HOT WATER RESSES AND DORS.	INCLUDII	NG RE AND		

C. Suspect medication(s)					
Name: Nix					
LICE AV	WAY, VEGI	ETAB	BLE OIL, AND LINDAN		
Dose, frequency	, route use	Ther	Therapy dates		
EACH TIME SH	EACH TIME SHE GETS		01		
THEM ABOUT EVERY			to 9/2001		
TWO WEEKS Diagnosis for use			Event abated after use		
ONCE EVERY 7-10 DAYS.			stopped or dose reduced		
ONCE EVERT /-	10 DATS.		doesn't apply		
Lot#	E-m Jo4a				
Lot #	Exp. date		Event reappeared after		
		r	reintroduction		
NDC # -			doesn't apply		
Concomitant me	- dical produ	ete			
Conconntant me	uicai produ	cis			
D. Suspect med	lical device	5			
Brand name		•			
Type of device					
Manufacturer na	me and add	lress	Operator of device		
			health professional		
			\square user facility		
			distributor		
			Expiration date		
model #					
catalog #			If implanted, give date		
serial #					
lot #			If explanted, give date		
other #					
Device available			anufacturer _/_/		
Concomitant me			·····		
E Domortor					
E. Reporter					
E. Reporter Name and addre	ss	ph	none # (781)449-6487		
Name and addre	diculosis A	ssoci	iation		
Name and addre The National Pe P.O. Box 610189 Health professio	diculosis A , Newton, M nal Occuj	ssoci 1A. 0	iation 2461 n Also reported to		
Name and addre The National Pe P.O. Box 610189 Health professio	diculosis A , Newton, N nal Occuj	ISSOCI	iation 2461		

A. Patient Information					
Patient Identifier	Date of b	irth	Sex	Weight	
678	10/24/62		female	115	lbs
B. Adverse event	or produ	ict pi	oblem		
Advers	e Event &	Prod	uct Proble	m	
Outcomes attribut	ed to adv	erse e	event		
\Box_{death}	□disat	oility			
□ _{life-threatening}	$\mathbf{V}_{\mathrm{cong}}$	enital	anomaly		
$\Box_{hospitalization}$	∠ requi	red in	tervention		
other: Antibotic Therapy for Infection					
Date of event 02/2	20/00	Date	of report	9/3/2	2001
Decerthe event on					

Describe event or problem

Trip by plane-had eggs/nits in hair, bump on forearms looked like a raised blister-pimple (3). Seen no Lice-but nits on hair strands. Initial home treatment, then office visit. Fever, Malaise, Impetigo first diagnosis-open sores.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Born handicapped, osteoporosis, (1 eye only)eye condition suddenly appeared. Rash over body every few months would appear then disappear after treatment with Steriods. Both Topical and by mouth. Rash always accompanies fever. Un-diagnosed for rash out-br Triage Unit Sequence #

C. Suspect medication(s) Name: lindane Kwell Shampoo Dose, frequency, route use Therapy dates 03/01 Apply, let dry rinse off. to 09/01 Diagnosis for use Event abated after use stopped or dose reduced Scabicide, body lice, pest removal. no Lot # Exp. date Event reappeared after reintroduction yes NDC

Concomitant medical products

Eurax Cream prescribed, Antibiotic oral dose for 10 day therapy 1 B.I.D. Levequin 500 mgs. For secondary skin infection; respitory infection. Then had to be re prescribed.

D. Suspect medical device

Brand name	
Type of device	
Manufacturer name 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 #	
Device available for evaluat $\square_{\text{yes}} \square_{\text{no}} \square_{\text{returned}}$	
Concomitant medical produ	
E. Reporter	
Name and address	phone # (781)449-6487
The National Pediculosis A	ssociation
P.O. Box 610189, Newton, M	1A. 02461
Health professional Occu	
⊻ _{yes} □ _{no}	manufacturer
If you do NOT want your ident	
disclosed to the manufacturer r	lace an distributor

A. Patient Inform	ation				
Patient Identifier	Date of bi	irth Se	x	Weight	
676	03-08-91	fe	male	055	lbs
B. Adverse event	or produ	ct prob	lem		
	Product	Problen	1		
Outcomes attributed to adverse event					
death disability					
\Box life-threatening \Box congenital anomaly					
hospitalization		red inter	vention		
other:					
Date of event 8-14	4/9-1	Date of	report	9/2/2	2001
Describe event or	problem				
we can not get rid o	f lice. i'v e	tried the	ree diffe	erent	
treatments. we've				1	
washed her bed line her room and the ho	-				v
for an hour at a time			-		У
	j		0		
Relevant tests/labo	oratory da	ta			
Kele vant tests/lab	natory da	u			
		- d'			(* a.e.
Other relevant his my daughter has ast					
and sulfa based drug		s allergi		s, aust fill	.68
	50.				

c. Suspect meu	C. Suspect medication(s)			
Name: Rid				
lindane ar	nd nix			
Dose, frequency,	route use	The	rapy d	ates
1st Rid. 2nd linda	1st Rid. 2nd lindane. 3rd 8-14			
nix. last rid				to 9-1-01
Diagnosis for use	2]	Event	abated after use
head lice		s	stoppe	d or dose reduced
			no	
Lot #	Exp. date		-	1.0
rid 01050015	Exp. uait			reappeared after duction
110 01050015			entro	ouuction
NDC # -	-		yes	
Concomitant med	lical produ	cts		
lidane used on 8-2	-		ilable.	purchased at
walgreens				1
2001 custer road	in plano tx 7	75075	i. next	was the nix used
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 #			If im _j	planted, give date
serial # lot #				planted, give date blanted, give date
serial #				
serial # lot # other # Device available :			If exp	planted, give date
serial # lot # other # Device available : 	returned	to ma	If exp	
serial # lot # other # Device available :	returned	to ma	If exp	planted, give date
serial # lot # other # Device available : 	returned	to ma	If exp	planted, give date
serial # lot # other # Device available : 	returned	to ma	If exp	planted, give date
serial # lot # other # Device available : Uves no Concomitant med	returned dical produc	to ma cts	If exp	olanted, give date
serial # lot # other # Device available : Uyes no Concomitant med E. Reporter	returned lical production	to ma cts ph	If exp anufact	blanted, give date
serial # lot # other # Device available : Uves no Concomitant med E. Reporter Name and addres	returned dical productions ss diculosis A	to ma cts pł	If exp anufact none # iation	blanted, give date
serial # lot # other # Device available : Uyes no Concomitant med E. Reporter Name and addres The National Ped	returned lical products ss diculosis A Newton, N	to ma cts ph ssoc 1A. 0	If exp anufact none # iation 2461	blanted, give date
serial # lot # other # Device available : Urgs Urgs Concomitant med E. Reporter Name and addres The National Peo P.O. Box 610189, Health profession	returned dical products ss diculosis A Newton, N hal Occup	to ma cts ph ssoc 1A. 0 patio	If exp anufact none # iation 2461	planted, give date urer _/_/ (781)449-6487 Also reported to

A. Patient Inform	ation				
Patient Identifier	Date of birt	h Sex	Weight		
672	10/31/55	female	127	lbs	
B. Adverse event	or product	problem			
Advers	e Event & Pr	oduct Prob	lem		
Outcomes attribut	ed to advers	e event			
death	∐ disabilit	y			
□ life-threatening		tal anomaly			
□ hospitalization □ required intervention					
other: has seen	doctors				
Date of event 10/3	31/00 D	ate of repor	·t 8/28/	2001	
Describe event or	-				
Hair falling out 4ind	ches worth				
teeth are loose					
finger nails stopped		d A	1.1.1		
headaches, chest pa vomiting, dark unde			-		
voiniting, dark unde	er eyes, asunn	ia - Dour ver	y tileu		
Relevant tests/labo	oratory data				
	2				
Other relevant his	tory, includ	ing preexis	ting cond	ition	
n/a					

C. Suspect med	lication(s)				
Name: Nix					
lindane s	hampoo 1%				
Dose, frequency	, route use	The	rapy d	ates	
Qty. 60 nurse said	l one time	10/3	1/00	to.	
left on for 8-10mi	n			to 10/31/00	
Diagnosis for us	e		Event	abated after use	
head lice			stoppe	d or dose reduce	
			no		
Lot #	Exp. date		Front	reappeared after	
rx6137375	F ·			duction	
180137373		ľ		Judenon	
NDC # -	-		yes		
Concomitant me	dical produ	cts			
Rid, Equate, Nix					
_					
D. Suspect med	lical device	•			
Brand name					
Type of device			-		
Manufacturer na	ame and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
			□d	istributor	
			Expii	ration date	
model #			Te :		
catalog #			II Im	planted, give dat	
serial # lot #			TC and	lantad atma dat	
other #			In exp	planted, give dat	
Device available	for evaluat	ion?	1		
			anufact	turer / /	
Concomitant me					
E. Reporter					
	~~			(791)440 6497	
Name and addre		Ľ.	ione #	(781)449-6487	
The National Pe					
P.O. Box 610189					
Health professio \mathbf{V}_{yes} \square_{nc}		oatio	n	Also reported t	
				\square user facility	
If you do NOT was disclosed to the ma		2	an 🔲		
disclosed to the ma	muraciurer, p	race	an 🔲	aistributor	

A. Patient Informa	ation				
Patient Identifier	Date of bi	rth	Sex	Weigh	t
667	5/9/93		female	85	lbs
B. Adverse event					
	e Event &			em	
Outcomes attribut			vent		
\Box death \Box life-threatening	∐ disab	•	anomaly		
\square hospitalization			tervention		
other: loss scho					
Date of event 3/10			of report	8/22	2/2001
Describe event or		Dutt	orreport	0/22	2001
products					
Relevant tests/labo	pratory da	ta			
Other relevant his na	tory, inclu	ıding	; preexisti	ng cono	lition

C. Suspect medication(s)				
Name: LiceGuard				
rid				
Dose, frequency,	route use	The	rapy d	ates
requiered	ed 000			4-
				to 0000
Diagnosis for us	e		Event	abated after use
Ona			stoppe	d or dose reduced
onu			doesn'	t apply
Lot #	Exp. date			
	Exp. uate			reappeared after
na]	reintro	oduction
NDC # -	-		yes	
Concomitant me	dical produ	cts		
tree oil works plea	use spread th	e wo	rd loca	ted in the health
food store please	call me ifyou	i nee	d input	
D. Suspect med	lical device	•		
Brand name				
Type of device				
Manufacturer na	me and add	lress		
				ealth professional
				ser facility istributor
			Expii	ration date
model #			If im	planted, give date
catalog # serial #				planteu, give unte
lot #			If ext	planted, give date
other #			•I	
Device available			1	
\square_{yes} \square_{no}			anufact	urer _/_/
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	SS	pl	10ne #	(781)449-6487
The National Pe				
P.O. Box 610189	, Newton, N	1A. (2461	
Health profession		patio	n	Also reported to
⊻ _{yes} □ _{nc}				manufacturer
If you do NOT was	5	2		User facility
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
656	05-03-94	female	60	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Prod	luct Proble	em	
Outcomes attribut	ed to adverse e	event		
death	∐ disability			
☐ life-threatening		anomaly		
hospitalization	required ir	ntervention		
other:				
Date of event 07-2	28-01 Date	e of report	8/8/2	001
Describe event or	problem			
Exposed on a Sunda	• •		-	
night. Retreated 1 v				
lice - adult, nympha viable lice next day.	-	Retreated	again. Foi	ind
viable lice liext day.				
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condit	ion

Name: Rid		on(s)			
i unic. Itic	ı				
Dose, frequ	ency, rout	e use	The	rapy d	ates
3 times	• /		7-28		
			. 20		to 8-6-01
Diagnosis f	or use			Event	abated after use
for treatmen		e and n			d or dose reduced
	U			no	
Lot #	Exp.	date		Event	reappeared after
	_				oduction
				yes	
NDC #	-	-		yes	
Concomitar	nt medical]	produo	cts		
				ed blow	dryer on hair,
picked throu	gh hair for 2	2 hours	5.		
D. Suspect	t medical o	device	•		
Brand name					
Type of dev	ice				
			_	-	
Manufactu	rer name a	nd add	lress	Ē	ator of device
Manufactui	rer name a	nd add	lress	h	ealth professional
Manufactu	rer name a	nd add	lress	□ _h	ealth professional ser facility
Manufactui	rer name a	nd add	lress	□ _h	ealth professional
Manufactu	rer name a	nd add	lress	□h □u □d	ealth professional ser facility
model #			Iress		ealth professional ser facility istributor ration date
model # catalog #			lress		ealth professional ser facility istributor ration date
model # catalog # serial #					ealth professional ser facility istributor ration date planted, give date
model # catalog # serial # lot #					ealth professional ser facility istributor ration date
model # catalog # serial # lot # other #				Expire If imp	ealth professional ser facility istributor ration date planted, give date
model # catalog # serial # lot # other # Device avai	lable for ev	valuati	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog # serial # lot # other # Device avai □ yes	lable for ev	v aluati turned	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog # serial # lot # other # Device avai	lable for ev	v aluati turned	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog # serial # lot # other # Device avai Device avai Concomitan	lable for ev no ret nt medical j	v aluati turned	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog # serial # lot # other # Device avai Device avai Device avai Concomitan	lable for ev no □ret nt medical j	v aluati turned	ion? to m cts	Expin Expin If imj	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog # serial # other # Device avai yes Concomitan E. Reporte Name and a	lable for et no ret nt medical j r address	valuati turned produce	to m cts	Liff exp anufact	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog # serial # lot # other # Device avai yes Concomitan E. Reporte Name and a The Nation	lable for ev no ret nt medical p nddress al Pediculo	valuati turned produce ossis A	ion? to m cts	If implement of the second	ealth professional ser facility istributor ration date planted, give date planted, give date
model # catalog # serial # other # Device avai yes Concomitan E. Reporte Name and a The Nation P.O. Box 61 Health prof	lable for ev no ret nt medical p address al Pedicule (0189, New fessional	valuati turned produce ossis A	ion? to m cts pi sssoc IA. (hone #	ealth professional ser facility istributor ration date planted, give date planted, give date urer _/_/ (781)449-6487
model # catalog # serial # other # Device avai Device avai Concomitan E. Reporte Name and a The Nation P.O. Box 61	lable for ev no ret nt medical p nddress al Pediculu (0189, New fessional no	valuati turned produce osis A ton, M Occup	to m to ssoc ssoc 1A. (patio	hone #	ealth professional ser facility istributor ration date planted, give date planted, give date urrer// (781)449-6487

Product Problem Outcomes attributed to adverse event death disability life-threatening congenital anomaly hospitalization required intervention other: Date of event 7-03-01 Date of report 8/3/2001 Describe event or problem nead lice and i can get them stopped Relevant tests/laboratory data
651 08-22-90 female 105 lbs 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 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: Oate of event 7-03-01 Date of report 8/3/2001 Oscribe event or problem ead lice and i can get them stopped Relevant tests/laboratory data
utcomes attributed to adverse event death disability life-threatening congenital anomaly hospitalization required intervention other: ate of event 7-03-01 Date of report 8/3/2001 escribe event or problem ead lice and i can get them stopped elevant tests/laboratory data
death disability life-threatening congenital anomaly hospitalization required intervention other: other Pate of event 7-03-01 Date of report 8/3/2001 Describe event or problem ead lice and i can get them stopped ead lice and i can get them stopped ead lice and i can get them stopped eader tests/laboratory data
life-threatening congenital anomaly hospitalization required intervention other:
hospitalization required intervention other: Date of event 7-03-01 Date of report 8/3/2001 Describe event or problem need lice and i can get them stopped
other:
Date of event 7-03-01 Date of report 8/3/2001 Describe event or problem nead lice and i can get them stopped 8/3/2001 Relevant tests/laboratory data 8/3/2001 8/3/2001
Describe event or problem nead lice and i can get them stopped
ead lice and i can get them stopped

C. Suspect medication(s)					
Name: Kwell					
over the counter, a pill, spray, etc.					
Dose, frequency,	, route use	Ther	apy da	ates	
folowed directions	s and	07-03	3-01		
repeated assaid				to 08-03-01	
Diagnosis for us	e	I	Event a	abated after use	
lice still there		s	toppe	d or dose reduced	
nee sun uiere			no		
Lot#	Even data		-		
LOI #	Exp. date			reappeared after	
		r	eintro	duction	
NDC # -	-		yes		
Concomitant me	dical produ	cts			
D. Suspect med	lical device)			
Brand name					
Type of device			1		
Manufacturer na	me and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
				stributor	
			Expir	ation date	
model #			Tf im	planted, give date	
catalog #			11 1111	planted, give date	
serial # lot #			If ovr	lanted, give date	
other #			II CAL	nanicu, give uale	
Device available	for evaluati	ion?	I		
\square_{yes} \square_{no}			nufact	urer//	
Concomitant me	dical produ	cts			
Concomitant me	dical produ	cts			
	dical produ	cts			
Concomitant me E. Reporter Name and addre			one #	(781)449-6487	
E. Reporter	SS	ph		(781)449-6487	
E. Reporter Name and addre	ss diculosis A	ph ssoci	iation	(781)449-6487	
E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	ss diculosis A , Newton, N nal Occuj	ph ssoci	iation 2461	(781)449-6487 Also reported to manufacturer	
E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	ss diculosis A , Newton, M nal Occuj	ph ssoci 1A. 0 pation	iation 2461	Also reported to	

	ation			
atient Identifier				eight
650	09/09/92	fema		lbs
. Adverse even				
	se Event & P		oblem	
Outcomes attribu	_			
death	∐ disabili	•	_	
☐ life-threatening		tal anoma	•	
hospitalization		d interver	ition	
other: hairloss				
Date of event 06/		ate of re	port	8/3/2001
elevant tests/labo	oratory data story, includ			

C. Suspect med	ication	(s)			
Name: Nix					
Dose, frequency,	route u	se	The	rapy d	ates
As recommended	by		0601	00	
physician					to 073100
Diagnosis for use	<u>,</u>		h	Event	abated after use
Headlice	-				d or dose reduced
пеацісе					
				yes	
Lot #	Exp. dat	te			reappeared after
			1	reintro	oduction
NDC# -			-	yes	
	-				
Concomitant mee		oduc	ets		
Lindane and Malat	thion				
D. Suspect med	ical de	vice			
Brand name					
Type of device Manufacturer na	ma and	hhe	rocc	Oper	ator of device
	ine anu	auu	1035	Ê.	
					ealth professional ser facility
					istributor
					ration date
model #				Expi	ation date
model # catalog #				If im	planted, give date
serial #					, , ,
lot #				If exp	planted, give date
other #					
Device available	for eval	uati	on?	•	
$\square_{\text{yes}} \square_{\text{no}}$	return	ned 1	to ma	anufact	urer _/_/
Concomitant mee					
E. Reporter					
Name and addres	s		nł	none #	(781)449-6487
The National Pe		is A	<u> </u>		(,
P.O. Box 610189,	Newton	n, M	(A. 0	2461	
Health profession	nal Oc	ccup	atio	n	Also reported to
⊻ _{yes} □ _{no}		1			manufacturer
If you do NOT war	it your ic	lenti	ty		user facility
disclosed to the ma			-		distributor

A. Patient Inform	ation			
Patient Identifier	Date of b	irth Sex	We	ight
644	5/13/92	fema	le 50	lbs
B. Adverse event	or produ	ict problei	n	
	Product	Problem		
Outcomes attribut	ted to adv	erse event		
death	disat	oility		
Life-threatening	_ `	enital anoma	-	
hospitalization	L requi	red interver	ntion	
other:				
Date of event 6/11	1/01	Date of re	port 7	7/30/2001
Describe event or	-			
constant reinfestatio			-	
first tried RID. Did		•	-	
Lindane, I have trea			with this	product.
What are the advers	se side effe	cts.		
Relevant tests/labo	oratory da	ta		
	· · · · ·	1.	•	1.4.
Other relevant his	story, incl	uaing pree	xisting c	ondition

	t medication(s)		
Name: lind	lane		
Dose, frequ	ency, route use	Therapy d	ates
shampooinh	air . then	6/11/01	to
reapply 1 we	eek later.		to 6/30/01
Diagnosis f	or use		abated after use
haed lice		stoppe	d or dose reduced
		doesn	't apply
Lot #	Exp. date	Event	reappeared after
			oduction
		yes	
NDC #		-	
Concomitar	nt medical produ	cts	
D. Suspect	medical device	e	
Brand name	e		
Type of dev			
	rer name and add	lress Oper	ator of device
		- I	ealth professional
			and fo gility
			ser facility
			listributor
model #		Expi	listributor ration date
model # catalog #		Expi	listributor ration date
catalog #		Expi	listributor ration date
catalog # serial #		Expi	listributor ration date planted, give date
catalog # serial # lot #		Expi	listributor ration date
catalog # serial # lot # other # Device av <u>ai</u>	lable f <u>or</u> evaluat	Expi If im If ex If ex If ex	listributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device avai	lable for evaluat	Expi	listributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device avai	lable f <u>or</u> evaluat	Expi	listributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device avai yes	lable for evaluat	Expi	listributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device avai yes Concomitar	lable for evaluat Ino ^{returned} Int medical produ	Expi	listributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device avai yes Concomitar E. Reported	lable for evaluat no returned nt medical produ	Expi Expi If im If ex ion? to manufac cts	listributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device avai yes Concomitar E. Reporte Name and a	lable for evaluat no returned nt medical produ	Expi Expi If im If ex ion? to manufac cts	listributor ration date planted, give date planted, give date turer/_/ (781)449-6487
catalog # serial # lot # other # Device avai yes Concomitan E. Reporte Name and a The Nation	lable for evaluat no returned nt medical produ nddress	Expi Expi If im If ex ion? to manufac cts phone #	listributor ration date planted, give date planted, give date turer/_/ (781)449-6487
catalog # serial # other # Device avai yes Concomitar E. Reporter Name and a The Nation P.O. Box 61 Health prof	lable for evaluat no returned nt medical produ nt medical produ nddress al Pediculosis A 0189, Newton, N cessional Occup	Expi Expi If im If ex ion? to manufac cts phone #	listributor ration date planted, give date planted, give date turer _/_/ (781)449-6487 Also reported to
catalog # serial # other # Device avai yes Concomitar E. Reporter Name and a The Nation P.O. Box 61	lable for evaluat no returned nt medical produ iddress al Pediculosis A 0189, Newton, N	Expi Expi If im If ex ion? to manufac cts phone # ssociation IA. 02461	listributor ration date planted, give date planted, give date turer _/_/ (781)449-6487 Also reported to manufacturer
catalog # serial # lot # Device avai yes Concomitar E. Reporte Name and a The Nation P.O. Box 61 Health prof V_yes	lable for evaluat no returned nt medical produ nt medical produ nddress al Pediculosis A 0189, Newton, N cessional Occup	Expi Expi If im If ex ion? to manufac cts phone # .ssociation 1A. 02461 pation	listributor ration date planted, give date planted, give date turer _/_/ (781)449-6487 Also reported to

	ation				
Patient Identifier	Date of bir	th Se	ex	Weight	
642	06/24/92	fe	emale	70	lbs
B. Adverse event	or produc	t prol	olem		
	Product P	roblei	n		
Outcomes attribut	ed to adver	se eve	nt		
death	∐ disabil	ity			
□ life-threatening		ital an	omaly		
hospitalization		ed inter	vention		
other:					
Date of event 07/1	4/01 I	Date of	f report	7/28	/2001
pediatrician and tha said NO	ts what they	wante	ed to giv	e her so	Ι
Relevant tests/labo	pratory data	1			

active nee doesn't apply Lot # Exp. date Event reappeared after reintroduction nDC # Oncomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device Is the serial # catalog # tot# lot # lot # <td< th=""><th>Vaseline,OLIVE oil se, frequency, route use ory 7 days Thera 7/14/0 agnosis for use ve lice Exp. date ve lice a c b c c t Exp. date c c t Exp. date c c c c c c c c c c c c c c c c c c c c c c c c c c c c c c c c del # </th><th></th></td<>	Vaseline,OLIVE oil se, frequency, route use ory 7 days Thera 7/14/0 agnosis for use ve lice Exp. date ve lice a c b c c t Exp. date c c t Exp. date c c c c c c c c c c c c c c c c c c c c c c c c c c c c c c c c del #	
Dose, frequency, route use every 7 days Therapy dates 7/14/01 to 7/28/01 Diagnosis for use active lice Event abated after use stopped or dose reduce doesn't apply Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # Operator of device Brand name Operator of device Type of device Operator of device Manufacturer name and address Operator of device model # Expiration date lot # If implanted, give date lot # If explanted, give date other # If explanted, give date Povice available for evaluation? If explanted, give data wyes no Preturned to manufacturer _/_/ Concomitant medical products	se, frequency, route use Thera ary 7 days 7/14/0 ngnosis for use E ve lice st at # Exp. date et # Exp. date oC # - ncomitant medical products Suspect medical device and name pe of device and address del # alog # ial # er # wice available for evaluation? ves Ino Ireturned to man ncomitant medical products Reporter me and address phe e National Pediculosis Associa b. Box 610189, Newton, MA. 02 alth professional Occupation	
every 7 days 7/14/01 to 7/28/01 Diagnosis for use Event abated after use active lice doesn't apply Lot # Exp. date Event reappeared after reintroduction doesn't apply Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device In the second secon	ary 7 days 7/14/0 agnosis for use E ve lice st if Exp. date f c c if Exp. date f oC # - ncomitant medical products Suspect medical device and name pe of device nufacturer name and address del # er # returned to main ncomitant medical products Reporter me and address Photocological devices Note: Suspect medical products Reporter me and address Photocological devices Note: Suspect medical products Reporter Metable for evaluation? Suspect medical products Reporter Metable for evaluation fo	
to 7/28/01 Diagnosis for use Event abated after use active lice doesn't apply Lot # Exp. date Event reappeared after reintroduction doesn't apply Lot # Exp. date Event reappeared after reintroduction doesn't apply Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device Manufacturer name and address Operator of device Isserial #	agnosis for use Exp. date ve lice ft ve lice ft att Exp. date ft Exp. date ft ft	rapy dates
7/28/01 Diagnosis for use active lice active lice Lot # Exp. date Event reappeared after reintroduction NDC # - Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device model #	ve lice st ve lice st if # Exp. date if # Exp. date if # Exp. date if # if #	
active lice stopped or dose reduced active lice doesn't apply Lot # Exp. date Event reappeared after reintroduction NDC # - Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device Manufacturer name and address Operator of device Istributor Expiration date model # catalog # serial # lot # lot # other # Device available for evaluation? yes no returned to manufacturer yes no returned to manufacturer /	ve lice st ve lice st if # Exp. date if # Exp. date if # Exp. date if # if #	
active lice stopped or dose reduced doesn't apply Lot # Exp. date Event reappeared after reintroduction NDC # Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device I health professional I user facility I distributor Expiration date If implanted, give date If explanted, give date If explanted, give date Device available for evaluation? I yes I 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	ve lice st ve lice st if # Exp. date if # Exp. date if # Exp. date if # if #	Event abated after use
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 Is health professional user facility distributor Expiration date model #	## Exp. date PC # - ncomitant medical products Suspect medical device and name pe of device unufacturer name and address del # alog # ial # er # returned to marine incomitant medical products Reporter me and address Reporter me and address phase Phase Products Phase P	stopped or dose reduced
Lot # Exp. date Event reappeared after reintroduction NDC # - doesn't apply Concomitant medical products D. Suspect medical device Brand name Type of device - - Manufacturer name and address Operator of device - Manufacturer name and address Operator of device - model # - - - catalog # - - - lot # - - - - pevice available for evaluation? - - -	# Exp. date E PC # - - Incomitant medical products - - Suspect medical device - - and name - - - pe of device - - - and name - - - - del #	doesn't apply
NDC # NDC # Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Manufacturer name and address Operator of device health professional user facility distributor Expiration date if implanted, give date other # Iot # other # Device available for evaluation? wes wes in o returned to manufacturer in the medical products E. Reporter Name and address phone # (781)449-6487 The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461	C # - ncomitant medical products Suspect medical device and name pe of device anufacturer name and address del # alog # alog # er # er # returned to main ncomitant medical products Reporter me and address Physical Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation	
NDC # . NDC # . Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Manufacturer name and address Operator of device Image: facility Image: facility <tr< td=""><td>AC # - ncomitant medical products Suspect medical device and name pe of device anufacturer name and address del # alog # alog # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address Reporter me and address pho e National Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation</td><td></td></tr<>	AC # - ncomitant medical products Suspect medical device and name pe of device anufacturer name and address del # alog # alog # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address Reporter me and address pho e National Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation	
NDC #	C# - ncomitant medical products Suspect medical device and name pe of device mufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes □ no □ returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation	
D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device health professional luser facility distributor model # catalog # istributor Expiration date if implanted, give date other # lot # other # Device available for evaluation? yes 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	Suspect medical device and name pe of device mufacturer name and address del # alog # ial # er # er # vice available for evaluation? yes □ no □ returned to man ncomitant medical products Reporter me and address pho e National Pediculosis Associa b. Box 610189, Newton, MA. 02 alth professional Occupation	doesn't apply
D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device health professional luser facility distributor model # catalog # serial # lot # lot # other # Device available for evaluation? yes 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	Suspect medical device and name pe of device mufacturer name and address del # alog # ial # er # er # vice available for evaluation? yes □ no □ returned to man ncomitant medical products Reporter me and address pho e National Pediculosis Associa b. Box 610189, Newton, MA. 02 alth professional Occupation	
Brand name Type of device Manufacturer name and address Operator of device health professional user facility distributor catalog # catalog # lot # <t< th=""><th>and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation</th><th></th></t<>	and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation	
Brand name Type of device Manufacturer name and address Operator of device health professional user facility distributor catalog # catalog # lot # <t< th=""><th>and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation</th><th></th></t<>	and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation	
Brand name Type of device Manufacturer name and address Operator of device health professional user facility distributor catalog # catalog # lot # <t< th=""><th>and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation</th><th></th></t<>	and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation	
Brand name Type of device Manufacturer name and address Operator of device health professional user facility distributor catalog # catalog # lot # <t< td=""><td>and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation</td><td></td></t<>	and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation	
Brand name Type of device Manufacturer name and address Operator of device health professional user facility distributor catalog # catalog # lot # <t< td=""><td>and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation</td><td></td></t<>	and name pe of device nufacturer name and address del # alog # alog # ial # er # er # vice available for evaluation? yes no returned to man ncomitant medical products Reporter me and address phe e National Pediculosis Association? D. Box 610189, Newton, MA. 02 alth professional Occupation	
Type of device Manufacturer name and address Operator of device health professional user facility user facility distributor model # Expiration date catalog # If implanted, give date serial # If explanted, give date other # If explanted, give date other # If explanted, give date Device available for evaluation? / yes no returned to manufacturer/_/ Concomitant medical products E. Reporter	pe of device nufacturer name and address del # alog # alog # ial # ger # vice available for evaluation? lyes no ncomitant medical products Reporter me and address pho e National Pediculosis Associa 0. Box 610189, Newton, MA. 02 alth professional Occupation	
Manufacturer name and address Operator of device Image:	del #	
health professional user facility distributor Expiration date fi implanted, give data serial # lot #	del #	1
user facility distributor model #	del #	Operator of device
user facility distributor model #	del #	health professional
Image: Construction of the second	del #	
model # Expiration date catalog # If implanted, give data serial # If explanted, give data lot # If explanted, give data other # If explanted, give data other # If explanted, give data Device available for evaluation? yes no returned to manufacturer Ves no returned to second yes no returned to manufacturer Ves no returned to second phone # (781)449-6487 The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461	del #	
model #	del #	
catalog # If implanted, give data serial # If explanted, give data lot # If explanted, give data other # If explanted, give data other # If explanted, give data Device available for evaluation? yes no returned to manufacturer Ves no returned to manufacturer 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	alog #	Expiration date
serial # If explanted, give data other # If explanted, give data other # If explanted, give data Device available for evaluation? Uyes Ono Oreturned 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	ial # ial # er # vice available for evaluation? Jyes □no □returned to man ncomitant medical products Reporter me and address pho e National Pediculosis Associa b. Box 610189, Newton, MA. 02 alth professional Occupation	If implanted give date
lot #	#	ii inipianteu, give uate
other # If explainted, give data Device available for evaluation?	er #	
Device available for evaluation? yes 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	vice available for evaluation? ves no returned to main ncomitant medical products Reporter me and address pho- e National Pediculosis Associa b. Box 610189, Newton, MA. 02 alth professional Occupation	If explanted, give date
yes 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	yes no returned to main medical products ncomitant medical products Reporter me and address photometric e National Pediculosis Association D. Box 610189, Newton, MA. 02 alth professional Occupation	
Concomitant medical products E. Reporter Name and address phone # (781)449-6487 The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461	ncomitant medical products Reporter me and address pho- e National Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation	
E. ReporterName and addressphone # (781)449-6487The National Pediculosis AssociationP.O. Box 610189, Newton, MA. 02461	Reporter me and address photes e National Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation	anufacturer/_/
Name and addressphone # (781)449-6487The National Pediculosis AssociationP.O. Box 610189, Newton, MA. 02461	me and address pho e National Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation	
Name and addressphone # (781)449-6487The National Pediculosis AssociationP.O. Box 610189, Newton, MA. 02461	me and address pho e National Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation	
The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461	e National Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation	
The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461	e National Pediculosis Associa D. Box 610189, Newton, MA. 02 alth professional Occupation	none # (781)449-6487
	alth professional Occupation	
	alth professional Occupation	
Health professional Occupation Also reported to		
If you do NOT want your identity	ou do NOT want your identity	
	closed to the manufacturer, place a	

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
641	21/05/91	female	70 lbs	s
B. Adverse event	t or product p	roblem		
Advers	e Event & Prod	luct Proble	em	
Outcomes attribut	ted to adverse o	event		
\Box_{death}	disability			
✓ life-threatening	$\Box_{\text{congenital}}$	anomaly		
hospitalization	\Box required in	ntervention		
other:				
Date of event 10/0	01/1993 Dat	e of report	7/28/2001	1
Describe event or	problem			
after treat.for scabi			-	
shutdownShe ws in	hosp.for a wee	k, put on P	rednisone for	
a year				
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condition	1

C. Suspec		ion(s)			
Name: line	dane				
Dose, frequ	iency, rout	te use	Ther	apy d	ates
at least 4 tre	aments one	e week	06/92	2	
apart					to 09/92
Diagnosis f	or use		F	vent	abated after use
-	of use				d or dose reduced
scabies					
				doesn'	t apply
Lot #	Exp.	date	E	lvent i	reappeared after
			r	eintro	oduction
				doesn'	t apply
NDC #	-	-			
Concomita	nt medical	produc	ets		
D. Suspec	t medical	device	•		
Brand nam	e				
Type of dev				1	
Manufactu	rer name a	and add	lress	Ē	ator of device
					ealth professional
					ser facility
					istributor
				Expir	ration date
model #				Te	
catalog #				If im	planted, give date
serial # lot #				7.0	
other #				If exp	planted, give date
Device avai	$\begin{bmatrix} able for e \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ $			nufaat	uror / /
Concomita				nuraci	ulei _/_/
Conconnta	meurear	Product			
E. Reporte	r				
Name and a	address		ph	one #	(781)449-6487
The Natior	al Pedicu	losis A	ssoci	ation	
P.O. Box 6	10189, Nev	vton, M	IA. 02	2461	
Health pro	fessional	Occup	oation	1	Also reported to
V _{yes}	no				manufacturer
If you do NC)T want voi	ur idanti			user facility
	<i>i</i>	in identi	ty		

	ation				
Patient Identifier	Date of bir	th S	Sex	Weight	t
640	7-11-76		male	170	lbs
8. Adverse event	or produc	et pro	oblem		
	Product F				
utcomes attribut			vent		
death	∐ disabil	•			
\Box life-threatening			nomaly		
hospitalization	- require	ed int	erventior	1	
other:					10001
escribe event or		Date	of report	t 7/27	/2001
Relevant tests/labo	ratory data	a			

head lice stop doe Lot # Exp. date Ever rein	
three times in one week 7-15-200 Diagnosis for use bead lice doe Lot # Exp. date Even NDC # - doe Concomitant medical products D. Suspect medical device Brand name Type of device	01 to 7-22-2001 nt abated after use oped or dose reduced esn't apply nt reappeared after itroduction
three times in one week 7-15-200 Diagnosis for use fead lice doe Lot # Exp. date rein NDC # - doe Concomitant medical products D. Suspect medical device Brand name Type of device	01 to 7-22-2001 nt abated after use oped or dose reduced esn't apply nt reappeared after itroduction
Diagnosis for use head lice doe Lot # Exp. date Ever rein NDC # doe Concomitant medical products D. Suspect medical device Brand name Type of device	to 7-22-2001 nt abated after use oped or dose reduced esn't apply nt reappeared after itroduction
head lice stop doe Lot # Exp. date Ever rein NDC # doe Concomitant medical products D. Suspect medical device Brand name Type of device	7-22-2001 nt abated after use oped or dose reduced esn't apply nt reappeared after itroduction
head lice stop doe Lot # Exp. date Ever rein NDC # doe Concomitant medical products D. Suspect medical device Brand name Type of device	oped or dose reduced esn't apply nt reappeared after atroduction
Lot # Exp. date Ever NDC # - doe Concomitant medical products doe D. Suspect medical device Brand name Type of device	esn't apply nt reappeared after troduction
Lot # Exp. date Every rein doe NDC # doe Concomitant medical products D. Suspect medical device Brand name Type of device	nt reappeared after troduction
NDC # doe Concomitant medical products D. Suspect medical device Brand name Type of device	troduction
NDC # - doe Concomitant medical products D. Suspect medical device Brand name Type of device	
NDC # Concomitant medical products D. Suspect medical device Brand name Type of device	esn't apply
NDC # Concomitant medical products D. Suspect medical device Brand name Type of device	
D. Suspect medical device Brand name Type of device	
Brand name Type of device	
Brand name Type of device	
Brand name Type of device	
Brand name Type of device	
Brand name Type of device	
Brand name Type of device	
Brand name Type of device	
Type of device	
Type of device	
Manufacturer name and address 10a	
	perator of device
L	health professional
	user facility
	distributor
F	
	piration date
model #	implanted, give date
	implanteu, give uate
serial #	
	explanted, give date
other #	
Device available for evaluation?	
Uyes Ino Ireturned to manuf	acturer _/_/
Concomitant medical products	
E. Reporter	
Name and address phone	e # (781)449-6487
The National Pediculosis Association	on
P.O. Box 610189, Newton, MA. 0246	
	51
Health professional Occupation	
	Also reported to
✓ _{yes} □ _{no}	Also reported to manufacturer
	Also reported to

	ation			
Patient Identifier	Date of birth	Sex	Weight	
636	05/09/1990	female	85	lbs
3. Adverse even	t or product p	roblem		
	Product Prob	olem		
Outcomes attribu	ted to adverse	event		
∐ death	disability			
□ life-threatening		anomaly		
hospitalization	required in	ntervention		
other:				
Date of event 07/	10/2001 Dat	e of report	7/25/2	001
Relevant tests/labo	oratory data			

C. Suspect med	lication(s)					
Name: Kwell						
A-200, r	id , lice awa	ylice of	combs,	etc, every thing		
Dose, frequency,	, route use	Ther	herapy dates			
every 4-6 wks		09/19	996	4-		
				to 07/2001		
Diagnosis for us	e		Event abated after use			
head lice		s	toppe	d or dose reduced		
			doesn'	t apply		
Lot #	Exp. date					
	Exp. uate			reappeared after duction		
n/a		ľ	reintro	auction		
NDC # -	-	\neg	yes			
Concomitant me	dical produ	cts				
all of the above						
D. Suspect med	lical device	;				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
				ealth professional		
				ser facility		
			\square_d	istributor		
			Expir	ration date		
model #						
catalog #			If im	planted, give date		
serial #						
lot # other #			lf exp	planted, give date		
	<u> </u>					
	Device available for evaluation?					
			illulaci	uiei//		
Concomitant medical products						
E. Reporter						
	Name and address phone # (781)449-6487					
The National Pe						
P.O. Box 610189						
Health professio		patio	n	Also reported to		
\mathbf{V}_{yes} \square_{no}				manufacturer		
If you do NOT was	•	•		user facility distributor		
disclosed to the ma	nutacturer, p	lace a	ın 🔲	-uisuibutor		

A. Patient Information							
Patient Identifier	Date of b	irth	Sex	Weight			
631	09/07/94		female	70	lbs		
B. Adverse event	or produ	ict pr	oblem				
Adverse Event & Product Problem							
Outcomes attribut	Outcomes attributed to adverse event						
Death	\Box_{death} $\Box_{\text{disability}}$						
□ life-threatening □ congenital anomaly							
\square hospitalization \square required intervention							
other: severe itching							
Date of event 07/9/01			e of report	7/21/2	2001		

Describe event or problem

Dr. prescribed lindane for reinfestation. Both daughter and mother (who used gloves while applying) had severe itching and lice were not dead. Reported to dr. who wanted both of us to use lindane again. Still itching 2 weeks later.

Relevant tests/laboratory data

Other relevant history, including preexisting condition Mother has had allergies all her life. Daughter is allergic to pencillin, but usually okay with most products.

C. Suspec	t medicatio	on(s)			
Name: line	dane				
Niz	x (twice)				
Dose, frequ	ency, rout	e use	The	rapy d	ates
4 minute sha	ampoo with		07/0	09/01	
lindane - use	ed once				to 07/09/01
Diagnosis f	or use			Event	abated after use
Head lice re	infestation			stoppe	d or dose reduced
				no	
Lot #	Exp.	date		Event	reappeared after
	1.				duction
NDC #	-	-		doesn	t apply
Concomita	nt medical	produ	cts		
Nix 05/25/0	1 and 06/01/	01			
D. Suspec	t medical o	device	9		
Brand nam					
Type of dev				1.	
Manufactu	rer name a	nd add	iress	_	ator of device
					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 avai					
				anufact	urer _/_/
Concomita	nt medical	produ	cts		
E. Reporte	r				
Name and a	address		р	hone #	(781)449-6487
The Nation	al Pedicul	osis A	sso	ciation	
P.O. Box 6	10189, New	rton, N	1A. (02461	
Health pro	fessional	Occuj	patic	n	Also reported to
⊻yes	\square_{no}				manufacturer
If you do NO					User facility
disclosed to	the manufact	turer, p	lace	an 🔲	□distributor

A. Patient Inform	ation				
Patient Identifier	Date of birth	Sex	Weight		
628	12/20/93	female	75 lbs		
B. Adverse event	or product p	roblem			
Adverse Event					
Outcomes attribut	ed to adverse o	event			
⊔ death	∐ disability				
✓ life-threatening					
hospitalization	required ir	ntervention			
other:					
Date of event 11/1	5/98 Date	e of report	7/19/2001		
Describe event or p I treated our 4 year of Less than one week later she turned jaundice. Liver Biopsy showo	old daughter for later she was vo . Her liver was ed Stage 4 Infla	omiting abo not working	out a week		
Relevant tests/labo					
Other relevant his		g preexisti	ng condition		
Very healthy until t We are still treating					

C. Suspect med	ication(s)	
Name: Nix		
Dose, frequency,	route use	Therapy dates
Used once. 10 minutes. 11/		11/15/98
		to 11/15/98
Diagnosis for use	<u>,</u>	Event abated after use
Head lice		stopped or dose reduced
ricadi nec		
Lot #		doesn't apply
Lot #	Exp. date	Event reappeared after
		reintroduction
NDC # -		doesn't apply
Concomitant med	lical produ	ots
Concomitant met	iicai produ	cis
D. Suspect med	ical device	2
Brand name Type of device		
	me and add	dress Operator of device
	ine unu uu	health professional
		\square user facility
		Expiration date
model #		
model # catalog #		If implanted, give date
serial #		
lot #		If explanted, give date
other #		
Device available	for evaluat	ion?
$\square_{\text{yes}} \square_{\text{no}}$	returned	to manufacturer//
Concomitant med	lical produ	cts
E. Reporter		
-	s	phone # (781)449-6487
Name and addres		phone # (781)449-6487
Name and address The National Peo	diculosis A	ssociation
Name and addres The National Peo P.O. Box 610189,	diculosis A , Newton, N	Association IA. 02461
Name and addres The National Peo P.O. Box 610189, Health profession	diculosis A , Newton, M nal Occuj	Also reported to
Name and address The National Peo	diculosis A , Newton, N nal Occuj	Also reported to

A. Patient Inform	ation			
atient Identifier	Date of birth	Sex	Weight	
627	12-27-96	female	46	lbs
Adverse event	t or product p	oroblem		
	Product Pro	blem		
itcomes attribut	ted to adverse	event		
death	∐ disability			
life-threatening		-		
hospitalization	required i	ntervention		
other:				
te of event 20/0		e of report	7/19/2	2001
scribe event or	problem			
evant tests/labo	oratory data			
her relevant his	tory includir	a proovist	ng condi	tion
	story, meruum	ig pi cexisti	ing conu	tion

C. Suspect medication(s)					
Name: generic li	ce shampoo				
Dose, frequency,	route use	The	rapy d	ates	
1 BODLE		2000			
120222				to 2001	
	-	<u> </u>	F 4	abated after use	
Diagnosis for us	e			d or dose reduced	
RF			stoppe	u of uose feutceu	
			no		
Lot #	Exp. date]	Event	reappeared after	
D		1	reintro	oduction	
			VAS		
NDC # -	-		yes		
Concomitant me	dical produ	cts			
ALL					
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	
			□ □ 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			c ,		
Concomitant me	=letuineu		anuraci	urer _/_/	
conconntant incurcar products					
E. Reporter					
Name and addre	SS	pł	10ne #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189, Newton, MA. 02461					
Health profession	nal Occuj	patio	n	Also reported to	
\mathbf{V}_{yes} \square_{nc})			manufacturer	
If you do NOT wa	nt your ident	ity		user facility	
disclosed to the ma	nufacturer, p	lace	an 🔳	□distributor	

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weigh	nt
622	6/30/92		female	85	lbs
B. Adverse event					
Advers	e Event &	Prod	luct Prob	lem	
Outcomes attribut			event		
☐ death	∐ disat	•	_		
\Box life-threatening			anomaly		
hospitalization other: hives	- requi	ired in	ntervention	1	
	1/01	D (0		2/2001
Date of event 7/13 Describe event or		Date	e of repor	t 7/1	3/2001
Relevant tests/labo	sratory da	ita			
Other relevant his			2 preexist	ting con	dition
N/A			-	_	

C. Suspect medication(s)					
Name: Rid					
Dose, frequency,	route us	e Th	erapy d	ates	
approx 1 oz of sha	umpoo foi	r 7/1	13/01		
10 minutes			to 7/13/01		
Diagnosis for use			Fvont	abated after use	
_	-			d or dose reduced	
Lice treatment					
			doesn	't apply	
Lot #	Exp. date	•		reappeared after	
			reintro	oduction	
			doesn	't apply	
NDC # -	-				
Concomitant mee	tical pro	ducts			
N/A					
D. Suspect med	ical dev	ice			
Brand name					
Type of device			-		
Manufacturer na	me and a	addres		ator of device	
				ealth professional	
				ser facility istributor	
			Expi	ration date	
model #			- If im	planted, give date	
catalog #			-	planteu, give uate	
serial # lot #			- If our	alantad size data	
other #				planted, give date	
Device available	for avalu	otion	- ,		
				turer / /	
Concomitant me			lunurue		
	r				
E. Reporter					
Name and addres		Ē		(781)449-6487	
The National Pe					
P.O. Box 610189	, Newton	, MA.	02461		
Health profession	nal Oc	cupati	on	Also reported to	
\mathbf{V}_{yes} \square_{no}				manufacturer	
If you do NOT war	nt your ide	entity	_	user facility	
disclosed to the ma	nufacture	r, place	an 🔲	□distributor	

	ation					
Patient Identifier	Date of birt	h Sex		Weight		
619	02-18-82	fema	ıle	175	lbs	
B. Adverse event or product problem						
Adverse Event						
Outcomes attributed to adverse event						
\Box death \Box disability						
$\Box_{\text{hospitalization}} \Box_{\text{congenital anomaly}}$						
other: dizziness	_	1 milei ve	nuon			
Date of event 05-2		ate of re	nort	7/10/	2001	
Describe event or			port	//10/	2001	
Relevant tests/labo	ratory data					

C. Suspect medication(s)					
Name: lindane					
Dose, frequency,	, route use	Ther	apy d	ates	
Applied from nec	k down for	05-20	0	4 -	
one night.				to 05-21	
Diagnosis for us	e	I	Event	abated after use	
Scabies		s	toppe	d or dose reduced	
Seubles			no		
Lot #	Even data				
L01 #	Exp. date			reappeared after oduction	
		r	reintro	auction	
NDC # -	-		doesn'	t apply	
Concomitant me	dical produ	cts			
	uicui prouu	eus			
D. Suspect med	lical device	e			
Brand name					
Type of device					
Manufacturer na	me 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 #			7.0		
other #			If exp	planted, give date	
Device available	C				
			nufact	urer / /	
Concomitant me			maraet		
	1				
E. Reporter					
Name and addre				(781)449-6487	
The National Pe					
P.O. Box 610189	, Newton, N	1A. 0	2461		
Health professio	nal Occu	patio	n	Also reported to	
⊻ _{yes} ⊔ _{nc})				
If you do NOT was	•	•		User facility	
disclosed to the ma	unufacturer, p	lace a	ın 🔲	distributor	

A. Patient Inform	ation				
Patient Identifier	Date of bir	th	Sex	Weight	ţ
616	3-16-1995		female	49	lbs
B. Adverse event	or produc	ct pi	oblem		
	Product P	rob	lem		
Outcomes attribut			event		
death	∐ disabil	-			
			anomaly		
hospitalization		ed in	tervention		
other:					
Date of event 6-2: Describe event or		Date	e of report	7/4	/2001
Each time reinvesta but the generic we g Relevant tests/lab o	got was Lind	ane.		cribed K	well
Other relevant his	story, inclu	dinş	g preexisti	ng cond	lition

C. Suspect med	lication(s)			
Name: Nix				
also Lind	ane			
Dose, frequency,	route use	Ther	apy d	ates
Nix (2nd dose sev	en days	6-25-	2001	
after inital dose.				to 7-3-2001
Diagnosis for us	e	F	Event	abated after use
Treatment of lice.		s	toppe	d or dose reduced
			no	
Lot #	Exp. date			1 - 64
	Exp. uut			reappeared after oduction
		1	cinti	Juiction
NDC # -	-		yes	
Concomitant me	dical produ	cts		
D. Suspect med	lical device	•		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Ē	
				ealth professional
				ser facility
			□d	istributor
			Expii	ration date
model #			T£ :	ulantad sina data
catalog #				planted, give date
serial # lot #			Ifor	planted, give date
other #			n exp	nameu, give uale
Device available		ion?		
$\square_{\text{yes}} \square_{\text{no}}$			nufact	urer//
Concomitant me				
E. Reporter				
Name and addres	55	nh	one #	(781)449-6487
The National Pe				(,.) 0107
P.O. Box 610189	, Newton, N	1A. 02	2461	
Health profession				Also reported to
\mathbf{V}_{yes} \square_{no}				manufacturer
If you do NOT war	nt your identi	ity		user facility
disclosed to the ma	•	•	n 🔲	distributor

A. Patient Inform	ation				
Patient Identifier	Date of bi	irth	Sex	Weight	
610	5/1967		female	236	lbs
B. Adverse event	or produ	ict pr	oblem		
	Product	Prob	lem		
Outcomes attribut	ed to adve	erse e	event		
death	∐disab	ility			
□ life-threatening		enital	anomaly		
hospitalization	□requi	red in	tervention		
other:					
Date of event 6/20	001	Date	of report	6/27/2	001
Describe event or	-				
been fighting head l					ıds
of rid,lice free,lindar			-		
pyrethin, &vaseline				vithin hou	rs
of washing them ou	i, i m geum	ig biu	en agam.		
Relevant tests/labo	oratory da	ta			
	·				
Other relevant his	story, inclu	uding	g preexisti	ng condit	ion

Triage Unit Sequence #

C. Suspect medication(s)

Name:			
Acticin-	5%		
Dose, frequency	, route use	The	rapy dates
leave on 8hrs w/ s	leave on 8hrs w/ shower cap 6/01		/2001 to
each night for 3 da	ays.		6/30/2001
Diagnosis for us	e		Event abated after use
persistent head lic	e	:	stopped or dose reduced
			no
Lot #	Exp. date		Event reappeared after
			reintroduction
			doesn't apply
NDC $\#$ -	-		11.5
Concomitant me	-		
walmart & kmart	-		
			lane. treatments used lped, but within hours of
D. Suspect med			iped, but within hours of
Brand name		5	
Type of device			
Manufacturer na	me and add	Irocc	Operator of device
	une une uot	11 000	health professional
			user facility
			Expiration date
model #			Expiration date
catalog #			- If implanted, give date
serial #			-
lot #			If explanted, give date
other #			
Device available			
			anufacturer _/_/
Concomitant me	dical produ	cts	
E. Reporter			
Name and addre	SS	pl	hone # (781)449-6487
The National Pe	diculosis A	ssoc	ciation
P.O. Box 610189	, Newton, M	1A. (02461
Health professio		patio	Also reported to manufacturer
If you do NOT wa	nt your ident	ity	user facility

disclosed to the manufacturer, place an

distributor

A. Patient Inform	ation					
Patient Identifier	Date of birth	Sex	Weight			
609	6/4/73	female	100	lbs		
B. Adverse event	or product p	roblem				
	e Event & Pro		em			
Outcomes attribut		event				
☐ death ☐ disability						
\Box life-threatening \Box congenital anomaly						
hospitalization		ntervention				
other: see below	V					
Date of event 7/15	5/00 Dat	e of report	6/26/2	2001		
Describe event or						
continually re-occur			-			
ccassional random	memory loss, f	atigue, depi	ression.			
Relevant tests/labo	oratory data					
Other relevant his	tory including	a prosvicti	ng oond:	tion		
Guler relevant fils	, menudin	g pi eexisti	ng condi	1011		

C. Suspect medication(s)				
Name: lindane				
Dose, frequency	, route use	The	rapy d	ates
		7/00		
per week for 3 mo		,, 00		to 10/15/00
-			F	abated after use
Diagnosis for us	e			d or dose reduced
scabies				
			doesn	t apply
Lot #	Exp. date			reappeared after
]	reintro	oduction
			doesn'	t apply
NDC # -	-			
Concomitant me	dical produ	cts		
D. Suspect med	lical device	•		
Brand name				
Type of device			-	
Manufacturer na	ame 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 # other #			If exp	planted, give date
Device available			c .	, ,
□ _{yes} □ _{no} Concomitant me			anuraci	urer//
Concomitant me	uicai produ	cis		
E. Reporter				
Name and addre	SS	pl	hone #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	1A. (02461	
Health professio		patio	n	Also reported to
⊻ _{yes} □ _{nc}				□ manufacturer □ user facility
If you do NOT was disclosed to the me	•	•		
disclosed to the ma	inutacturer, p	lace a	an 🔲	-uisuibutoi

A. Patient Inform	ation				
Patient Identifier	Date of bi	rth	Sex	Weight	
607	6-11-78		female	152	lbs
3. Adverse event	or produ	ct pr	oblem		
	Product	Prob	lem		
Outcomes attribut			vent		
□ death	∐ disabi	•			
□ life-threatening			anomaly		
hospitalization	- requir	red in	tervention		
other:	T		-		
Date of event 06/2		Date	of report	6/26	/2001
eleanings. This has has has has has has has has has ha					
Other relevant his			; preexist	ng cond	lition

Name: lindane			
·······			
Dose, frequency, route use	The	rapy d	ates
1% once	6-5-(01	to
			06/26/01
Diagnosis for use		Event	abated after use
none	5	stoppe	d or dose reduced
		no	
Lot # Exp. date		-	1 64
			reappeared after duction
	ľ	emtr(
NDC #		doesn	t apply
Concomitant medical produ	cts		
generic shampoo, RID, NIX, L		iel nlu	s nit combing
generie shampoo, Rib, 1012, 1		Jei più	, int comong
D. Suspect medical device			
	•		
Brand name			
Type of device			
Manufacturer name and add	iress	Oper	
			ator of device
		h	ealth professional
			ealth professional ser facility
		□ _h □ _u □ _d	ealth professional ser facility istributor
		□ _h □ _u □ _d	ealth professional ser facility
model #			ealth professional ser facility istributor ration date
catalog #			ealth professional ser facility istributor ration date
catalog # serial #		□h □u □d Expin	ealth professional ser facility istributor ration date planted, give date
model # catalog # serial # lot #		□h □u □d Expin	ealth professional ser facility istributor
catalog # serial # lot # other #		□h □u □d Expin	ealth professional ser facility istributor ration date planted, give date
catalog # serial # lot # other # Device available for evaluat		□h □u □d Expin If im	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for evaluat yesnoreturned	to ma	□h □u □d Expin If im	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for evaluat yesnoreturned	to ma	□h □u □d Expin If im	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for evaluat	to ma	□h □u □d Expin If im	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for evaluat Uyes Oncomitant medical produ	to ma	□h □u □d Expin If im	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for evaluat	to ma cts	Expin If im	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available for evaluat $\Box_{yes} \Box_{no} \Box_{returned}$ Concomitant medical produ E. Reporter Name and address	to ma cts pl	If im	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # other # Device available for evaluat: yesnoreturned Concomitant medical produ E. Reporter Name and address The National Pediculosis A	to ma cts pl	If im anufact	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog #	to ma cts pl assoc IA. 0	If im anufact	ealth professional ser facility istributor ration date planted, give date planted, give date urer _/_/
catalog #	to ma cts pl assoc IA. 0	If im anufact	ealth professional ser facility istributor ration date planted, give date planted, give date urrer _ /_ / (781)449-6487
catalog #	to ma cts pl assoc 1A. 0 patio	If im anufact	ealth professional ser facility istributor ration date planted, give date planted, give date urer _/_/

Patient Inform tient Identifier		Sou	Waiaka	
605	6-11-95	Sex male	Weight 40	lbs
Adverse even				100
	Product Prob			
comes attribu	ted to adverse e	event		
death	□disability			
life-threatening	$\Box_{\text{congenital}}$	anomaly		
hospitalization	\Box required in	itervention		
other:				
te of event 5-3	1-01 Date	e of report	6/24/2	2001
elevant tests/labo	oratory data			
ther relevant his		g preexisti	ng condit	tion

C. Suspect med	lication(s)				
Name: lindane					
1%					
Dose, frequency,	, route use	Thera	apy d	ates	
apply at bedtime	repeat in 7	5-31-(01	to.	
days				to 6-07-01	
Diagnosis for us	e	E	vent	abated after use	
scabies		st	oppe	d or dose reduced	
		r	10		
Lot #	Exp. date			1 - 64	
	Lap. auto			reappeared after oduction	
		1	emure	Juuction	
NDC # -	-	У	/es		
Concomitant me	dical produ	cts			
	-				
D. Suspect med	lical device	9			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			□h	ealth professional	
			Uu	ser facility	
			\Box_d	istributor	
			Expi	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
Device available uessian			nufaci	turer / /	
Concomitant me			luiue		
····· · · · · · · · · · · · · · · · ·					
E. Reporter	E. Reporter				
Name and addre	SS	pho	one #	(781)449-6487	
The National Pe	diculosis A	ssoci	ation		
P.O. Box 610189, Newton, MA. 02461					
Health professio \mathbf{V}_{yes} \mathbf{D}_{nc}		pation		Also reported to manufacturer	
-				\square user facility	
If you do NOT was disclosed to the ma	•	•	, 🔳		
disclosed to the ma	muracturer, p	nace at	1 📖		

A. Patient Inform	ation				
Patient Identifier	Date of b	irth S	ex	Weigh	ıt
602	5/17/94	fe	emale	60	lbs
B. Adverse even	t or prod	uct prol	olem		
Adverse Event & Product Problem					
Outcomes attribu	ted to adv	erse eve	ent		
∐ death		oility			
□ life-threatening		enital an	-		
hospitalization	□requ	ired inter	rvention	l	
other:					
Date of event 6/9	/01	Date of	f report	t 6/2	1/2001
Describe event or					
48 hours after nix t					
laugther ran a temp	perature the	e next m	orning a	fter use	, may
not be related.					
Relevant tests/lab	oratory da	nta			
Other relevant hi	story, incl	uding n	reexist	ing con	dition
	,				

C. Suspect med	ication(s)			
Name: Nix				
Dose, frequency,	route use	Ther	apy d	ates
one application		6/9/0	1	4
				to 6/9/01
Diagnosis for use	!	F	Event	abated after use
head lice		s	toppe	d or dose reduced
			doesn'	t apply
Lot #	Exp. date			
				reappeared after duction
NDC # -	-		doesn	t apply
Concomitant med	lical produ	cts		
D. Suspect med	ical device	è		
Brand name				
Type of device				- 4
Manufacturer na	me and add	iress	Ē	ator of device
				ealth professional
				ser facility istributor
			Expi	ation date
model # catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device available f				
	returned		nufact	urer _/_/
Concomitant med	lical produ	cts		
E. Reporter				
Name and addres	s	ph	one #	(781)449-6487
The National Pec	liculosis A	ssoci	ation	
P.O. Box 610189,	Newton, N	1A. 02	2461	
Health profession	al Occuj	oatior	1	Also reported to
\mathbf{V}_{yes} \square_{no}				manufacturer
If you do NOT wan	t your identi	ity		user facility
disclosed to the man	nufacturer, p	lace a	n	distributor

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
600	24/01/19	58	female	100	lbs
B. Adverse even	t or produ	uct p	roblem		
	Advers	se Ev	ent		
Outcomes attributed to adverse event					
∐ death	⊘ disat				
☐ life-threatening			anomaly		
hospitalization	-	ired ir	nterventi	on	
other: menstrua	ıl disorder				
Date of event 9/5/	96	Date	e of repo	ort 6/20/	/2001
fumigate my house having more and me don,t have my men regular before.	ore menstr	ual dis	sorders. S	Sometimes	I
Relevant tests/labo	oratory da	nta			
Other relevant his I have tried to find a the funigation with not the right place f help me to find an a	a link betw out any luc or my que	veen n ck. I k estion,	ny health now tha but cou	n problems t maybe thi ld you plea	and s is se

C. Suspect med	dication(s)				
Name: pesticida	ıl spray				
fumigatio	on				
Dose, frequency	, route use	The	rapy d	ates	
1 day		9/5/9			
1 duy		1012	.0	to 9/5/96	
			- /		
Diagnosis for us	e			abated after use	
termites			scoppe	d or dose reduced	
			no		
Lot #	Exp. date]	Event	reappeared after	
			reintroduction		
				41	
NDC # -	-		uoesn	t apply	
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	
				ealth professional	
			\square_{u}	ser facility	
				istributor	
			Expir	ration date	
model #			ľ		
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #			-		
Device available	_		anufact	urer / /	
Concomitant me					
	unom proud				
E. Reporter					
Name and addre	SS	pl	none #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	1A. (2461		
Health professio	-	patio	n	Also reported to	
\mathbf{V}_{yes} $\Box_{\text{normalized}}$)				
If you do NOT wa				\square user facility	
disclosed to the ma	anufacturer, p	lace	an 🔲	□distributor	

A. Patient Informa	ation				
Patient Identifier		Sex	Weight		
598	02/06/1990	female	80	lbs	
B. Adverse event	or product p	roblem			
	Product Pro	blem			
Outcomes attribut	ed to adverse	event			
death	disability				
\Box life-threatening \Box congenital anomaly					
hospitalization	required i	ntervention		_	
other:					
Date of event 05/0	1/2000 Dat	e of report	6/18/2	001	
Palavant taste/laba	rotory data				
Relevant tests/labo Other relevant his					

C. Suspect med	lication(s)				
Name: lindane					
ovide					
Dose, frequency,	, route use	The	rapy d	ates	
Q 2weeks for a pe	eriod of	0801	1999	<i>t</i> 0	
approximately 6 r	nonths.			to	05012000
Diagnosis for us	e]	Event	abate	d after use
headlice		5	stoppe	d or d	lose reduced
			doesn'	t app	y
Lot #	Exp. date	J	Event	reapp	eared after
		1	reintro	duct	ion
			doesn'	t appl	y
NDC $\#$ -	-				-
Concomitant me	-				
dessert essence tea	a tree oil sha	mpoo	b. 0501	2000	removed
lice					
D. Suspect med	lical dovice				
		;			
Brand name Type of device					
Manufacturer na	me and add	lress	Oper	ator o	of device
			Ē		professional
				ser fa	
				istrib	•
			Expir	ration	date
model #					
catalog #			If im	plant	ed, give date
serial #					
lot # other #			If exp	olante	ed, give date
Device available	for evaluati		anufact	urer	/ /
Concomitant me			anulaci	uici	//
		*			
E. Reporter					
Name and addre	SS	pł	10ne #	(781)449-6487
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	1 A. 0	2461		
Health professio \mathbf{V}_{yes} \mathbf{D}_{nc}		oatio	n		reported to
					nanufacturer ser facility
If you do NOT was disclosed to the ma		2	.n 🔳		istributor
disclosed to the ma	muracturer, p	nace a	an 🔲	u	isaioutoi

A. Patient Inform	ation				
Patient Identifier	Date of bi	rth	Sex	Weight	
593	03/05/65		female	135	lbs
B. Adverse event	or produ	ct pi	oblem		
Advers	e Event &	Prod	uct Proble	m	
Outcomes attribut	ted to adve	rse e	vent		
death	□ disabi	ility			
□ life-threatening	\Box_{conge}	nital	anomaly		
hospitalization	∠ requir	ed in	tervention		
other:					
Date of event 05/0	09/01	Date	of report	6/12/2	.001
Describe event or	problem				
Head became itchy,	found nits	, use	d RID, foll	owed up v	vith
RID seven days late		whol	e house wa	as covered	
with little black dot	S				
Relevant tests/labo	ratory dat	a			
	futory du	a			
Other relevant his					ion
Postive Rheumatoic		-			
Degenerative Disc I	Disease, Chi	ronic	Pain with	chronic El	3V
titers (1200+)					

C. Suspect medication(s)				
Name: Kwell				
Dose, frequency	, route use	The	rapy d	ates
Shampooed with I		5/10		
the Kwell lotion	xwen, ulu	5/10	/01	to
				06/13/01
Diagnosis for us	e			abated after use
Lice		2	stoppe	d or dose reduced
			no	
Lot #	Exp. date		Event	reappeared after
				oduction
		ĺ		
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
			Ē	ealth professional
				ser facility
				istributor
				ration date
model #				
catalog #			If im	planted, give date
serial #				,0
lot #			If ext	planted, give date
other #				, Brie unte
Device available	for evaluati	ion?	1	
	returned		anufact	urer _/_/
Concomitant me				
E. Reporter				
Name and address phone # (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
		itaz		\square user facility
If you do NOT was disclosed to the ma	•	•	an 🔲	
disclosed to the life	muraciurer, p	iace	an 🔲	assarbutor

A. Patient Informa	ation			
Patient Identifier	Date of birt	h Sex	Weight	
592	9-30-94	female	90	lbs
B. Adverse event	or product	problem		
	Product Pr	oblem		
Outcomes attribut	ed to advers	e event		
death	∐ disabilit	y		
☐ life-threatening		tal anomaly		
hospitalization		l intervention		
other:				
Date of event 05-2	27-01 D	ate of report	6/12/	2001
Relevant tests/labo	oratory data			
Other relevant his Recurrent UTI'S	tory, includ	ing preexisti	ing cond	ition

C. Suspect med	ication(s)			
Name: Ovide				
NIX,RID,MAYO,CLEAR,VINEGAR				
Dose, frequency,	route use	Ther	apy d	ates
EVERY 5 DAYS		05-2´	7-01	
				to 06-11-01
Diagnosis for use		I	Event	abated after use
LICE		s	toppe	d or dose reduced
5102			no	
Lot #	Exp. date			1.0
	Exp. date			reappeared after oduction
		ľ	entro	buuction
NDC # -	-		yes	
Concomitant med	lical produ	ets		
	1			
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
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #			Te	
lot # other #			lf exp	planted, give date
Device available f	Para ana 1			
$\square_{\text{yes}} \square_{\text{no}}$			nufact	urer / /
<u>Concomitant med</u>			inuraci	
E. Reporter				
Name and addres		_		(781)449-6487
The National Pec	liculosis A	ssoci	iation	
P.O. Box 610189,	Newton, N	IA. 0	2461	
Health profession	al Occup	oatio	n	Also reported to
\mathbf{V}_{yes} \square_{no}				manufacturer
If you do NOT wan	2	5		user facility
disclosed to the man	nufacturer n	lace a	n I I	□ distributor

	ation			
Patient Identifier	Date of birth	Sex	Weight	
585	4-6-95	female	48	lbs
B. Adverse event	or product p	roblem		
	Product Prob			
Outcomes attribut	_	event		
death	☐ disability			
□ life-threatening				
hospitalization	required in	itervention		
other:				
Date of event 3/01		e of report	6/10/2	2001
Relevant tests/labo	oratory data			

C. Suspect med	C. Suspect medication(s)				
Name: lindane					
10%					
Dose, frequency,	, route use	The	rapy d	ates	
Left on 5 minutes		3/01		4 -	
				to 6/01	
Diagnosis for us	e		Event	abated after use	
to kill lice			stoppe	d or dose reduced	
			doesn'	t apply	
Lot #	Exp. date				
L01 #	Exp. uate			reappeared after	
			reintro	oduction	
NDC # -	_		doesn	t apply	
Concomitant me	dical produ	cts			
conconntant inc	uicui prouu				
D. Suspect med	lical device	<u> </u>			
Brand name		, 			
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
	une une une		L Â	ealth professional	
				ser facility	
				istributor	
				ration date	
model #					
catalog #			- If im	planted, give date	
serial #			-		
lot #			If exp	planted, give date	
other #					
Device available				, ,	
	returned dical produc		anulaci	urer//	
conconnunt inc	Concomitant medical products				
E. Reporter	F Reporter				
Name and address phone # (781)449-6487					
The National Pe	diculosis A	ssoc	ciation		
P.O. Box 610189, Newton, MA. 02461					
Health professio		patio	n	Also reported to	
\mathbf{V}_{yes} \square_{no}				manufacturer	
If you do NOT was		•		User facility	
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor	

A. Patient Informat	tion			
Patient Identifier D	Date of birth	Sex	Weight	
581 (03/27/97	female	30	lbs
3. Adverse event o	or product p	roblem		
	Product Prob	lem		
Dutcomes attributed death life-threatening hospitalization other:	□ disability □ congenital			
Date of event 10/00)/ Date	e of report	6/1/20	001
products and even ba er hair and making s ack! What do I do?I follow no one else in the ho	w the direction	e nits and a	-	• its
Relevant tests/labor	atory data			
Other relevant histo	ory, including	g preexisti	ng conditi	ion

C. Suspect medication(s)					
Name: Lice Be Gone					
Nix,Kwe	ll,Generic,Ri	d			
Dose, frequency,	, route use	Thera	apy d	ates	
every ten days or	as directed	10/00		to	
				to 05/01	
Diagnosis for us	e	E	vent	abated after use	
head lice		st	toppe	d or dose reduced	
neuu nee			loesn	t apply	
Lot#	Exp. date				
LOI #	Exp. date			reappeared after	
		r	eintro	oduction	
NDC # -		Ċ	loesn'	t apply	
Concomitant me	dical produ	rts			
Conconntant life	arear produ	~ 65			
D. Suspect med	lical device	9			
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	
			Expii	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot # other #			If exp	planted, give date	
Device available					
Concomitant me	<u>returned</u>	to mai	nuraci	urer//	
conconntant inc	uicai prouu	C15			
E. Reporter					
Name and addre	SS	pho	one #	(781)449-6487	
The National Pe	diculosis A	ssoci	ation		
P.O. Box 610189	, Newton, N	1 A. 02	2461		
Health professio	nal Occuj	oation	L	Also reported to	
\mathbf{V}_{yes} \square_{no})			manufacturer	
If you do NOT was	nt your identi	ity	_	user facility	
disclosed to the ma	unufacturer, p	lace ai	n 🔳	distributor	

A. Patient Inform	ation				
Patient Identifier	Date of bi	rth	Sex	Weight	
578	03-06-88		female	135	lbs
B. Adverse event	or produ	ct pi	oblem		
	Product	Prob	lem		
Outcomes attribut	ed to adve	erse e	event		
death	\Box_{disab}	ility			
□ life-threatening		enital	anomaly		
hospitalization	□ requi	red in	tervention		
other:					
Date of event 05-2	29-01	Date	of report	5/29	/2001
Describe event or	problem				
the lindane shampoo			-	-	
worried about the ad	lverse reac	tion i	t will have	on my c	hild
Relevant tests/labo	ratory da	ta			
	natory ua	la			
Other relevant his					
head lice is a very b	ig problem	that	we can't se	em to ge	t rid
of with this child.					

C. Suspect med	lication(s)				
Name: Kwell					
1%					
Dose, frequency,	route use	The	rapy d	ates	
1 1/2 2oz. bottle		05-2	29-01		
				to 05-29-01	
Diagnosis for use	e		Event	abated after use	
head lice			stoppe	d or dose reduced	
nead nee					
T (11)	F 14		no		
	Exp. date			reappeared after	
not known			reintro	oduction	
NDC # -			doesn	t apply	
Concomitant me	dical produ	cts			
over the counter m	-				
	leuleation				
D. Suspect med	ical device)			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			\square_{h}	ealth professional	
			□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 Uves no	for evaluati		anufaat		
Concomitant me			anuraci	uiei//	
concommunt incurcar products					
E. Reporter					
Name and addres	SS	p	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	ciation		
P.O. Box 610189	, Newton, N	1A. ()2461		
Health profession	nal Occuj	patio	n	Also reported to	
\mathbf{V}_{yes} \square_{no}				manufacturer	
If you do NOT war		2		\Box user facility	
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform	ation			
atient Identifier	Date of birt	n Sex	Weight	
576	5-12-82	female	150	lbs
3. Adverse even	t or product	problem		
	Product Pr	oblem		
Outcomes attribut	ted to advers	e event		
∐ death	∐ disabilit	•		
☐ life-threatening				
hospitalization		intervention	n	1
other: prescipti				
Date of event 5-2	5-01 D a	ate of repor	t 5/27	/2001
Describe event or				
Ay daughter has no		-	er lice. Sh	ne's
een sick/cause lice	. reeus to get	nd of them		
Relevant tests/labo	oratory data			
Other relevant his	story, includi	ing preexist	ting cond	ition
She is otherwise he	althy.			

C. Suspect medication(s)				
Name: lindane				
Dose, frequency,	route use	Ther	apy d	ates
one time		5/01-		
one unic		5/01		to 5/01
Diagnosis for us	e			abated after use
lice		s	toppe	d or dose reduced
			doesn'	t apply
Lot #	Exp. date	F	Event	reappeared after
		r	eintro	oduction
			doesn'	t apply
NDC # -	-			
Concomitant me	dical produ	cts		
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
				istributor
			Expir	ration date
model #			-	
catalog #			If im	planted, give date
serial #				
lot #			If exr	planted, give date
other #				
Device available	for evaluat	ion?	1	
$\square_{\text{yes}} \square_{\text{no}}$	Image: The second se	to ma	nufact	urer _/_/
Concomitant me	dical produ	cts		
E. Reporter				
Name and addres	SS	ph	one #	(781)449-6487
The National Pe	diculosis A	ssoci	iation	
P.O. Box 610189	, Newton, N	1A. 0	2461	
Health profession ↓ _{yes} □ _{no}		pation	1	Also reported to manufacturer
-		• .		
If you do NOT was	•	•		user facility distributor
disclosed to the ma	nufacturer, p	lace a	in 🔲	uistributor

A. Patient Inform	ation			
Patient Identifier		irth Sex	Weight	ţ
575	19/55/	male	200	lbs
B. Adverse event	t or produ	uct problem		
	Advers	se Event		
Outcomes attribut	ted to adv	erse event		
death	\Box_{disat}	oility		
□ life-threatening	$\Box_{\rm cong}$	enital anomal	у	
hospitalization	□ _{requi}	red intervent	ion	
other:				
Date of event 8/97	7	Date of rep	ort 5/27	/2001
Describe event or	problem			
Nix caused me (45-	year old m	ale) to stop b	reathing twi	ice
one night while >sleeping (very sca	ry to wake	un not breat	hing) so I h	ad to
get up and	iy to wake	up not oreat	iiiig) so i ii	au to
>shampoo, change	pillowslip	and put on m	y wife's sh	ower
cap. Then no				
problem.				
	4	4-		
Relevant tests/labo	bratory da	ita		
Other relevant his	story, incl	uding nreev	isting cond	lition
Very sensitive to fu				
for atrial fibrillation				

	dication(s)		
Name: Nix			
Dose, frequency	, route use	Therap	y dates
directions on box,	used once	8/97	
,			to 8/97
Diagnosis for us	e	Eve	nt abated after use
Found nit in hair		stop	ped or dose reduced
round int in nan			-
<i>u</i>	D	no	
Lot #	Exp. date		nt reappeared after
		rein	troduction
NDC# -	_	no	
	- diaal nuadu	ota	
Concomitant me	uicai produ	cis	
atenolol			
D. Suspect med	hical davier		
-		;	
Brand name Type of device			
	ma and add		
		iress Oi	perator of device
	anie anu au		perator of device
			health professional
	ame anu au		
			health professional user facility distributor
			health professional user facility
		[[Ех	health professional user facility distributor
model # catalog #		[[Ех	health professional user facility distributor piration date
model # catalog # serial #		Ex	health professional user facility distributor piration date
		Ex	health professional user facility distributor piration date implanted, give date
model # catalog # serial # lot # other # D <u>evice avail</u> able	for evaluat	Ex Ex If If ion?	health professional user facility distributor piration date implanted, give date explanted, give date
model # catalog # serial # lot # other # Device available □ yes □ no	for evaluat	Ex Ex If If ion? to manuf	health professional user facility distributor piration date implanted, give date explanted, give date
model # catalog # serial # lot # other # D <u>evice avail</u> able	for evaluat	Ex Ex If If ion? to manuf	health professional user facility distributor piration date implanted, give date explanted, give date
model # catalog # serial # lot # other # Device available □ yes □ no	for evaluat	Ex Ex If If ion? to manuf	health professional user facility distributor piration date implanted, give date explanted, give date
model # catalog # serial # lot # other # Device available □_yes □_no Concomitant me	for evaluat	Ex Ex If If ion? to manuf	health professional user facility distributor piration date implanted, give date explanted, give date
model # catalog # serial # lot # other # Device available yesno Concomitant me E. Reporter	for evaluat returned dical produ ss	Ex Ex If If If ion? to manuf cts	health professional user facility distributor piration date implanted, give date explanted, give date
model # catalog # serial # lot # other # Device available Device available Device available Concomitant me E. Reporter Name and addre	for evaluat returned dical produ ss ediculosis A	Ex Ex If If ion? to manuf cts	health professional user facility distributor piration date implanted, give date explanted, give date cacturer _/_/ e # (781)449-6487 on
model # catalog # serial # other # Device available Uyes 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 p, Newton, M nal Occuj	Ex Ex If If ion? to manuf cts	health professional user facility distributor piration date implanted, give date explanted, give date cacturer _/_/ e # (781)449-6487 on il Also reported to
model # catalog # serial # lot # other # Device available Device available Device available Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189	for evaluat returned dical produ ss ediculosis A p, Newton, N nal Occuj	Ex Ex Ex If If ion? to manuf cts phone ssociati 1A. 0246 pation	health professional user facility distributor piration date implanted, give date explanted, give date cacturer/_/ e # (781)449-6487 on

A. Patient Inform						
Patient Identifier		rth So	ex	Weight		
573	1/31/95		emale	45	lbs	
B. Adverse event		-				
Product Problem						
Outcomes attribut	_		nt			
\Box_{death}	disab					
☐ life-threatening	<u> </u>	enital an	-			
hospitalization			vention			
other: nothing r	now, I've us	sed linda	ine and	nix 8-10 t	ime	
Date of event 1/02	1	Date of	f report	5/21/2	2001	
Describe event or	problem					
not informed of pro	ducts letha	lness, a	nd am te	errified the	at	
my girls may be aff	ecteddo	i have	them tes	ted for an	у	
blood disorders, spl					-	
Relevant tests/labo	oratory da	ta				
	•					
Other relevant his	story, inclu	uding p	reexisti	ng condi	tion	
none						

C. Suspect med	dication(s)					
Name: Kwell						
nix						
Dose, frequency	, route use	The	rapy d	ates		
8-10 times in last	5 mos	01/0	1			
				to 5/19/01		
Diagnosis for us	e		Event	abated after use		
head lice			stoppe	d or dose reduced		
neuu nee			doesn'	t apply		
Lot #	Exp. date	_				
Lot #	Exp. date			reappeared after		
			reintro	oduction		
NDC # -	-		doesn'	t apply		
Concomitant me	dical produ	cts				
nix, nix spray	£					
iin, iin sprag						
D. Suspect med	dical device	è				
Brand name						
Type of device						
Manufacturer na	ame and add	lress	Oper	ator of device		
				ealth professional		
				ser facility		
				istributor		
			Expir	ration date		
model #						
catalog #			If im	planted, give date		
serial # lot #			TO			
other #			If exp	planted, give date		
	C					
Device available			anufact	urer / /		
Concomitant me			anuraet			
E. Reporter				(701) 440 (407		
Name and addre		Ē	hone #	(781)449-6487		
The National Pe						
P.O. Box 610189		1A. ()2461			
Health professio		patio	n	Also reported to		
\mathbf{V}_{yes} $\square_{\text{normalized}}$						
If you do NOT wa	-	-		User facility		
disclosed to the ma	anufacturer, p	lace	an 🔲	distributor		

	D (a	TT7	
Patient Identifier		Sex	Weigh	
572	07/92/	female	56	lbs
3. Adverse event				
	Product Pro			
Dutcomes attribut				
	\Box disability			
\Box life-threatening \Box hospitalization		nterventio		
other: continued	-	mervenno	Π	
Date of event 05/1 Describe event or		e of repoi	rt 5/21	/2001
C				
Relevant tests/labo	ratory data			

C. Suspect med	lication(s)				
Name: lindane					
1% lotio	n				
Dose, frequency,	, route use	The	rapy d	ates	
Apply cream from	n neck to	05/1	5/01		
toes.Remove p 8				to	05/20/01
Diagnosis for us	e		Event	abate	ed after use
Scabies			stoppe	d or (dose reduced
			doesn	't app	ly
Lot #	Exp. date		Event	reap	peared after
NDC 0472-			reintro		
0570-16					
NDC # -	-		no		
Concomitant me	dical produ	cts			
D. Suspect med	lical device	è			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator	of device
			_		professional
				ser fa	cility
			\square_d	istrib	utor
					n date
			Елри	anoi	I uate
model # catalog #			If im	plant	ed, give date
serial #				r	, 8
lot #			Ifov	lont	ed, give date
other #				Janu	cu, give uate
Device available					
	returned		anufact	urer	_/_/
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	p	hone #	(781	1)449-6487
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	IA. ()2461		
Health professio \mathbf{V}_{yes} \mathbf{D}_{no}	-	oatio	n		o reported to nanufacturer
3					iser facility
If you do NOT was					listributor
disclosed to the ma	inutacturer, p	lace	an 🔲		insurroutor

A. Patient Inform	ation		
Patient Identifier		Sex	Weight
569	10/23/53	female	130 lbs
B. Adverse event			
	Product Prob		
Outcomes attribut	ted to adverse e	event	
death	disability		
□ life-threatening	$\Box_{\text{congenital}}$	anomaly	
hospitalization	required ir	-	
other:			
Date of event 2/01	Date	e of report	5/14/2001
Describe event or		<u>-</u>	
my son got scabies		2 tx failures	w/lindane
and 3 w/			
elimite. Now I have elimite	it since Feb and	l had 3 tx fa	ailure with
emme			
Relevant tests/labo	oratory data		
Other relevant his		g preexisti	ng condition
No preexisting conc	litions		

C. Suspect med	lication(s)			
Name:				
elimite				
Dose, frequency	, route use	The	rapy d	ates
apply ,leave on 12	2 hours	9/00		to
then wash off				to 5/01
Diagnosis for us	e]	Event	abated after use
scabies		5	stoppe	d or dose reduced
seasies			doesn'	t apply
Lot #	Exp. date	_		
L01 #	Exp. uate			reappeared after oduction
		ľ	rennro	
NDC # -	-		yes	
Concomitant me	dical produ	cts		
	£			
D. Suspect med	lical device	9		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
				ealth professional
				ser facility
				istributor
			Expii	ration date
model #			If im	planted, give date
catalog # serial #				planteu, give uate
lot #			If ev	planted, give date
other #				, give unit
Device available	for evaluat	ion?	1	
	returned		anufact	urer _/_/
Concomitant me				
E. Reporter				
Name and addre	SS	pł	none #	(781)449-6487
The National Pe				,
P.O. Box 610189	, Newton, M	1 A. 0	2461	
Health professio	nal Occu	patio	n	Also reported to
\mathbf{V}_{yes} $\square_{\text{normalized}}$)			manufacturer
If you do NOT wa	nt your ident	ity	_	\Box user facility
disclosed to the ma	nufacturer, p	lace a	in 🔲	distributor

A. Patient In				a		
Patient Ident		Date of b	irth	Sex	Wei	ght
5	65			female	105	lb
B. Adverse e	event	t or produ	ict p	roblem		
Α	dvers	e Event &	Prod	luct Prob	lem	
Outcomes att	ribut			event		
death		🗹 disab	oility			
✓ life-threat	ening	$\Box_{\rm cong}$	enital	anomaly		
hospitaliz	ation	🗹 requi	red ir	terventio	1	
other: Ho	me ar	nd property	v cont	aminatior	l	
Date of event	19/9	99/2000	Date	e of repor	t.	5/8/200
			Date	e of repor	t	5/8/2002
Describe ever	nt or	problem				
Describe even Allercare Spra abelled or reg	nt or y by istere	problem SC Johnso d as pestic	n 8/9 ide. A	9- recall 1 ct.ingred.	/00.No same	ot in many
Describe even Allercare Spra abelled or reg scabies treatm	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,
Describe even Allercare Spra abelled or reg scabies treatm	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,
Describe even Allercare Spra abelled or reg scabies treatm	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,
Describe even Allercare Spra abelled or reg scabies treatm	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,
Describe even Allercare Spra abelled or reg scabies treatm	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,
Describe even Allercare Spra abelled or reg scabies treatm	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,
Describe even Allercare Spra abelled or reg scabies treatm	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,
Date of event Describe even Allercare Spra labelled or reg scabies treatm gastrointestina	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,
Describe even Allercare Spra abelled or reg scabies treatm	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,
Describe even Allercare Spra abelled or reg scabies treatm	nt or y by istere ents:	problem SC Johnso d as pestici Benzyl Be	n 8/99 ide. A enzoa	9- recall 1 ct.ingred. te, causin	/00.No same g: resp	ot in many biratory,

Other relevant history, including preexisting condition Nothing relevant to the poisoning. While SCJohnson is saying that only individuals who are highly sensitive and have pre-existing severe allergies were reacting to the product, the reality is that anyone can be poisoned. I was poisoned by the product and Triage Unit Sequence #

C. Suspect medication(s) Name: Allercare Dust Mite Spray by SC Johnson-not a m Dose, frequency, route use Therapy dates miniscule-much less than on 7-8/99 to label for usage 1/2000Diagnosis for use Event abated after use stopped or dose reduced To rid home of dust mites no Lot # Exp. date Event reappeared after No EPA reintroduction registration # yes NDC # **Concomitant medical products** not related 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

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
563	10/09/90		female	92	lbs
B. Adverse event	or produ	ict pr	oblem		
	Product	Prob	lem		
Outcomes attribut	ted to adv	erse e	vent		
death	\Box_{disat}	oility			
□ life-threatening	$\Box_{\rm cong}$	enital	anomaly		
hospitalization	L requi	ired in	tervention		
other: reoccurre	ence				
Date of event 04/2	24/01	Date	of report	5/7/2	2001
Describe event or	problem				
When I bought the r					
(pediatrician highly					vas
already something v	white betw	een th	e metal tee	eth.	
I wish I took the Li	comoistors	to the	nadiatrici	on to find	out
what the white thing		to the	e peulairiei		out
what the white thing	gs were.				
Relevant tests/labo	oratory da	ita			
Other relevant his		-	-	-	tion
I have a dandruff co	ondition.	Hemo	rroids. Gei	neralized	
Anxiety Disorder.					

C. Suspect med	ication(s)		
Name: lindane			
Dose, frequency,	route use	Therapy	dates
1% weekly		4/24/01	
- / · · · · · · · · · · · · · · · · · ·			to 5/6/01
Diagnosis for use		Event	t abated after use
headlice			ed or dose reduced
lleaunce			
		no	
Lot #	Exp. date		t reappeared after
		reint	roduction
NDC # -		yes	
	-		
Concomitant med	lical produ	cts	
D. Suspect med	ical device	9	
Brand name			
Type of device			
Manufacturer na	me and add	lress Ope	erator of device
		l Î	health professional
			user facility
			distributor
			distributor
		Exp	iration date
model #			
catalog #		If in	nplanted, give date
serial #			
lot #		If ex	xplanted, give date
other #			
D <u>ev</u> ice av <u>ail</u> able f	<u>`or</u> evaluat	ion?	
$\square_{\text{yes}} \square_{\text{no}}$	returned	to manufa	cturer//
Concomitant med	lical produ	cts	
E. Reporter			
Name and addres	G	phone	# (781)449-6487
The National Pec		-	, ,
			11
P.O. Box 610189,			
Health profession	al Occu	pation	Also reported to
⊻ _{yes} □ _{no}			manufacturer
If you do NOT wan			user facility
ii you do ito i wan	t your ident	ity	

	ation			
ient Identifier			Weight	
559	3-29-62	female	160	lbs
dverse even	Product P			
comes attribu				
death				
]life-threatening		ital anomaly	7	
hospitalization		d interventi		
other:				
te of event 3-2	3-01 Г	Date of repo	ort 4/28/	2001
scribe event or	problem			
d lice problem a	nd wont go a	way		
	. 1.			
levant tests/lab	oratory data	l		
her relevant hi	story, includ	ling preexi	sting condi	ition
	<i>,</i> ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	81		

C. Suspect med	lication(s)			
Name: lindane				
egentric	form			
Dose, frequency,	, route use	Thera	apy d	ates
2 Oz - 7 to 10 da	ys	3-23-0	01	
				to 4-23-01
Diagnosis for us	e	E	vent	abated after use
head lice		st	oppe	d or dose reduced
neud nee			10	
Lot #	Exp. date			
	Exp. date			reappeared after
na		re	eintro	oduction
NDC # -	-	У	/es	
Concomitant me	dical produ	cts		
none	£			
D. Suspect med	lical device	9		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
				ealth professional
				ser facility
				istributor
			Expii	ation date
model #			If im	planted, give date
catalog # serial #				planteu, give uate
lot #			If evi	planted, give date
other #			•	Since and Since and
Device available	for evaluati	ion?		
\square_{yes} \square_{no}	returned	to mai	nufact	urer//
Concomitant me				
E. Reporter				
Name and addre	SS	pho	one #	(781)449-6487
The National Pe	diculosis A			
P.O. Box 610189	, Newton, N	1A. 02	461	
Health professio ✓ _{yes} □ _{nc}		pation		Also reported to
		4.17		user facility
If you do NOT was disclosed to the ma		•	, 🔳	

A. Patient Inform	ation			
Patient Identifier	Date of bi	rth Sex	Weight	
556	11-09-55	female	250	lbs
B. Adverse event	or produ	ct problem	1	
	Adverse	Event		
Outcomes attribut	ted to adve	rse event		
death	□disabi	lity		
□ life-threatening		nital anomaly		
hospitalization		ed interventio	on	-
other: rash and	blisters			
Date of event 9/19	996	Date of repo	rt 4/25/2	2001
Used lice killing sha blisters on my scal doctor prescribed T my scalp twice a d Relevant tests/labo	p. My scalp 'imovate lot ay.	o was itchy a tion that I had	nd tender .	My
Other relevant his	story, inclu	ding preexis	sting condi	tion

C. Suspect med	dication(s)				
Name: Nix					
Dose, frequency	route use	The	rapy d	ates	
				ates	
I shampood my hair with this product ONCE!		9/1996 to			
-				9/1996	
Diagnosis for us	e			abated after use	
Head lice		5	stoppe	d or dose reduced	
			yes		
Lot #	Exp. date	-	Event	reappeared after	
				oduction	
NDC # -	-		doesn	t apply	
Concomitant me	dical produ	cts			
	-				
	dical device)			
D. Suspect med					
D. Suspect med Brand name					
Brand name					
Brand name Type of device	ame and add	lress	Oper	ator of device	
Brand name	ame and ado	lress	L Â	ator of device	
Brand name Type of device	ame and add	lress	h	ealth professional	
Brand name Type of device	ame and add	lress		ealth professional ser facility	
Brand name Type of device	ame and add	lress	\square_{h} \square_{u} \square_{d}	ealth professional ser facility istributor	
Brand name Type of device Manufacturer na	ame and add	lress	\square_{h} \square_{u} \square_{d}	ealth professional ser facility	
Brand name Type of device Manufacturer na model #	ame and add	lress	Expin	ealth professional ser facility istributor ration date	
Brand name Type of device Manufacturer na model # catalog #	ame and add	lress	Expin	ealth professional ser facility istributor	
Brand name Type of device Manufacturer na model #	ame and add	lress	Expin	ealth professional ser facility istributor ration date planted, give date	
Brand name Type of device Manufacturer na model # catalog # serial #	ame and add	lress	Expin	ealth professional ser facility istributor ration date	
Brand name Type of device Manufacturer na model # catalog # serial # lot # other #			Expin	ealth professional ser facility istributor ration date planted, give date	
Brand name Type of device Manufacturer na model # catalog # serial # lot # other # Device available	f <u>or</u> evaluat	 ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date	
Brand name Type of device Manufacturer na model # catalog # serial # lot # other # Device available	for evaluat	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date	
Brand name Type of device Manufacturer na model # catalog # serial # lot # other # Device available yes □_no	for evaluat	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date	
Brand name Type of device Manufacturer na model # catalog # serial # lot # other # Device available □_yes □_no Concomitant me	for evaluat	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date	
Brand name Type of device Manufacturer na model # catalog # serial # lot # other # Device available Uyes Dno Concomitant me E. Reporter	for evaluat returned dical produ	ion? cts	If impand	ealth professional ser facility istributor ration date planted, give date olanted, give date	
Brand name Type of device Manufacturer na model # catalog # serial # lot # other # Device available □_yes □_no Concomitant me	for evaluat returned dical produ ss	ion? to ma cts	hone #	ealth professional ser facility istributor ration date planted, give date planted, give date	
Brand name Type of device Manufacturer na model # catalog # serial # other # Device available Uyes Dno Concomitant me E. Reporter Name and addre	for evaluat returned dical produ ss sdiculosis A	to ma to ma cts	hone #	ealth professional ser facility istributor ration date planted, give date olanted, give date	
Brand name Type of device Manufacturer na model # catalog # serial # other # Device available Uyes Dno Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189	for evaluat returned dical produ ss diculosis A , Newton, N	ion? to ma cts pl sssoc 1A. 0	hone #	ealth professional ser facility istributor ration date planted, give date planted, give date turer _/_/ (781)449-6487	
Brand name Type of device Manufacturer na model # catalog # serial # other # Device available Urice available Urice available Urice available Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	for evaluat returned dical produ ss diculosis A p, Newton, M nal Occuj	ion? to ma cts pl sssoc 1A. 0	hone #	ealth professional ser facility istributor ration date planted, give date olanted, give date	
Brand name Type of device Manufacturer na model # catalog # serial # other # Device available □_yes □_no 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	to ma to ma cts pl sssoc 1A. 0 patio	hone #	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 b	irth	Sex	Weigh	ıt
549	05/14/95		female	35	lbs
B. Adverse event	t or produ	ict pi	oblem		
	Product				
Outcomes attribut			event		
\Box death	∐ disab	•			
\Box life-threatening			anomaly		
hospitalization	□ requi	red in	tervention	n	
other:					
Date of event 03/2 Describe event or		Date	e of repor	t 4/1	1/2001
on a daily basis. Ha			lovering		
Relevant tests/labo			g preexis	ting con	dition

C. Suspect med	dication(s)		
Name: lindane			
NIX			
Dose, frequency	, route use	Thera	apy dates
lindane 2x left on	10 minutes	03/28/	
			to 04/10/01
Diagnosis for us	e	E	vent abated after use
head lice		st	topped or dose reduced
		n	10
Lot #	Exp. date		
unknown	Lap. uut		vent reappeared after eintroduction
ulikilowii		10	
NDC # -	-	У	/es
Concomitant me	dical produ	cts	
NIX 3/28/01 & 3/	29/01		
lindane 03/30/01 &	& 03/09/01		
D. Suspect med	dical devic	e	
Brand name			
Type of device			
Manufacturer na	ame and ad	dress	Operator of device
			health professional
			user facility
			distributor
			Expiration date
model #			
catalog #]	If implanted, give date
serial #			
lot #			If explanted, give date
other #			
Device available			6
Uyes uno Concomitant me			nufacturer _/_/
conconntant inc	uicai produ	cis	
E. Reporter			
Name and addre	SS	pho	one # (781)449-6487
The National Pe	diculosis A	ssocia	ation
P.O. Box 610189	, Newton, N	1A. 02	2461
Health professio		pation	
■ 14 // I			
⊻ _{yes} □ _{nc})		manufacturer
¥yes □nc		ity	user facility

A. Patient Inform	ation				
Patient Identifier	Date of bi	irth	Sex	Weigh	nt
548	8/28/92		female	45	lbs
B. Adverse event	t or produ	ict p	oblem		
	Advers	-	-		
Outcomes attribut			event		
death	∐ disab	-			
✓ life-threatening✓ hospitalization					
other:	i requi	red II	iterventio	n	1
	2 01	D (0	4 4/1	0/2001
Date of event 3-22 Describe event or	-	Date	e of repoi	rt 4/1	0/2001
remedy in the middle of Decembe	r. We think	c it w	as RID.		
Relevant tests/labo	oratory da	ta			
Other relevant his		uding	g preexis	ting con	dition
Very healthy up un	til now!				

C. Suspect med	ication(s)				
Name: Rid					
we THINK it was rid					
Dose, frequency,	route use	The	rapy d	ates	
1x			5/00		
17		12/1	5/00	to	
				12/15/00	
Diagnosis for use	9			abated after use	
headlice			stoppe	d or dose reduced	
			doesn	t apply	
Lot #	Exp. date		Event	reappeared after	
			reintro	oduction	
			doesn'	t apply	
NDC # -	-				
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	
			$\square_{\rm h}$	ealth professional	
				ser facility	
				istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If ext	planted, give date	
other #					
Device available	for evaluati	ion?			
\square_{yes} \square_{no}			anufact	urer / /	
Concomitant mee					
	-				
E. Reporter					
Name and addres	ss	p	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	IA. ()2461		
Health profession ▼ _{yes} □ _{no}	-	oatio	n	Also reported to	
				manufacturer	
If you do NOT war		•		⊔user facility □distributor	
disclosed to the ma	nutacturer, p	lace	an 🔲	uisuibutor	

A. Patient Inform	ation				
Patient Identifier	Date of b	oirth	Sex	Weigł	nt
545	11/20/98		male	32	lbs
B. Adverse event	or prod	uct p	roblem		
Advers	e Event &	: Prod	luct Prol	olem	
Outcomes attribut	ed to adv	erse e	event		
death	disal	oility			
☐ life-threatening	_ ĭ		anomaly		
hospitalization	□requ	ired ir	terventio	on	
other: secondar	y rash				
Date of event 04/0	02/00	Date	e of repo	rt 4/	8/2001
Describe event or	problem				
Intense itching and	raised rash	n on c	hest. Loo	oks worse	e than
t was. Itching and	discomfor	t are a	lot wors	e.	
Relevant tests/labo	ratory da	ata			
	i utor y u				
Other relevant his	torv. incl	uding	y preexis	sting con	dition
			5 F		

C. Suspect med	dication(s)			
Name: lindane				
Dose, frequency	, route use	The	rapy d	ates
received big bottle	e for family.	03/1	5/00	to
2x within 3 weeks	5			to 04/07/00
Diagnosis for us	e		Event	abated after use
scabies			stoppe	d or dose reduced
			no	
Lot #	Exp. date		Event	reappeared after
				oduction
			Ves	
NDC # -	-		yes	
Concomitant me	dical produ	cts		
Doctor has now p	-			
with Lac-hydrin 1				
Stopped use after	one day beca	ause	it irrita	ted rash
D. Suspect med	dical device	•		
Brand name				
Type of device			1	
Manufacturer na	ame and add	lress	Oper	ator of device
				ealth professional
			📙 u	ser facility
			□d	istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot # other #			If exp	planted, give date
	a 1 (1)			
Device available			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 ▼ _{yes} □ _{nc}		patio	n	Also reported to manufacturer
If you do NOT wa				user facility
	nt your menn	ιιν		

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weig	ht
543	19/97/		female	40	lbs
B. Adverse event	or produ	uct pi	roblem		
	Product		-		
Outcomes attribut	_		event		
death	∐ disat	•			
☐ life-threatening			anomaly		
hospitalization		ired in	terventio	n	
other:		1			
Date of event 01/0 Describe event or		Date	e of repor	t 4	/7/2001
R&C , and Kwellad 10 days repeated co environment treated Relevant tests/labo	nstantly s	ince J	anuary. H	louseho	-
Kelevant tests/fabb	fratory da	11.21			
Other relevant his	tory, incl	udinş	g preexis	ting cor	ndition

Triage Unit Sequence #

C. Suspect medication(s) Name: R&C Nix, Kwellada - P Dose, frequency, route use Therapy dates 01/01/01 as directed, every 7-10 days to 07/04/01 Diagnosis for use Event abated after use stopped or dose reduced headlice doesn't apply Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # **Concomitant medical products** Nix, R&C, and Kwellada-P1%, alternately as directed, every 7-10 days repeated since January. Household environment treated with R & C spray insecticide. 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_{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 birth	Sex	Weight		
540	06-06-91	female	80 lbs		
B. Adverse even	t or product p	roblem			
Product Problem					
Outcomes attributed to adverse event					
\Box_{death} $\Box_{\text{disability}}$					
\Box life-threatening \Box congenital anomaly					
hospitalization	required in	ntervention	1		
other:					
Date of event 199	9-2001 Date	e of report	4/4/2001		
Describe event or	problem				
over the counter or	perscription me	eds,shampo	os,etc. DO		
NOT WORK NIX-RID-A-200I					
MIX-KID-A-2001	LINDANE				
Relevant tests/labo	oratory data				
Kelevant tests/lab	fiatory uata				
Other relevant his	story, including	g preexisti	ng condition		

C. Suspect mee	dication(s)					
Name: Nix						
several						
Dose, frequency	, route use	The	rapy d	ates		
bottle (20z)and th	e same	1999)			
10days later				to 2001		
Diagnosis for us	e		Event abated after use			
head lice			stoppe	d or dose reduced		
neud nee			doesn'	t apply		
Lot #	Exp. date					
Lot #	Exp. uate			reappeared after oduction		
]	reintro	duction		
NDC # -	-		doesn'	t apply		
Concomitant me	dical produ	cts				
severalthe most	-		ave use	d is cooking oil		
and garlic powder		-		-		
the top of thights						
D. Suspect med	dical device	9				
Brand name						
Type of device			_			
Manufacturer na	ame and add	lress		ator of device ealth professional ser facility		
				istributor		
			Expir	ration date		
model #			Ifim	planted, give date		
catalog #				planteu, give uate		
serial # lot #			Iforr	planted, give date		
other #				Janicu, give uale		
Device available for evaluation?						
E. Reporter						
Name and addre	SS	pl	none #	(781)449-6487		
The National Pe	diculosis A	.ssoc	iation			
P.O. Box 610189	, Newton, M	1A. (2461			
Health profession \mathbf{V}_{yes} \square_{no}		oatio	n	Also reported to manufacturer		
If you do NOT wa	nt your identi	ity	_	user facility		
disclosed to the ma	anufacturer, p	lace	an 🔳	distributor		

A. Patient Inform	ation						
Patient Identifier	Date of bi	rth	Sex	Weight			
537	05/07/197	8	male	200	lbs		
B. Adverse event	or produ	ct p	roblem				
Adverse Event							
Outcomes attributed to adverse event							
death disability							
\Box life-threatening \Box congenital anomaly							
hospitalization required intervention							
other: mania							
Date of event 8/97	7	Date	e of report	3/28/2	2001		
Describe event or	problem						
Within about two n	-	ıy la	st exposure	, my			
behaviour became v		-	-	-			
decreased need for s	-		-		ner		
symptoms of mania							
diagnosed as bipola							
U 1							
Relevant tests/labo	oratory da	ta					
Other relevant his	story, inclu	ıdin	nreexisti	ng condi	ion		
I have congenital ny				-			
depression.	staginus.	aist	, nave a 1115	101 y 01			
acpression.							

C. Suspect med	dication(s)			
Name: lindane	~ /			
Dose, frequency	, route use	The	rapy d	ates
lice shampoo twic	e and	1/97	,	
scabies cream onc				to 6/97
Diagnosis for us	e		Event	abated after use
pubic lice, scabies			stoppe	d or dose reduced
_			yes	
Lot #	Exp. date			reappeared after
	-			duction
			doorn	t opply
NDC # -	-		doesn	t apply
Concomitant me	dical produ	cts		
I was taking st. jo		was a	also tak	ing various
nutritional supple	ments.			
D. 0		_		
D. Suspect med	dical device	9		
Brand name				
Type of device Manufacturer na	ome and add	Iroco	Oper	ator of device
	anic and aut	11 055	L Â	
				ealth professional
				ser facility istributor
			Expir	ration date
model # catalog #			- If im	planted, give date
serial #				, g- ·
lot #			If exp	planted, give date
other #				, , ,
Device available				
	returned		anufact	urer//
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. ()2461	
Health professio ▼ _{yes} □ _{nc}		patio	n	Also reported to manufacturer
If you do NOT wa		itv		user facility
disclosed to the ma			an 🔲	distributor

A. Patient Informa	ation				
Patient Identifier		h Sex		Weight	
536	19/59/	fem	ale	122	lbs
B. Adverse event	or product	proble	m		
	e Event & P			em	
Outcomes attribut	ed to advers	se event			
death	□disabili	ty			
□ life-threatening	\Box_{congent}	tal anon	naly		
hospitalization	□ require	d interve	ntion		
other:					
Date of event 03-1	14-01 D	ate of r	eport	3/28/	2001
Describe event or	problem				
Relevant tests/labo	oratory data				
Other relevant his No preexisting medi healthy.					

o. ouspect met	C. Suspect medication(s)					
Name: Rid						
Permethrin Cream 5%						
Dose, frequency	, route use	Ther	apy da	tes		
RID 5 times/2 wk		03/09	9/01			
Permethrin twice				to 03/28/01		
Diagnosis for us	-	l IT	Event abated after use			
U				or dose reduced		
body lice		5	ropped	of ubse reduced		
	•		yes			
Lot #	Exp. date	I	Event r	eappeared after		
		r	eintro	luction		
			doesn't	apply		
NDC # -	-		4000111	"PP-J		
Concomitant me	dical produ	cts				
March 7 - March	14, 2001					
D. Suspect me	dical device	9				
Brand name						
Type of device			1			
Manufacturer na	ame and add	lress	<u> </u>	tor of device		
			he	alth professional		
				er facility		
				stributor		
				stributor ation date		
			Expira	stributor ation date		
catalog #			Expira	stributor		
catalog # serial #			Expira If imp	stributor ation date lanted, give date		
catalog # serial # lot #			Expira If imp	stributor ation date		
catalog # serial # lot # other #			Expira If imp	stributor ation date lanted, give date		
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	f <u>or</u> evaluati	ion?	Expira If imp If expl	stributor ation date lanted, give date anted, give date		
catalog # serial # lot # other # Device available	for evaluati	ion? to ma	Expira If imp If expl	stributor ation date lanted, give date anted, give date		
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	for evaluati	ion? to ma	Expira If imp If expl	stributor ation date lanted, give date anted, give date		
catalog # serial # lot # other # Device available Uves 0 no Concomitant me	for evaluati	ion? to ma	Expira If imp If expl	stributor ation date lanted, give date anted, give date		
catalog # serial # lot # other # Device available	for evaluati	ion? to ma	Expira If imp If expl	stributor ation date lanted, give date anted, give date		
catalog # serial # lot # other # Device available Uves 0 no Concomitant me	for evaluati	ion? to ma cts	Expira If imp If expl	stributor ation date lanted, give date anted, give date		
catalog # serial # lot # other # Device available yesno Concomitant me E. Reporter	for evaluation of the second s	ion? to ma cts ph	Expira If imp If expl	stributor ntion date lanted, give date anted, give date		
catalog # serial # lot # other # Device available Uves Ino Concomitant me E. Reporter Name and addre	for evaluati returned edical produce ess ediculosis A	ion? to ma cts ph	Expira If imp If expl anufactu	stributor ntion date lanted, give date anted, give date		
catalog # serial # other # Device available Uyes Uno Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health profession	for evaluati returned dical produces ess ediculosis A 0, Newton, M mal Occup	ion? to ma cts ph ssoci	Expira If imp If expl anufactu intion 2461	stributor ation date lanted, give date anted, give date		
catalog # serial # other # Device available Urges Ino Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health profession	for evaluati returned edical product ess ediculosis A o, Newton, N onal Occup	ion? to ma cts ph ssoci 1A. 0 pation	Expira If imp If expl anufactu intion 2461	stributor ntion date lanted, give date anted, give date urer _/_/ (781)449-6487 Also reported to		

A. Patient Inform	ation					
Patient Identifier	Date of birth	Sex	Weight			
535	7/28/92	male	93 lbs			
B. Adverse event	t or product	problem				
Adverse Event						
Outcomes attributed to adverse event						
□ _{death} □ _{disability}						
□ life-threatening □ congenital anomaly						
\Box hospitalization \blacksquare required intervention						
other:						
Date of event 7/16	5/00 D a	te of report	3/27/2001			
Describe event or						
Parent told by pedia		ly Kwell to	whole body.			
Adam had to be awa						
directed by poison	control to prev	ent poisonir	ig. He had			
temporary respirate	ory difficulty.					
Relevant tests/labo	protory data					
Relevant tests/fab	n ator y uata					
Othon polo-cont 1			ng oon 1:4!			
Other relevant his			ng condition			
Adam is learning di		1s extra				
DISGUSTING!!!!!						

Triage Unit Sequence #

C. Suspect medication(s) Name: Kwell Dose, frequency, route use Therapy dates 7/16/00 One whole dermal to application left on for 10 7/16/00 Diagnosis for use Event abated after use stopped or dose reduced Scabies, head lice and crab lice in evelashes yes Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # **Concomitant medical products** 7/2/0 to 7/16/00--Nix and Rid carefully used at pediatrician's direction. NO adverse reactions prior to Kwell 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 ⊻ves \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 bir	th Sex		Weigh	t	
534	10/2/90	fem	ale	80	lbs	
B. Adverse event	or produc	t proble	em			
	Adverse					
Outcomes attributed to adverse event						
\Box death	∐ disabil	2				
\Box life-threatening		ital anon	-			
hospitalization required intervention						
other:						
Date of event 7/16	5/00 I	Date of r	eport	3/27	7/2001	
Describe event or	-					
Kwell shampoo w					-	
pediatrician, and lef her several times wa					wasn	
directed by poison					atory	
difficulty.						
Relevant tests/labo	oratory data					
Other relevant his	tory, inclu	ling pre	existi	ng con	dition	
None						

Triage Unit Sequence #

C. Suspect medication(s) Name: Kwell Dose, frequency, route use Therapy dates 7/16/00 One whole body application to left on for 10 hours 7/16/00 Diagnosis for use Event abated after use stopped or dose reduced Scabies, head lice and crab lice in evelashes yes Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # **Concomitant medical products** 7/2/00 to 7/16/00--Rid and Nix were used before Kwell at physician's direction. There were NO adverse reactions prior to Kwell. 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_{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	
533	5/28/62		female	154	lbs
B. Adverse event	or produ	uct pi	roblem		
	Advers				
Outcomes attribut					
death	disat				
☐ life-threatening		•	anomaly		
\square hospitalization			-		
	- requ	irea ir	nterventio	011	
other:					
Date of event 7/16	5/00	Date	e of repo	rt 3/27/	2001
I was told to apply children by a pediat was having trouble hospitalized for psy	rician. I ha breathing. /chosis.	ad to g Two	go to the l	ER because	-
Relevant tests/labo	oratory da	nta			
Other relevant his No physical problem and psychiatric help depression. I have the use of the Kwel psychiatrist and a n	ms, but I h o for anxie NO histor l shampoo	nave r ety and y of p . I ha	eceived p l sychotic ve also co	osychother illness pri	apy or to

Triage Unit Sequence #

C. Suspect medication(s) Name: Kwell Dose, frequency, route use Therapy dates One whole dermal 7/16/00 to application of Kwell 7/16/00 Event abated after use Diagnosis for use stopped or dose reduced Scabies, crab and head lice no Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # **Concomitant medical products** I had also used Nix and Rid treatments and Pronto and Rid sprays with minimal side effects. We had been lice infested for more than two weeks, from about July 2 to July 16, 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 ⊻ves \square_{no} user facility If you do NOT want your identity

disclosed to the manufacturer, place an

distributor

death disability life-threatening congenital anomaly hospitalization required intervention other: treatments not working Date of event 02/20/2001 Date of report 3/25/2001 Describe event or problem we have use over the counter and doctor prescribed neds.I've sprayed every thing. Removed all nits buy cutting but that strand of hair. But two to three days later she has hem agian. Also we all have done the treatments. What else can I do?
Adverse event or product problem Product Problem Dutcomes attributed to adverse event death disability life-threatening congenital anomaly hospitalization required intervention other: treatments not working Date of event 02/20/2001 Date of report 3/25/2001 Describe event or problem we have use over the counter and doctor prescribed neds.I've sprayed every thing. Removed all nits buy cutting but that strand of hair. But two to three days later she has hem agian. Also we all have done the treatments. What else an I do?
Product Problem Dutcomes attributed to adverse event death disability life-threatening congenital anomaly hospitalization required intervention other: treatments not working Date of event 02/20/2001 Date of report 3/25/2001 Describe event or problem we have use over the counter and doctor prescribed neds. I've sprayed every thing. Removed all nits buy cutting put that strand of hair. But two to three days later she has hem agian. Also we all have done the treatments. What else tan I do?
Dutcomes attributed to adverse event death disability life-threatening congenital anomaly hospitalization required intervention other: treatments not working Date of event 02/20/2001 Date of report 3/25/2001 Describe event or problem we have use over the counter and doctor prescribed neds.I've sprayed every thing. Removed all nits buy cutting but that strand of hair. But two to three days later she has hem agian. Also we all have done the treatments. What else can I do?
life-threatening congenital anomaly hospitalization required intervention other: treatments not working Date of event 02/20/2001 Date of report 3/25/2001 Describe event or problem we have use over the counter and doctor prescribed neds.I've sprayed every thing. Removed all nits buy cutting put that strand of hair. But two to three days later she has hem agian. Also we all have done the treatments. What else can I do?
life-threatening congenital anomaly hospitalization required intervention other: treatments not working Date of event 02/20/2001 Date of report 3/25/2001 Describe event or problem we have use over the counter and doctor prescribed meds.I've sprayed every thing. Removed all nits buy cutting put that strand of hair. But two to three days later she has them agian. Also we all have done the treatments. What else can I do?
hospitalization required intervention other: treatments not working Date of event 02/20/2001 Date of report 3/25/2001 Describe event or problem we have use over the counter and doctor prescribed meds.I've sprayed every thing. Removed all nits buy cutting but that strand of hair. But two to three days later she has them agian. Also we all have done the treatments. What else can I do?
other: treatments not working Date of event 02/20/2001 Date of report 3/25/2001 Describe event or problem we have use over the counter and doctor prescribed meds.I've sprayed every thing. Removed all nits buy cutting out that strand of hair. But two to three days later she has them agian. Also we all have done the treatments. What else can I do?
Date of event 02/20/2001 Date of report 3/25/2001 Describe event or problem we have use over the counter and doctor prescribed meds.I've sprayed every thing. Removed all nits buy cutting out that strand of hair. But two to three days later she has them agian. Also we all have done the treatments. What else can I do?
Describe event or problem we have use over the counter and doctor prescribed meds.I've sprayed every thing. Removed all nits buy cutting out that strand of hair. But two to three days later she has them agian. Also we all have done the treatments. What else can I do?
we have use over the counter and doctor prescribed meds.I've sprayed every thing. Removed all nits buy cutting out that strand of hair. But two to three days later she has them agian. Also we all have done the treatments. What else can I do?
meds.I've sprayed every thing. Removed all nits buy cutting out that strand of hair. But two to three days later she has them agian. Also we all have done the treatments. What else can I do?
but that strand of hair. But two to three days later she has them agian. Also we all have done the treatments. What else can I do?
them agian. Also we all have done the treatments. What else can I do?
can I do?
Relevant tests/laboratory data
Kelevant tests/laboratory data
Other relevant history, including preexisting condition
none

C. Suspect med	lication(s)				
Name: lindane					
nix/rid					
Dose, frequency,	, route use	The	rapy d	ates	
as instucted	,		2202001		
as instacted		0220	to 03192001		
Diagnosis for us	e			abated after use	
as directed		5	stopped or dose reduced		
			no		
Lot #	Exp. date		Event	reappeared after	
				oduction	
NDC #			yes		
Concomitant me	dical produ	cts			
we've been treating	g once a wee	k sind	ce 2/20	/01	
D. Suspect med	lical device	9			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			L Â	ealth professional	
				ser facility	
				istributor	
			схрп	ration date	
model #			Ifim	planted, give date	
catalog # serial #			11 111	planteu, give uate	
lot #			Te		
other #			If exp	planted, give date	
Device available			nufact	uror / /	
Concomitant me			inunaei		
	_				
E. Reporter					
Name and addre	SS	pł	none #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, N	1 A. 0	2461		
Health professio		patio	n	Also reported to	
\mathbf{V}_{yes} \square_{no})			manufacturer	
If you do NOT was	-	-		user facility	
disclosed to the ma	nufacturer, p	lace a	an 🔳	□distributor	

A. Patient Inform	ation			
Patient Identifier	Date of bir	th Sex	Weigh	ıt
520	01/06/91	female	60	lbs
B. Adverse event	or produc	t problem		
Advers	e Event & I	Product Prob	lem	
Outcomes attribut	ed to adver	rse event		
death	disabi	lity		
life-threatening		nital anomaly		
hospitalization		ed interventio	n	
other:				
Date of event 01/1	6/01 I	Date of report	rt 3/	9/2001
Describe event or	problem			
The day after treating		nters head flr	lice mv h	ands
became VERY swo				
adults on her head.				
	riist intesta	lion accurred	III uecen	liber of
2000.				
Relevant tests/labo	oratory data	a		
	v			
Other relevant his	story, inclu	ding preexis	ting con	dition

	dication(s)			
Name:				
Rid, Nix	, Lice Free, v	inega	r	
Dose, frequency	, route use	The	rapy d	ates
first Rid and Lice		12/0	0	
weeks later Nix				to 03/01
Diagnosis for us	0	h	Event	abated after use
_				d or dose reduced
Treatment for hea	dlice			
	1		doesn	t apply
Lot #	Exp. date]	Event	reappeared after
		1	reintro	oduction
NDC #			doesn'	t apply
NDC $\#$ -	-			
Concomitant me	dical produ	cts		
D. Suspect med	dical device	9		
Brand name				
Type of device				
Manufacturer na	ame and add	lress	Oner	
			oper	ator of device
			L Â	
			⊡ _h	ealth professional
				ealth professional ser facility
			\square_{h} \square_{u} \square_{d}	ealth professional ser facility istributor
			\square_{h} \square_{u} \square_{d}	ealth professional ser facility
model #			Expin	ealth professional ser facility istributor ration date
catalog #			Expin	ealth professional ser facility istributor
catalog # serial #			Expin	ealth professional ser facility istributor ration date planted, give date
catalog # serial # lot #			Expin	ealth professional ser facility istributor ration date
catalog # serial #			Expin	ealth professional ser facility istributor ration date planted, give date
catalog # serial # lot # other # Device available	for evaluat	 ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available □_yes □_no	for evaluat	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date
catalog # serial # lot # other # Device available	for evaluat	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available □_yes □_no	for evaluat	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available □_yes □_no	for evaluat	ion?	Expire If imp	ealth professional ser facility istributor ration date planted, give date planted, give date
catalog # serial # lot # other # Device available Device available Oves no Concomitant me	for evaluat	ion? to ma	Expire If imp	ealth professional ser facility istributor ration date planted, give date olanted, give date
catalog # serial # lot # other # Device available yesno Concomitant me E. Reporter	for evaluat	ion? to ma cts	hone #	ealth professional ser facility istributor ration date planted, give date olanted, give date
catalog # serial # lot # other # Device available yesno Concomitant me E. Reporter Name and addre	for evaluat returned dical produ ss ediculosis A	to ma to ma cts	hone #	ealth professional ser facility istributor ration date planted, give date olanted, give date
catalog # serial # lot # other # Device available yesno Concomitant me E. Reporter Name and addre The National Pe	for evaluat returned dical produ ss ediculosis A o, Newton, N	ion? cts ph sssoc IA. 0	hone #	ealth professional ser facility istributor ration date planted, give date olanted, give date
catalog # serial # lot # other # Device available yesno Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	for evaluat returned dical produ ss ediculosis A p, Newton, M nal Occuj	ion? cts ph sssoc IA. 0	hone #	ealth professional ser facility istributor ration date planted, give date planted, give date urer/_ / (781)449-6487
catalog # serial # other # Device available \Box_{Ves} \Box_{no} 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	to ma to ma cts ph sssoc 1A. 0 patio	hone #	ealth professional ser facility istributor ration date planted, give date planted, give date urrer// (781)449-6487 Also reported to

	ation				
Patient Identifier	Date of bi	irth	Sex	Weight	
517	08/16/42		female	140	lbs
B. Adverse event	or produ	ict pr	oblem		
	Advers	e Eve	nt		
Outcomes attribut	ed to adve	erse e	vent		
death	∐ disab	ility			
□ life-threatening			anomaly		
hospitalization	□requi	red in	tervention		
other:					
Date of event 19/9	98/	Date	of report	3/8/	2001
weekly basis.					
Relevant tests/labo	oratory da	ta			

C. Suspect medication(s)			
Name: Kwell			
Dose, frequency, route use	The	rapy dates	
every few months	1975		
every lew months	1775	to	
	<u> </u>	1999	
Diagnosis for use		Event abated after use	
for scabies treatment	5	stopped or dose reduced	
		no	
Lot # Exp. date	J	Event reappeared after	
MDC6043254		reintroduction	
7-60		doesn't apply	
NDC #		doesn't appry	
Concomitant medical produ	icts		
D. Suspect medical device	е		
Brand name			
Type of device			
Manufacturer name and add	dress	Operator of device	
		health professional	
		\square user facility	
		distributor	
		Expiration date	
model #		p union- unio	
catalog #			
		If implanted, give date	
_		If implanted, give date	
serial #			
serial # lot #		If implanted, give date If explanted, give date	
serial # lot # other #			
serial # lot # other # D <u>ev</u> ice av <u>ail</u> able f <u>or</u> evaluat	ion?	If explanted, give date	
serial # lot # other # Device available for evaluat	ion? to ma	If explanted, give date	
serial # lot # other # Device available for evaluat	ion? to ma	If explanted, give date	
serial # lot # other # Device available for evaluat	ion? to ma	If explanted, give date	
serial # lot # other # Device available for evaluat Upes no returned Concomitant medical produ	ion? to ma icts	If explanted, give date	
serial #	ion? to ma icts pł	If explanted, give date anufacturer/_/ none # (781)449-6487	
serial # lot # other # Device available for evaluat u_{yes} u_{no} $u_{returned}$ Concomitant medical produ E. Reporter Name and address	ion? to ma icts pł	If explanted, give date anufacturer/_/ none # (781)449-6487 iation	
serial #	ion? to ma icts ph Assoc /IA. 0	If explanted, give date anufacturer _/_/ none # (781)449-6487 iation 2461 n Also reported to	
serial #	ion? to ma icts ph Assoc /IA. 0 patio	If explanted, give date anufacturer/_/ none # (781)449-6487 iation 2461	

· ·				
A. Patient Inform	ation			
Patient Identifier	Date of bir	th Sex	Weig	ht
513	9-1-90	female	e 82	lbs
B. Adverse event	or produc	t problen:	n	
	Product F	roblem		
Outcomes attribut	ed to adver	rse event		
death	disabi	lity		
□ life-threatening		nital anoma	ly	
hospitalization		ed interven	tion	
other:				
Date of event 2-25	5-01 I	Date of rep	oort 2/2	26/2001
Describe event or	problem			
We need help.				
Relevant tests/labo	oratory dat:	a		
Other relevant his	story, inclu	ding pree	cisting co	ndition
Seizure disorder, me				

C. Suspect medic	cation(s)			
Name: Nix				
Rid, Linda	ne			
Dose, frequency, r	oute use	Ther	apy d	ates
every 7-10 days		1-200	01	
				to 2-25-2001
Diagnosis for use		F	Event	abated after use
head lice & nits		s	toppe	d or dose reduced
			no	
Lot # E	vn data			
	xp. date			reappeared after
		r	eintro	oduction
NDC# -	-	-	yes	
Concomitant medi	cal produ	rts		
concommant incu	cai prouu			
D. Suspect medie	cal device	è		
Brand name				
Type of device				
Manufacturer nan	ne and add	lress	Oper	ator of device
			\square_{h}	ealth professional
				ser facility
				istributor
			Expir	ation date
model #				
catalog #			If im	planted, give date
serial # lot #			7.0	
ot # other #			lf exp	planted, give date
Device available for \square_{yes} \square_{no}	returned		nufact	urer / /
Concomitant medi			inuraci	
	F			
E. Reporter				
Name and address		ph	one #	(781)449-6487
The National Pedi	iculosis A	ssoci	ation	
P.O. Box 610189, 1	Newton, M	IA. 02	2461	
Health profession:	al Occup	oatior	1	Also reported to
\mathbf{V}_{yes} \square_{no}				manufacturer
If you do NOT want	your identi	ty		user facility
disclosed to the man	ufacturer, p	lace a	n 🔲	distributor

Patient Identifier	ation				
	Date of b	irth	Sex	Weight	ţ
510	07-24-93		female	56	lbs
B. Adverse even	t or produ	ict pr	oblem		
	Product	Prob	lem		
Outcomes attribut	ted to adv	erse e	vent		
\Box_{death}	□ disab	oility			
□ life-threatening		enital	anomaly		
hospitalization	Lrequi	red in	tervention		
other:					
Date of event 1-1	6-01	Date	of report	2/22	/2001
Describe event or	problem				
My daughter had lie	ce 7 times l	last ye	ar and aga	in 2 time	es
this year		-	-		
J					
Relevant tests/labo	oratory da	ıta			
Relevant tests/labo	oratory da	ıta			
Relevant tests/labo	oratory da	ita			
Relevant tests/labo	oratory da	ıta			
Relevant tests/labo	oratory da	ta			
Relevant tests/labo	oratory da	ta			
Relevant tests/labo	oratory da	ta			
Relevant tests/labo	oratory da	ta			
			nreevisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition
Relevant tests/labo Other relevant his no medical conditio	story, incl		; preexisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition
Other relevant his	story, incl		; preexisti	ng cond	lition

C. Suspect med	lication(s)			
Name: lindane				
Nex				
Dose, frequency,	, route use	The	rapy d	ates
lindane 3 times		01-1	6-02	
				to 02-22-01
Diagnosis for us	e]	Event	abated after use
put on dry hair for		h s	stoppe	d or dose reduced
out			no	
Lot #	Exp. date		-	
L0t #	- P			reappeared after
]		reintro	oduction
NDC #			yes	
Concomitant medical products		cts		
conconntant inc	uicui prouu			
D. Suspect med	lical device	2		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			D h	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				
Uyes Uno			anufact	urer _/_/
Concomitant me	aicai produ	cis		
E. Reporter				
Name and addre	SS	pł	none #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	1 A. 0	2461	
Health professio	nal Occup	oatio	n	Also reported to
\mathbf{V}_{yes} \square_{no})			manufacturer
If you do NOT wa	nt your identi	ty		user facility
disclosed to the ma	unufacturer, p	lace a	an 🔳	□ distributor

A. Patient Inform	ation			
Patient Identifier		Sex	Weight	
507	12-12-90	female	70	lbs
. Adverse event	or product p	roblem		
	Product Prob			
utcomes attribut	ed to adverse o	event		
death	∐ disability			
☐ life-threatening		-		
hospitalization				1
other: resiliant				
ate of event 12/2 escribe event or		e of report	2/18/2	2001
Relevant tests/labo	oratory data			
Other relevant his	tory, includin;	g preexisti	ng condit	tion

C. Suspect med	lication(s)			
Name: Nix				
Rid				
Dose, frequency,	route use	The	rapy d	ates
Every seven days		12/2	12/23/2000	
				to 2/17/2001
Diagnosis for us	ρ	ŀ	Event	abated after use
lice	•			d or dose reduced
lice				
T	F		no	
Lot #	Exp. date			reappeared after
			reintro	oduction
			yes	
NDC # -	-		-	
Concomitant me	dical produ	cts		
D. Suspect med	lical device	•		
Brand name				
Type of device			1-	
Manufacturer na	me and add	lress	1 .	ator of device
				ealth professional
				ser facility
				istributor
			Expi	ration date
model #				ulantad atus data
catalog #				planted, give date
serial # lot #			TC	
other #			If exp	planted, give date
	e 1 4			
Device available yes no			anufact	uror / /
Concomitant me			anuraci	uiei//
	arear proud			
E. Reporter				
Name and addre	SS	pl	hone #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	IA . (02461	
Health professio	nal Occuj	patio	n	Also reported to
\mathbf{V}_{yes} \square_{nc})			manufacturer
If you do NOT was	nt your identi	ty	_	user facility
disclosed to the ma	nufacturer, p	lace	an 🔲	□ distributor

A. Patient Inform				
ient Identifier		Sex	Weight	
505	19/55/	male	148	lbs
Adverse even				
4	Adverse Ev			
u tcomes attribu death	$\Box_{\text{disability}}$	event		
□ life-threatening		anomaly		
$\Box_{\text{hospitalization}}$	_	-		
other: chronis				
ate of event 19/		e of report	2/14/2	2001
escribe event or		1		
elevant tests/lab	oratory data			
ther relevant hi	story, includin	g preexisti	ng condi	tion

C. Suspect medication(s)					
Name: Kwell					
Dose, frequency, route use	e The	erapy d	ates		
,	197				
		4	to		
			1980		
Diagnosis for use			abated after use		
Scabies		stoppe	d or dose reduced		
		no			
Lot # Exp. date		Event	reappeared after		
			oduction		
NDC #		doesn	t apply		
Concomitant medical prod	lucts				
Please contact me (description		dow w	on't take all)		
(description)			· · ····· · ····· · · · · · · · · · ·		
D. Suspect medical devi	се				
Brand name					
Type of device					
Manufacturer name and a	ddres	s Oper	ator of device		
		-	ealth professional		
			ser facility		
			istributor		
		Expi	ration date		
model #		p			
catalog #		- If im	planted, give date		
serial #		-			
lot #		If exp	planted, give date		
other #					
Device available for evalua	ation?				
□ _{yes} □ _{no} □ _{returne}	ed to n	nanufact	turer _/_/		
Concomitant medical prod					
E Poportor					
E. Reporter		1 "	(701) 440 (407		
Name and address			(781)449-6487		
The National Pediculosis	Asso	ciation			
P.O. Box 610189, Newton,	MA.	02461			
Health professional Occ	upati	n	Also reported to		
∠ _{yes} □ _{no}			manufacturer		
If you do NOT want your iden	ntity		user facility		
disclosed to the manufacturer,	, place	an 🔲	□distributor		

A. Patient Informa	ation			
Patient Identifier	Date of birth	Sex	Weight	
500	08/25/91	female	66 II	bs
B. Adverse event	or product p	oroblem		
Advers	e Event & Pro	duct Probl	em	
Outcomes attribut	ed to adverse	event		
death	∐ disability			
☐ life-threatening		l anomaly		
hospitalization		ntervention		
other: rash				
Date of event 02/0	06/01 Da t	te of report	2/7/200)1
Describe event or	problem			
Head lice, used Clea	r, Lice B Gone	, Rid, Nix,	and Ryobi	
electric comb and no	othing seems to	kills the lic	e, or there	
eggs will not come o	off folice.			
Relevant tests/labo	ratory data			
Other relevant his	tory, includir	ig preexisti	ing conditio	n
Over 2 years ago, ou	ur school was a	almost close	d due to the	
number of head lice				
		-		
as bas as my daught	er has it that w	e could be i	n the same	
direction				

C. Suspect medication(s)					
Name: Clear					
Rid, Nix,	Clear and L	lice E	3 Gone		
Dose, frequency,	, route use	The	rapy d	ates	
treatment for 4 da	iys	02/0	2/01	to	
			to 02/07/01		
Diagnosis for us	e		Event	abated after use	
Head Lice			stoppe	d or dose reduced	
			yes		
Lot #	Exp. date	_	•	1.64	
	Exp. date			reappeared after oduction	
		1	entro	Juuction	
NDC # -	-		yes		
Concomitant me	dical produ	cts			
	arear produ				
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	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
Device available	_		64		
Concomitant me	returned dical produ		anuraci	lurer//	
	Ĩ				
E. Reporter					
Name and addre	SS	pl	10ne #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, N	1 A. 0	2461		
Health professio	nal Occuj	patio	n	Also reported to	
\mathbf{V}_{yes} $\square_{\text{normalized}}$)			manufacturer	
If you do NOT was	nt your identi	ity	_	user facility	
disclosed to the ma	unufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform	ation						
Patient Identifier		irth	Sex	Weight			
499	9-7-1959)	female	120	lbs		
B. Adverse event	or prod	lct pi	roblem				
Advers	Adverse Event & Product Problem						
Outcomes attribut	ed to adv	erse e	event				
death	death disability						
□ _{life-threatening}	$\Box_{\rm cong}$	enital	anomaly				
hospitalization	□ _{requ}	ired in	itervention				
other: used spra	y and fou	nd it t	o be irritati	ing to lun	igs a		
Date of event 2/6/	2001	Date	e of report	2/6/	2001		
Describe event or	problem						
head lice, used nix f night i left it on for cup vinager, 1/2 cup	60 minute	s, rins	ed, then rir	nsed with	1/2		
min. then applied ol	ive oil and	l left i	n hair in to	wel overr	night		

Relevant tests/laboratory data

Other relevant history, including preexisting condition My head had been itching for quite awhile, didnt know

what cause was till 3 weeks ago and brushed out a live louse

C. Suspect med	lication(s)					
Name: Nix						
vinager, olive oil and rid spray were used,						
Dose, frequency,	, route use	Therapy d	lates			
enough to saturate		1/13/2001				
hair, every six day	-		to 2/5/2001			
Diagnosis for us	ρ	Event	abated after use			
detected live lice	C		ed or dose reduced			
detected live lice						
Lot #	E l-4-	no				
	Exp. date		reappeared after			
0c1694		reintr	oduction			
NDC # -		yes				
Concomitant me	dical produ	ets				
none	aicai produ	~~~				
none						
D. Suspect med	lical device	2				
Brand name						
Type of device						
Manufacturer na	me and add	Iress Oper	rator of device			
			nealth professional			
			iser facility			
			listributor			
		Expi	ration date			
model #						
catalog #		If im	planted, give date			
serial #						
lot # other #		If ex	planted, give date			
Device available yes no	for evaluat		turnon ()			
Concomitant me			turer//			
2011-2011-2011-2011-2011-2011-2011-2011						
E. Reporter						
Name and addre		-	[#] (781)449-6487			
The National Pe	diculosis A	ssociation	l			
P.O. Box 610189	, Newton, M	IA. 02461				
Health professio	nal Occuj	pation	Also reported to			
⊻ _{yes} □ _{nc})		manufacturer			
If you do NOT was			User facility			
disclosed to the ma	nufacturar r	laca an	distributor			

A. Patient Inform	ation				
Patient Identifier	Date of birtl	n Sex	Weight		
493	8/9/93	female	50 lb	bs	
B. Adverse event		-			
Product Problem					
Outcomes attribut	_				
death	∐ disabilit	•			
☐ life-threatening		al anomaly			
hospitalization		intervention			
other:					
Date of event 1/19		ate of report	1/20/200	1	
Describe event or			11		
have treated live inf out nits and retreate					
mayonaise!	a and suil nav	e nee and na	ve even tried		
Relevant tests/labo	oratory data				
Other relevant his	story, includi	ing preexisti	ing condition	n	

C. Suspect med	lication(s)			
Name: Kwell				
Dose, frequency,	route use	Ther	apy d	ates
3 times in 2 weeks		1/8/0		
	,	1,0,0	-	to 1/20/02
		 	7	
Diagnosis for us				abated after use d or dose reduced
treat remove eggs	retreat in 10	5	toppe	u of dose feduced
days			no	
Lot #	Exp. date	F	Event	reappeared after
		r	eintro	oduction
			no	
NDC # -	-			
Concomitant me	dical produ	cts		
D. Suspect med	lical device	9		
Brand name				
Type of device				
Manufacturer na	me 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				
	Internet		nufact	urer _/_/
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	SS	ph	one #	(781)449-6487
The National Pe	diculosis A	_		
P.O. Box 610189	, Newton, N	1A. 02	2461	
Health profession	nal Occuj	pation	n	Also reported to
\mathbf{V}_{yes} \square_{nc}	,			manufacturer
If you do NOT wa	nt your identi	ity	_	user facility
disclosed to the ma	nufacturer, p	lace a	in 🔲	□distributor

A. Patient Inform		•	q		T 7 • •	
Patient Identifier			Sex		Weight	
492	06-15-93		female		50	lbs
3. Adverse event						
	Product		-			
Outcomes attribut			vent			
∐ death	∐ disat	•				
\Box life-threatening			anomal			
hospitalization	□ requi	ired in	terventi	ion		
other:		1				
Date of event 01-0	01-01	Date	of rep	ort	1/15/	/2001
Relevant tests/labo	ratory da	ata				
Other relevant his	tory, incl	uding	g preex	istir	ıg cond	ition

C. Suspect medi	cation(s)				
Name: Kwell					
Dose, frequency, r	oute use	Ther	apy d	ates	
one application		01-15-01			
				to 01-15-01	
Diagnosis for use		Event a		abated after us	e
lice		stopped or dose r		d or dose reduc	
			no		
Lot # E	xp. date				
	Ap. uate			reappeared afte	r
		r	eintro	oduction	
NDC # -	-		yes		
Concomitant medi	ical produ	ete			
	icai prouu	cis			
D. Suspect medi	cal device	_			
Brand name					
Type of device					
Type of device	ne and add	lress	Oper	ator of device	
Type of device	ne and add	lress	Ē		a1
Type of device	ne and ado	lress	h	ealth profession	al
Type of device	ne and add	lress	h u	ealth profession ser facility	al
Type of device	ne and add	lress	h u	ealth profession	al
Type of device	ne and add	lress	\square_{h} \square_{u} \square_{d}	ealth profession ser facility	al
<u>Type of device</u> Manufacturer nan	ne and add	lress	\square_{h} \square_{u} \square_{d}	ealth profession ser facility istributor	al
<u>Type of device</u> Manufacturer nan model #	ne and add	lress	□h □u □d Expin	ealth profession ser facility istributor	
Type of device Manufacturer nan model # catalog # serial #	ne and add	lress	□h □u □d Expin	ealth profession ser facility istributor ration date	
<u>Type of device</u> Manufacturer nan model # catalog #	ne and add	lress	Expin	ealth profession ser facility istributor ration date planted, give da	nte
<u>Type of device</u> Manufacturer nan model # catalog # serial #	ne and add	1ress	Expin	ealth profession ser facility istributor ration date	nte
Type of device Manufacturer nan model # catalog # serial # lot # other #			Expin	ealth profession ser facility istributor ration date planted, give da	nte
Type of device Manufacturer nan model # catalog # serial # lot # other # Device available for	<u>or</u> evaluat	 	Expir If im	ealth profession ser facility istributor ration date planted, give da	nte
Type of device Manufacturer nan model # catalog # serial # lot # other # Device available for	or evaluat	 ion? to ma	Expir If im	ealth profession ser facility istributor ration date planted, give da	nte
Type of device Manufacturer nam model # catalog # serial # lot # other # Device available for yesn	or evaluat	 ion? to ma	Expir If im	ealth profession ser facility istributor ration date planted, give da	ate
Type of device Manufacturer nam model # catalog # serial # lot # other # Device available fe Uyes D_no Concomitant medi	or evaluat	 ion? to ma	Expir If im	ealth profession ser facility istributor ration date planted, give da	nte
Type of device Manufacturer nam model # catalog # serial # lot # other # Device available for yes □_no [] Concomitant medi E. Reporter	or evaluat Dreturned ical produ	ion? to ma cts	Expin If im	ealth profession ser facility istributor ration date planted, give da	ate
Type of device Manufacturer nam model # catalog # serial # lot # other # Device available fe Uyes D_no Concomitant medi E. Reporter Name and address	or evaluat returned ical produ	ion? to ma cts	If implication	ealth profession ser facility istributor ration date planted, give da	ate
Type of device Manufacturer nam model # catalog # serial # lot # other # Device available fe Uyes D_no Concomitant medi E. Reporter Name and address	or evaluat returned ical produ	ion? to ma cts	If implication	ealth profession ser facility istributor ration date planted, give da	ate
Type of device Manufacturer nam model # catalog # serial # lot # other # Device available for yes long no log Concomitant medi E. Reporter Name and address The National Ped	or evaluat Treturned ical produ iculosis A	ion? to ma cts ph	If implication	ealth profession ser facility istributor ration date planted, give da	ate
Type of device Manufacturer nam model # catalog # serial # other # Device available for Uyes D_no Concomitant medi E. Reporter Name and address The National Ped P.O. Box 610189, 1 Health professional	or evaluat returned ical produ iculosis A Newton, M	ion? to ma cts ph sssoci	If implementation	ealth profession ser facility istributor ration date planted, give da	te
Type of device Manufacturer nam model # catalog # serial # tot # other # Device available for Uyes □_no [] Concomitant media E. Reporter Name and address The National Ped P.O. Box 610189,]	or evaluat returned ical produ iculosis A Newton, M	ion? to ma cts ph sssoci	If implementation	ealth profession ser facility istributor ration date planted, give da planted, give da urer/_/ (781)449-6487	ite
Type of device Manufacturer nam model # catalog # serial # other # Device available for Uyes D_no Concomitant medi E. Reporter Name and address The National Ped P.O. Box 610189, 1 Health professional	or evaluat Treturned ical produ iculosis A Newton, N al Occuj	ion? to ma cts ph .ssoci IA. 0: pation	If implementation	ealth profession ser facility istributor ration date planted, give da planted, give da urer/_/ (781)449-6487	te to

A. Patient Inform				
Patient Identifier		th Sex	Weight	ţ
491	03/29/94	female	52	lbs
B. Adverse event				
Advers	e Event & I	Product Prol	blem	
Outcomes attribut	ed to adver	se event		
∐ death	∐ disabil	ity		
□ life-threatening		nital anomaly		
hospitalization		ed intervention	on	
other: dunno if	reaction or	not, but she i	s breaking	out
Date of event 4/98	3 1	Date of repo	rt 1/15	/2001
Describe event or	problem			
got rid of furniture,			•	
nothing working! no		-		
thought was ringwo			-	
dunno what it is! re	d whelps, th	at itch & ble	ed, & scab	over
Delevent tests/lebs	motory date			
Relevant tests/labo	oratory data	d		
Other relevant his	tory inclu	dina proovi	sting cord	lition
	story, metu	ung preexis	sung cono	nuon
none				

Triage Unit Sequence #

C. Suspect medication(s) Name: lindane pronto, kwell, nix, cooking oil Dose, frequency, route use Therapy dates once a week, used the lotion 04/98 to 01/01 Diagnosis for use Event abated after use stopped or dose reduced lice no Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # **Concomitant medical products** we have used everything under the sun.... nix pronto kwell robo-comb the gold handle comb (that worked, but got broke) rid dog shampoo 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_{no} user facility If you do NOT want your identity distributor

disclosed to the manufacturer, place an

	ation			
atient Identifier	Date of birth	Sex	Weight	
484	09/10/54	female	132	lbs
. Adverse even				
	Adverse Ev			
outcomes attribu	_	event		
death	☐ disability			
☐ life-threatening ☐ hospitalization				
other:		ner vention		
ate of event 12/	01/00 Det	e of report	1/7/2	001
escribe event or		e of report	1///2	.001
elevant tests/lab	anatony data			
Other relevant hi s	story, includin	g preexisti	ng condit	tion

C. Suspect med	lication(s)					
Name: Kwell						
NIX						
Dose, frequency,	route use	The	rapy d	ates		
2 Times 120			0100			
		to 121000				
Diagnosis for use			Event abated after use			
head lice			stoppe	d or dose reduced		
			doesn't apply			
Lot #	Exp. date		Event reappeared afte			
Unknown				oduction		
			doesn't apply			
NDC #			abesh	t uppiy		
Concomitant medical products						
N/A						
D. Suspect med	lical device	;				
Brand name						
Type of device			1-			
Manufacturer na	me and add	lress	Ĺ.	ator of device		
				ealth professional		
			user facility distributor			
			Expiration date			
model #			planted, give date			
catalog # serial #						
lot #			Ifex	planted, give date		
other #						
Device available	Device available for evaluation?					
\square_{yes} \square_{no} $\square_{\text{returned to manufacturer}} _/_/\$						
Concomitant medical products						
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. ()2461			
Health profession	-	oatio	n	Also reported to		
\mathbf{V}_{yes} \square_{no}						
If you do NOT wai				\Box user facility		
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor		

A. Patient Inform	ation				
Patient Identifier	Date of bir	th S	Sex	Weight	
482	6-30-73		female	65	lbs
B. Adverse event	or produc	t pro	oblem		
	Product P	robl	em		
Outcomes attribut	ed to adver	se ev	vent		
death	disabili	ity			
□ life-threatening		ital a	anomaly		
hospitalization	\Box_{require}	d int	tervention		
other: nothing is working					
Date of event 01-0	01-01 E	Date	of report	1/5/	2001
Describe event or	problem				
am doing everythin	ng exactly rig	ght, h	nave had th	e ongoin	g
problem for over a 1	month and ar	n ou	t of ideas	adn mone	ey. I
have had the proble	m before and	d kno	ow the pro	per	
procedure, but noth	ings working	g! Al	13 of us h	ave them	
Relevant tests/labo	ratory data				
iterevant tests/habe	futory duta	•			
Other relevant his	tory, includ	ling	preexisti	ng condi	tion
		8	F		

C. Suspect me	dication(s)					
Name: lindane						
nix, and	rid					
Dose, frequency	, route use	Ther	apy d	ates		
1 time per week			10-31-00			
_			to 01-05-01			
Diagnosis for us	se	I	Event	abated after use		
not workign at all	s	toppe	d or dose reduced			
not workign at an		doesn'	t apply			
Lot #	Exp. date					
L01 #	_			reappeared after duction		
		r				
NDC #			doesn't apply			
Concomitant me	dical produ	cts				
	F					
D. Suspect me	dical device	e				
Brand name						
Type of device						
Manufacturer n	ame and add	dress	Oper	ator of device		
			\square_{h}	ealth professional		
				ser facility		
			distributor			
			Expiration date			
model #		-				
catalog #	If implanted, give dat					
serial #						
lot #			If exp	olanted, give date		
other #						
Device available	_					
	Ireturned		nufact	urer _/_/		
Concomitant me	edical produ	cts				
E. Reporter						
Name and addre	ess	ph	one #	(781)449-6487		
The National Pe	ediculosis A	ssoci	ation			
P.O. Box 610189), Newton, N	4A. 0	2461			
Health professio	onal Occu	patio	ı	Also reported to		
		•		manufacturer		
If you do NOT wa	nt your ident	ity		user facility		
disclosed to the m	-		n 🔲	□distributor		

A. Patient Inform	ation					
Patient Identifier	Date of bi	rth	Sex	Weight		
478	11/11/90		female	80	lbs	
B. Adverse even	or produ	ct pr	oblem			
Product Problem						
Outcomes attribut	ted to adve	rse e	vent			
death	disabi	ility				
Life-threatening congenital anomaly						
hospitalization required intervention						
other:						
Date of event 11/0)0/	Date	of report	1/1/2	001	
Describe event or problem						
We have been trying to get rid of lice from my						
granddaughter for o	-			-		
medications plus ov						
combed and tried to coming back.	remove the	e eggs	s and bugs	but they I	ceep	
coming back.						
Relevant tests/labo	oratory dat	a				
Other relevant his	story, inclu	ıding	preexisti	ng condit	ion	
Other relevant his	story, inclu	ıding	preexisti	ng condit	ion	
Other relevant his	story, inclu	ıding	preexisti	ng condit	ion	
Other relevant his	story, inclu	ıding	preexisti	ng condif	ion	
Other relevant his	story, inclu	ıding	preexisti	ng condif	ion	
Other relevant his	story, inclu	ıding	preexisti	ng condit	ion	
Other relevant his	story, inclu	ıding	preexisti	ng condif	ion	
Other relevant his	story, inclu	ıding	preexisti	ng condit	ion	

Triage Unit Sequence #

C. Suspect medication(s) Name: Rid olive oil, ovide, pronto, Dose, frequency, route use Therapy dates every two weeks about half 090199 to the bottle. 123100 Diagnosis for use Event abated after use stopped or dose reduced use once and then wait a week and do it again no Lot # Exp. date Event reappeared after reintroduction yes NDC # **Concomitant medical products** olive oil. gemeric shampoos, rid mousse, We are ready to shave her head and get her a wig 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_{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	
475	04/08/60		female	130	lbs
B. Adverse event	or produ	lct p	roblem		
	Advers	se Eve	ent		
Outcomes attributed to adverse event					
death disability					
\Box life-threatening \Box congenital anomaly					
hospitalization		ired ir	tervention		
other:					
Date of event 07/0	01/00	Date	e of report	12/28/2	2000
Describe event or	_				
Used lindane two ti			-		
scalp tingling and pa	ain, has se	en thr	ee different	t neurolog	gists
Relevant tests/labo	oratory da	nta			
Other relevant his					
Using hormone repl	acement p	rescri	ption, has s	since been	1
taken off.					

C. Suspect medication(s)				
Name: lindane				
Nix, Rid				
Dose, frequency,	, route use	The	rapy dates	
Three treatments	in approx.	07/0	07/01/00	
2 weeks of 3 shan	npoos		to 12/28/00	
Diagnosis for us	e]	Event abated after use	
Head lice		5	stopped or dose reduced	
			doesn't apply	
Lot #	Exp. date	I	Event reappeared after	
]	reintroduction	
			doesn't apply	
NDC # -	-		TT J	
Concomitant me	dical produ	cts		
Still seeing neurol	ogists, treate	d wit	th different meds.	
D. Suspect med	lical device	9		
Brand name				
Type of device				
Manufacturer na	ime and add	iress	-	
			health professional	
			user facility distributor	
			Expiration date	
model #			If implanted, give date	
catalog # serial #			In implanted, give date	
lot #			If explanted, give date	
other #			In explaneed, give date	
Device available			1	
yes no returned to manufacturer _/_/				
Concomitant medical products				
Concomitant me		cts		
Concomitant me		cts		
Concomitant me E. Reporter		cts		
	dical produ		hone # (781)449-6487	
E. Reporter	dical produ	pł	hone # (781)449-6487	
E. Reporter Name and addre	dical produ ss diculosis A	pł .ssoc	hone # (781)449-6487	
E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	dical products ss diculosis A , Newton, N nal Occup	pł ssoc 1A. 0	hone # (781)449-6487 tiation)2461 n Also reported to	
E. Reporter Name and addre The National Pe P.O. Box 610189	dical products ss diculosis A , Newton, M nal Occup	pł ssoc IA. 0 patio	hone # (781)449-6487 viation)2461	

A. Patient Inform	ation				
Patient Identifier		inth	Sex	Weight	
472	3-18-196		male	140	lbs
B. Adverse event				140	103
B. Auverse even	Product				
Outcomes attributed to adverse event					
\Box_{death}			vent		
	∐ disab	•			
\Box life-threatening	– ř		anomaly		
hospitalization	□ requi	red int	tervention		
other:					
Date of event 12-2	21-00	Date	of report	12/21/	2000
Describe event or	problem				
three months of tryi	ng everyth	ing ind	cluding al	l the over-	-the
counter products and	-		-		
am an RN, may hav					
haven't tried the ant	ibiotic or r	nalathi	ion, or the	kerosine	
still infested					
stin intested					
Relevant tests/labo	oratory da	ta			
Other relevant his					
my wife and I plan					
back from xmas vac	cation - if t	hat do	esn't work	we may	have
to cut them off.					

C. Suspect med	lication(s)				
Name: Nix					
lindane					
Dose, frequency,	route use	The	rapy d	ates	
several times		9/20	9/2000		
				to 12/2000	
Diagnosis for us	<u>م</u>	l I	Event	abated after use	
head lice	C .			d or dose reduced	
neau nee					
			doesn	t apply	
Lot #	Exp. date			reappeared after	
]	reintroduction		
			doesn'	t apply	
NDC # -	-			11.5	
Concomitant me	dical produ	cts			
D. Suspect med	lical device	e e e e e e e e e e e e e e e e e e e			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
				ealth professional	
			🛄 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					
U _{yes} U _{no}			anufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addres	SS	pl	none #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189	, Newton, M	1A. (2461		
Health profession	nal Occuj	patio	n	Also reported to	
\mathbf{V}_{yes} \square_{no}				manufacturer	
If you do NOT war	nt your ident	ity		user facility	
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform	ation			
Patient Identifier	Date of b	irth Sex	Weigh	ıt
470	02/08/92	female	48	lbs
B. Adverse event	t or produ	ict problem		
Advers	e Event &	Product Pro	blem	
Outcomes attribut	ted to adv	erse event		
death	□disab	ility		
Life-threatening congenital anomaly				
hospitalization	□ _{requi}	red interventi	on	
other: severe as	sthma			
Date of event 18/1	12/00	Date of repo	ort 12/1	8/2000
Describe event or	problem			
After treating with		-		
diagnosed with asth	ma requirii	ng stronger m	edication (han
ever before.				
Relevant tests/labo	oratory da	ta		
Other relevant his			-	dition
Mild asthma not rec	luiring prev	venter medica	tion.	

C. Suspect medication(s)					
Name:					
KP24					
Dose, frequency,	, route use	The	herapy dates		
10ml washed in ha	air for 5	12/0	2/00		
minutes thenrepea	ated.		to 12/00		
Diagnosis for us	e	ŀ	Event	abated after use	
10				d or dose reduced	
10			doesn	t apply	
Lot #	Exp. date				
Lot #	Exp. date			reappeared after	
		-	reintroduction		
NDC # -	_		doesn't apply		
Concomitant me	dical produ	cts			
none	produ				
none					
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	
			\Box_d	istributor	
			Expir	ation date	
model #					
catalog #			If im	planted, give date	
serial # lot #			-		
other #			If exp	planted, give date	
	C				
Device available	returned		anufact	urer / /	
<u>Concomitant me</u>			anuraet		
	ł				
E. Reporter					
Name and addre	SS	p	hone #	(781)449-6487	
The National Pe	diculosis A	Ľ.			
P.O. Box 610189	, Newton, N	1A. (02461		
Health professio	nal Occuj	oatio	n	Also reported to	
\mathbf{V}_{yes} \square_{no})			manufacturer	
If you do NOT wa	nt your identi	ty		user facility	
disclosed to the ma	unufacturer, p	lace	an 🔲	distributor	

A. Patient Inform	ation				
Patient Identifier	Date of birth	Sex	Weight		
466	1-2-94	female	50	lbs	
B. Adverse event	or product p	oroblem			
	Product Pro	blem			
Outcomes attribut	ed to adverse	event			
death	∐ disability				
☐ life-threatening		-			
hospitalization required intervention					
other:					
Date of event 8-00	D Dat	e of report	12/9/	2000	
Describe event or					
After using Nix crer	ne rinse 2 time	s live kice w	vere still		
letected. We have been battli	ng this for mor	ths ANd h	ave used		
Manual Removal, va	-		ure used		
····, ···, ···,	8,	0			
Relevant tests/labo	oratory data				
Other relevant his	tory, includir	ig preexisti	ing condi	tion	

C. Suspect medication(s)				
Name: Nix				
Dose, frequency, route use	The	rapy d	ates	
1/2 bottle 2 times	8/00			
			to 12/00	
Diagnosis for use	ŀ	Fvont	abated after use	
-			d or dose reduced	
live lice and nits			a of abbe feateeu	
		no		
Lot # Exp. date		Event	reappeared after	
		reintroduction		
NDC #		yes		
	ota			
Concomitant medical produ	cis			
Pronto, Rid				
D. Suspect medical device	<u> </u>			
Brand name	<i>.</i>			
Type of device				
Manufacturer name and add	dress	Oper	ator of device	
		_	ealth professional	
		□ □ 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 for evaluat				
yes no returned		anufact	urer _/_/	
Concomitant medical produ	cts			
E. Reporter				
Name and address	pl	hone #	(781)449-6487	
The National Pediculosis A	ssoc	iation		
P.O. Box 610189, Newton, N	1 Α. (02461		
Health professional Occu	patio	n	Also reported to	
\mathbf{V}_{yes} \square_{no}			manufacturer	
If you do NOT want your ident	ity		user facility	
disclosed to the manufacturer, p	olace	an 🔲	distributor	

A. Patient Inform	ation					
Patient Identifier	Date of birth	Sex	Weight			
465	11/30/92	female	48	lbs		
B. Adverse event	or product p	oroblem				
	e Event & Pro		em			
Outcomes attributed to adverse event						
☐ death ☐ disability						
\Box life-threatening \Box congenital anomaly						
hospitalization	_	ntervention				
other: nausea &	1					
Date of event 6/00) Dat	e of report	12/6/2	2000		
Relevant tests/labo	ratory data					
Other relevant his		g preexisti	ng condi	tion		

C. Suspect med	lication(s)				
Name: Kwell					
nix, all					
Dose, frequency,	, route use	The	rapy d	ates	
as prescribed		6/00			
				to 9/00	
Diagnosis for us	e	ŀ	Event	abated after use	
head lice	C			d or dose reduced	
neau nee					
T	F 1 (yes		
Lot #	Exp. date			reappeared after	
		•	reintro	oduction	
NDC # -			doesn	t apply	
	-	ota			
Concomitant me	aicai produ	cis			
D. Suspect med	lical dovice				
		;			
Brand name Type of device					
Manufacturer na	me and add	ress	Oner	ator of device	
	une une uue	1 055	L Â	ealth professional	
				ser facility	
				istributor	
				ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
Device available	for evaluati	ion?			
□ _{yes} □ _{no}	returned	to m	anufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	pl	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occuj	patio	n	Also reported to	
\mathbf{V}_{yes} $\square_{\text{normalized}}$)			manufacturer	
If you do NOT was	nt your identi	ty	_	user facility	
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
463	1-22-1993	female	45 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Prod	luct Proble	em
Outcomes attribut	ed to adverse e	event	
death	∐ disability		
☐ life-threatening		-	
hospitalization	required ir	ntervention	
other: listless,la	ack of appetite.		
Date of event 20/0	00/ Date	e of report	12/4/2000
Describe event or	-		
Can't seem to keep		-	
try. No matter how licenothing.	many ways I've	e tried noth	ing kills the
Relevant tests/labo	oratory data		
	i utor y uutu		
Other relevant his	story, including	g preexisti	ng condition
None			

C. Suspect med	lication(s)				
Name: Hair Clean 1-2-3					
RID,may	onaise,Nix,	vaseli	ne, all.		
Dose, frequency,	, route use	The	rapy d	ates	
As recomended or	n product	6/20	00	to	
lable.			to 12/2000		
Diagnosis for us	e]	Event	abated after use	
I don't understand.		s	stoppe	d or dose reduced	
			no		
Lot #	Exp. date]	Event	reappeared after	
		1	reintroduction		
			doesn'	t apply	
NDC $\#$ -	-				
Concomitant me	dical produ	cts			
D. Suspect med	lical device	9			
Brand name					
<u>Type of device</u> Manufacturer na	mo and add	Inoco	Oner	ator of dorigo	
Manufacturer na	ine and add	iress	L Â	ator of device	
				ealth professional ser facility	
				istributor	
			Ехри	ration date	
model # catalog #			If im	planted, give date	
serial #					
lot #			If ext	planted, give date	
other #					
Device available					
Upper the second			anufact	urer//	
	uicai produ	.15			
E. Reporter					
Name and addre	SS	ph	none #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professio \mathbf{V}_{yes} \square_{nc}		patio	n	Also reported to manufacturer	
-		4.77		\square user facility	
If you do NOT was disclosed to the ma	•	•	m 🔲		
anserosed to the life	maracturer, p	1400 6			

A. Patient Inform	ation				
Patient Identifier	Date of bir	th Se	X	Weight	
462	04-14-94	m	ale	49	lbs
B. Adverse event	or produc	t prob	lem		
	Adverse				
Outcomes attribut	ed to adver	se ever	nt		
\Box_{death}	∐ disabil	•			
\Box life-threatening			-		
hospitalization					1
other: Stomach			-		
Date of event 12-(Describe event or		Date of	report	12/2/2	2000
After treating with 1 woke up crying with temp of 102 Relevant tests/labo	h stomach cr	amps, v	-	-	
Other relevant his None	story, includ	ling pr	eexisti	ing condi	tion

C. Suspect medication(s)						
Name: Rid						
tea tree oil						
Dose, frequency,	route use	The	rapy d	ates		
Rid Mon Tea tree	oil Thurs.	11-2	7-00	to		
Both shampoo				to 11-30-00		
Diagnosis for us	e		Event	abated after use		
School Nurse Pos	sibly lice. Th	reat	stoppe	d or dose reduced		
			doesn'	t apply		
Lot #	Exp. date			reappeared after		
	-			duction		
NDC # -	-		uoesn	t apply		
Concomitant me	dical produ	cts				
I also used the sam			-	-		
daughter and mys	elf and so fa	r no s	sympto	ms.		
D. Suspect med	lical device	9				
Brand name						
<u>Type of device</u> Manufacturer na	mo and add	Irocc	Oper	ator of dovice		
	ine and add	11 855				
				ealth professional ser facility		
				istributor		
			Ехріі	ration date		
model #			r			
catalog #			If im	planted, give date		
serial #						
lot #			If exp	planted, give date		
other #						
Device available $\square_{\text{yes}} \square_{\text{no}}$			£4			
Concomitant me			anulaci	urer//		
Conconneunt me	produ					
E. Reporter						
Name and address phone # (781)449-6487						
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health profession		patio	n	Also reported to		
⊻ _{yes} □ _{nc}				manufacturer		
If you do NOT was disclosed to the ma	5	2		⊔user facility □distributor		
disclosed to the ma	mutacturer, p	race	aii 🔲	= 4154104101		

A. Patient Information							
Patient Identifier	Date of b	irth	Sex	Weight			
458	03/27/19	75	female	120	lbs		
B. Adverse event	or produ	ict pr	oblem				
	Adverse Event						
Outcomes attribut	ed to adv	erse e	event				
\Box_{death}	□disat	oility					
□ _{life-threatening}	$\Box_{\rm cong}$	enital	anomaly				
$\Box_{hospitalization}$	hospitalization required intervention						
other: heart problems and I sweat LINDANE							
Date of event 11/27/00 Da			of report	11/28/2	2000		

Describe event or problem

When I first put the lindane on (as a treatment for scabies) I felt nauseated and dizzy. I've had two treatments and when I sweat, I sweat Lindane (it's horrible) and I'm getting heart palpatations. I'm also having eye problems.

Relevant tests/laboratory data

Other relevant history, including preexisting condition I have allergies.

C. Suspect me	dication(s)			
Name: lindane				
Dose, frequenc	y, route use	The	rapy d	ates
cover once and		11/2	20/00	to
Repeat after 3 da	ays.			11/24/00
Diagnosis for u	se		Event	abated after use
to treat scabies			stoppe	d or dose reduced
			no	
Lot #	Exp. date		Event	reappeared after
				duction
			doesn'	t apply
NDC # -	-		uoesn	t uppiy
Concomitant m	-			
Allergra for aller	gies. To be us	ed in	definat	ely.
D. Suspect me	dical dovice			
Brand name		7		
Brand name Type of device				
Manufacturer 1	name and add	lress	6 Oper	ator of device
			\square_{h}	ealth professional
			\square_{u}	ser facility
			⊔d	istributor
			Expir	ration date
model #			- If im	planted, give date
catalog # serial #			-	plaitteu, give uate
lot #			- If ext	planted, give date
other #				, , , , ,
Device availabl				
	returned		anufact	urer _/_/
Concomitant m	edical produ	cts		
E. Reporter				
Name and addr	ess	p	hone #	(781)449-6487
The National P	ediculosis A	ssoc	ciation	
P.O. Box 61018	9, Newton, N	1A. (02461	
Health professi	onal Occu	patio	n	Also reported to
\mathbf{V}_{yes} \square_{r}	10			manufacturer
If you do NOT w				user facility
disclosed to the n	nanufacturer, p	lace	an 📃	□distributor

Patient Identifier	ation Date of birth	Sex	Weight	
454	12/10/53	female	200	lbs
3. Adverse event			200	105
	e Event & Pro		lem	
Outcomes attribut	ed to adverse	event		
death	disability			
□ life-threatening	$\Box_{\text{congenital}}$	anomaly		
hospitalization	□ required i	nterventic	n	
other: skin rash	all over body.	Chronic -	lasting m	onths
Date of event 07/2	20/00 Dat	e of repo	rt 11/24	/2000
Describe event or	problem			
Relevant tests/labo	oratory data			
Relevant tests/labo	oratory data			
Relevant tests/labo	oratory data			
		g preexis	ting cond	ition
		g preexis	ting cond	ition
		g preexis	ting cond	ition
Relevant tests/labo Other relevant his		g preexis	ting cond	ition
		g preexis	ting cond	ition
		g preexis	ting cond	ition
		g preexis	ting cond	ition

C. Suspect med	C. Suspect medication(s)						
Name: lindane							
RC at oth	RC at other times						
Dose, frequency	, route use	The	rapy d	ates			
50 ml - once a we	ek for a	05/2	000				
month or two.				to 11/2000			
Diagnosis for us	e	<u> </u>	Event	abated after use			
nits found on hair				d or dose reduced			
ints found on num			no				
Lot #	Exp. date		-				
LOI #	Exp. date			reappeared after			
			reintro	oduction			
NDC # -	-		yes				
Concomitant me	dical produ	cts					
conconnunt inc	uicui prouu						
D. Suspect med	lical devic	2					
Brand name		<i>.</i>					
Type of device							
Manufacturer na	ame and ad	dress	Oper	ator of device			
			<u> </u>	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							
ves no			anufact	urer _/_/			
Concomitant me	dical produ	cts					
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							
\mathbf{V}_{yes} $\square_{\text{normalized}}$				manufacturer			
If you do NOT wa	nt your ident	ity		user facility			
disclosed to the ma	anufacturer, p	olace	an 🔲	□distributor			

A. Patient Inform	ation				
Patient Identifier	Date of bir	th S	ex	Weight	
452	9/19/1990	1	female	105	lbs
B. Adverse event	or produc	t pro	blem		
	Product P				
Outcomes attribut	ted to adver	se ev	ent		
death	∐ disabil	•			
\Box life-threatening			•		
hospitalization		ed inte	ervention		
other:					
Date of event 2/99		Date of	of report	11/21/	2000
Describe event or		c -		F 1	
I have been treating				-	
1999 to the present. toys, use bedding sp					
and recommended.	pray. 1 mi-p	ick al	iu uo wiii	at is lequ	neu
and recommended.					
Relevant tests/labo	ratory dat	a			
	futory aut	•			
Other relevant his	story, inclu	ding	preexisti	ng condi	tion

C. Suspect med	lication(s)					
Name: Kwell						
generic lice shampoo						
Dose, frequency,		The	rapy d	ates		
Kwell: 1 oz		2/19	99			
Generic: as directe	ed			to 11/00		
Diagnosis for us	0		Evont	abated after use		
-				d or dose reduced		
Use for head lice a	and knit remo	oval	stoppe	u or uose reduced		
			no			
Lot #	Exp. date		Event	reappeared after		
			reintro	oduction		
			yes			
NDC # -	-		5-2			
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		
			\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						
□ _{yes} □ _{no}			anufact	urer _/_/		
Concomitant me	dical produ	cts				
E. Reporter	E. Reporter					
Name and address phone # (781)449-6487						
The National Pe	The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461						
Health professio		oatio	n	Also reported to		
\mathbf{V}_{yes} \square_{no}				manufacturer		
If you do NOT was	•	•		User facility		
disclosed to the ma	nufacturer, p	lace	an 🔲	□ distributor		

A. Patient Inform	ation				
Patient Identifier	Date of bi	rth	Sex	Weigh	t
451	2-12-93		female	70	lbs
B. Adverse event	or produ	ct pr	oblem		
	Product	Probl	em		
Outcomes attribut	ed to adve	rse e	vent		
death	∐disabi	ility			
☐ life-threatening		nital a	anomaly		
hospitalization		ed in	tervention		
other:					
Date of event 8/00)	Date	of report	11/20)/2000
Describe event or	problem				
constant use of lice	products re	sulte	d in \$100's	s of doll	ars
spent with no relief					
1					
Relevant tests/labo	oratory dat	a			
Other relevant his	story, inclu	iding	preexisti	ing cond	lition
	,		P- 001100		

C. Suspect med	C. Suspect medication(s)				
Name: Rid					
Nix, Lindane, Oil, Mayonnaise					
Dose, frequency,	Dose, frequency, route use Therapy dates				
standard dosage fo	or over the	8/00			
counter every wee	ek			to 11/00	
Diagnosis for us	e	ŀ	Event	abated after use	
Lice	•			d or dose reduced	
Liec			doesn	t apply	
Lot #	Even data				
LOI #	Exp. date			reappeared after	
			reintro	oduction	
NDC # -	-		yes		
Concomitant me	dical produ	cts			
oil with mayonnai	-		can ov	ernight and	
diligent searching					
the nits out with n					
D. Suspect med	dical device	2			
Brand name					
Type of device					
			🔲 u	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 yes no	for evaluation for ev		anufact	urer _/_/	
Concomitant me	dical produ	cts			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189	P.O. Box 610189, Newton, MA. 02461				
Health professio)		n	Also reported to manufacturer	
If you do NOT was	•	•		User facility	
disclosed to the ma	anufacturer, p	lace	an 🔲	distributor	

A. Patient Inform	ation				
Patient Identifier	Date of bi	irth	Sex	Weig	ht
450	12-17-92		female	58	lbs
B. Adverse event	or produ	ict pi	oblem		
	Product		-		
Outcomes attribut	_		event		
death	∐ disab	•			
☐ life-threatening			anomaly		
hospitalization		red ir	tervention	n	
other:	1				
Date of event 08-0		Date	e of repor	t 11/1	.9/2000
Describe event or My daughter has ha	_	is trea	tments to	head lie	ce, and
I regularly and vigo					
and pick the lice, Bu PLEASE HELP!	it all our ef	forts	have been	n for not	hing.
Relevant tests/labo	oratorv da	ta			
	,				
Other relevant his	story, inclu	udinş	g preexis	ting cor	ndition

C. Suspect med	lication(s)				
Name: lindane					
Rid					
Dose, frequency,	, route use	Ther	apy d	ates	
Rid 3x 10 days ap	art	08-00)		
Lindane 2X 10 da	ys apart			to 11-00	
Diagnosis for us	e	I	Event	abated after use	
Head Lice		s	toppe	d or dose reduced	
			no		
Lot #	Exp. date				
L0t #	Exp. uate			reappeared after	
		r	eintro	oduction	
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	
			h	ealth professional	
				ser facility	
			□d	istributor	
			Expir	ration date	
model #			TC		
catalog #			II Im	planted, give date	
serial # lot #			TC	1	
other #			n exp	planted, give date	
Device available	for evaluat	ion?	I		
			nufact	urer / /	
Concomitant me					
E. Reporter					
Name and addre					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occu	pation	ı	Also reported to	
\mathbf{V}_{yes} $\square_{\text{normalized}}$				manufacturer	
If you do NOT wa	nt your ident	ity		user facility	
disclosed to the ma	unufacturer, p	lace a	n 🔲	□ distributor	

Patient Identifier Date of birth Sex Weight 447 07/09/91 female 50 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:
Outcomes attributed to adverse event death disability life-threatening congenital anomaly hospitalization required intervention other:
death disability life-threatening congenital anomaly hospitalization required intervention other:
□ life-threatening □ congenital anomaly □ hospitalization □ required intervention other: □ □ Date of event 11/16/00 Date of report 11/17/2000 Describe event or problem After having treated her for the last 3 months with every over the counter product available, nothing helps clear this pest on a more permanent basis. After the last failure, I
hospitalization required intervention other:
other: Date of event 11/16/00 Date of report 11/17/2000 Describe event or problem After having treated her for the last 3 months with every over the counter product available, nothing helps clear this pest on a more permanent basis. After the last failure, I
Date of event 11/16/00 Date of report 11/17/2000 Describe event or problem After having treated her for the last 3 months with every over the counter product available, nothing helps clear this pest on a more permanent basis. After the last failure, I
Describe event or problem After having treated her for the last 3 months with every over the counter product available, nothing helps clear this pest on a more permanent basis. After the last failure, I
After having treated her for the last 3 months with every over the counter product available, nothing helps clear this pest on a more permanent basis. After the last failure, I
over the counter product available, nothing helps clear this pest on a more permanent basis. After the last failure, I
pest on a more permanent basis. After the last failure, I
-
Relevant tests/laboratory data
Other relevant history, including preexisting condition

Triage Unit Sequence #

C. Suspect medication(s)

Name:	Kwell

Dose, freque	ncy, route use	The	erapy dates
2 oz. one time days if needeo		9/05/00 to 11/16/00	
Diagnosis fo Nits	r use	_	Event abated after use stopped or dose reduced no
Lot #	Exp. date		Event reappeared after reintroduction
NDC #			yes

Concomitant medical products

I tried everything available at least once. Even went and bought a metal comb to get at the nits. Checked their head every day for a week following treatment, only to have

).	Sus	pect	med	lical	devi	ice	

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
Device available for evaluation? Dyes no returned to ma Concomitant medical products E. Reporter	nufacturer//
	one # (781)449-6487
The National Pediculosis Associ	
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	ation				
Patient Identifier	Date of bi	rth	Sex	Weight	ţ
444	01-21-96		female	35	lbs
B. Adverse event	or produ	ct pi	oblem		
	Product	Prob	lem		
Outcomes attribut			event		
\Box death	∐ disabi	•			
□ life-threatening			anomaly		
hospitalization	□ requi	red in	tervention		
other:			_		
Date of event 01-(Date	of report	11/16	/2000
Relevant tests/labo	ratory da	ta			
Other relevant his N/A	tory, inclu	ıdinş	g preexisti	ng cond	lition

C. Suspect med	lication(s)			
Name: lindane				
9 out of	the list.			
Dose, frequency,	route use	Ther	apy d	ates
Since January 199)	
-				to 11/00
Diagnosis for us	e	ŀ	Event	abated after use
Head lice - still the		s	toppe	d or dose reduced
unsuccessful treatments			no	
Lot #	Exp. date		-	
	Exp. uate			reappeared after oduction
N/A		r	eintro	duction
NDC # -	-		yes	
Concomitant me	dical produ	cts		
A-200, Clear, Rid,	-		lavonn	aise Vinegar
Lindane, Elimite a			-	-
and Elimite have o				
D. Suspect med	lical device)		
Brand name				
Type of device				
			□u	ealth professional ser facility istributor
			Ехрії	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device available yes no	for evaluati		nufact	urer _/_/
Concomitant me				
E. Reporter				
Name and addre		-	one #	(781)449-6487
The National Pe	diculosis A	ssoci	iation	
P.O. Box 610189	, Newton, N	1A. 0	2461	
Health profession ↓ yes □ nc		pation	1	Also reported to manufacturer
If you do NOT wai	-	-		\Box user facility
disclosed to the ma	nufacturer, p	lace a	in 🔲	□distributor

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
442	08/28/89	female	68 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	_	-	
hospitalization	✓ required i	ntervention	
other:			
Date of event 09/1	13/2000 Dat	e of report	11/11/2000
Describe event or	problem		
She has has head lic		-	
over. I have tried so	oo many treatn	neants for he	er, I'm afraid
it's dangerous.			
Dolomont to stallabe			
Relevant tests/labo	oratory data		
Other relevant his			
She is now getting v			
and her head is full washing and coming		r blood (this	s 18 with
the time).	, uii		
,-			

C. Suspect medication(s)				
Name: Rid				
mayonna	uise			
Dose, frequency,	route use	The	rapy dates	
approx every two	weeks	06/2		
			to 11/11/2000	
Diagnosis for use		L	Event abated after use	
head lice	-		stopped or dose reduced	
neud nee			doesn't apply	
Lot #	Exp. date	_		
	Exp. uate		Event reappeared after	
not known]	reintroduction	
NDC # -	-		doesn't apply	
Concomitant me	dical produ	cts		
She's had it consis			one year	
	,			
D. Suspect med	lical device)		
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 #				
Device available	_			
$\square_{\text{yes}} \square_{\text{no}}$	Image: The second se	to ma	anufacturer/_/	
	Image: The second se	to ma		
$\square_{\text{yes}} \square_{\text{no}}$	Image: The second se	to ma		
□ _{yes} □ _{no} Concomitant me	returned dical produc	to ma cts		
Concomitant me	returned dical produces	to ma cts pł	anufacturer/_/	
Concomitant me E. Reporter Name and addre	returned dical production ss diculosis A	to ma cts pł	anufacturer/_ / hone # (781)449-6487 iiation	
Concomitant me E. Reporter Name and addre The National Pe	returned dical products ss diculosis A , Newton, M nal Occup	to ma cts ph ssoc 1A. 0	anufacturer/_/ hone # (781)449-6487 :iation)2461	
Concomitant me E. Reporter Name and addres The National Pe P.O. Box 610189 Health profession	contract of the second	to ma cts ph ssoc 1A. 0 patio	anufacturer/_/ hone # (781)449-6487 itation)2461 n Also reported to	

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
435	12/26/63		female	130	lbs
B. Adverse event	or produ	lct p	roblem		
	Advers	se Eve	ent		
Outcomes attribut	ed to adv	erse e	event		
∐ death	∐disat	oility			
✓ life-threatening	_ `		anomaly		
▲ hospitalization			tervention	l	
other: THYRO	ID CANC	ER			
Date of event 07/1	19/99	Date	e of report	t 11/2	/2000
Describe event or	problem				
Freated with Lindar	ne/Qwell a	bout 1	13 yrs. ago	, not real	izing
t had any health pro	ecautions	with i	t. Diagnos	sed with	
Thyroid Cancer in J	uly, 1999.	Thro	ough resear	rch have	
ealized that my using	ng Qwell 1	nay h	ave had so	mething	to do
with getting Cancer.					
in getting culler					
		4 -			
Relevant tests/labo	oratory da	ita			
04 1 41		1.	• 4	• •	• . •
Other relevant his	story, incl	uaing	g preexist	ing cond	ition

Dose, frequency,	route use	Ther	apy da	ntes	
one treatment	1000000000	0000			
		0000	to		
		L		0000	
Diagnosis for us	e			bated after use	
scabies		S	topped	l or dose reduced	
			yes		
Lot #	Exp. date		Event r	eappeared after	
unkown				duction	
			doa!	annly	
NDC # -	-		doesn't	appiy	
Concomitant me	dical produ	cts			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Opere	4 C J	
			Opera	ator of device	
			<u> </u>		
			he	ealth professional er facility	
				ealth professional	
				ealth professional er facility stributor	
model #				ealth professional er facility	
model #			Expir	ealth professional er facility stributor	
model # catalog # serial #			Expir	ealth professional er facility stributor ation date	
catalog # serial #			Expir If imp	ealth professional er facility stributor ation date	
catalog # serial # lot #			Expir If imp	ealth professional er facility stributor ation date planted, give date	
catalog # serial # lot # other # Device available	f <u>or</u> evaluat	 ion?	Expir If imp	ealth professional eer facility stributor ation date blanted, give date lanted, give date	
catalog # serial # lot # other # Device available yesno	for evaluat	ion?	Expir If imp	ealth professional eer facility stributor ation date blanted, give date lanted, give date	
catalog # serial # lot # other # Device available yesno	for evaluat	ion?	Expir If imp	ealth professional eer facility stributor ation date blanted, give date lanted, give date	
catalog # serial # lot # other # Device available yesno	for evaluat	ion?	Expir If imp	ealth professional eer facility stributor ation date blanted, give date lanted, give date	
catalog # serial # lot # other # Device available Uves no Concomitant mee	for evaluat	ion?	Expir If imp	ealth professional eer facility stributor ation date blanted, give date lanted, give date	
catalog # serial # other # Device available yes no Concomitant med E. Reporter	for evaluat returned dical produ	ion? to ma	Expir If imp	ealth professional eer facility stributor ation date blanted, give date lanted, give date	
catalog # serial # other # Device available yes no Concomitant med E. Reporter Name and addres	for evaluat returned dical produ ss	ion? to ma cts	If exp	ealth professional eer facility stributor ation date planted, give date lanted, give date	
catalog # serial # other # Device available Device available Device available Device available Device available Device available Device available Device available Device available The National Pe	for evaluat returned dical produ ss diculosis A	ion? to ma cts	If exp anufactor	ealth professional eer facility stributor ation date planted, give date lanted, give date	
catalog # serial # other # Device available yes no Concomitant med E. Reporter Name and addres The National Pe P.O. Box 610189 Health profession	for evaluat returned dical produ ss diculosis A , Newton, M nal Occuj	ion? to ma cts	If imp iation 2461	ealth professional er facility stributor ation date lanted, give date lanted, give date urer _/_/ (781)449-6487	
catalog #	for evaluat returned dical produ ss diculosis A , Newton, M nal Occuj	to ma cts ph sssoc: 1A. 0 pation	If imp iation 2461	ealth professional er facility stributor ation date blanted, give date lanted, give date urer _/_/ (781)449-6487 Also reported to	
catalog # serial # other # Device available yes no Concomitant med E. Reporter Name and addres The National Pe P.O. Box 610189 Health profession	for evaluat returned dical produ ss diculosis A , Newton, M nal Occuj nt your ident	ion? to ma cts cts IA. 0 pation ity	iation	ealth professional er facility stributor ation date lanted, give date lanted, give date urer _/_/ (781)449-6487	

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weigh	nt
433	04/12/93		female	98	lbs
B. Adverse even					
	Product				
Outcomes attribu			event		
□ death	∐ disat	•	1		
□ life-threatening □ hospitalization			anomaly		
other:	Lequ	irea ir	iterventio	011	
Date of event 09/	08/00	Date	f	.4 11/	1/2000
		Date	e of repo	r i 11/	1/2000
Describe event or NOne of the over the	-	nrodu	icts have	worked	ven
prescription Ovide					
outbreak within 3 r					
Relevant tests/lab	oratory da	nta			
Other relevant hi	story, incl	uding	g preexis	ting con	dition

C. Suspect medication(s)					
Name: Ovide					
Nix, Rid	Pronto,Gene	eric L	ice Sha	ampo	
Dose, frequency,	route use	The	rapy d	ates	
followed direction	s however	0908	90800		
used every 5 days				to 110100	
Diagnosis for us	e		Event abated after use		
head lice	•			d or dose reduced	
nead nee	lead nee			t apply	
Lot #	Exp. date			reappeared after	
	_			duction	
				duction	
NDC # -	-		yes		
Concomitant me	dical produ	cts			
Currently on Bac	trim for the i	next (3 davs.	Take 4	
teaspoons by mou				-	
1 5		5			
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	
			\square_{u}	ser facility	
			\square_d	istributor	
			Expir	ation date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #	<u></u>				
Device available	for evaluat		anufact	urer / /	
Concomitant me					
	·				
E. Reporter					
Name and addre	SS	pl	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, N	1 A. (02461		
Health professio ✓ _{yes} □ _{nc}		patio	n	Also reported to manufacturer	
If you do NOT was	nt vour identi	itv		user facility	
disclosed to the ma	-	-	an 🔲	distributor	

A. Patient Information	ation			
Patient Identifier	Date of bir	th Sex	Weigl	nt
429	01/09/74	female	e 110	lbs
B. Adverse event				
	e Event & P		oblem	
Outcomes attribut	_			
\Box death	∐ disabil:			
☐ life-threatening		ital anoma	-	
hospitalization	•	d intervent	tion	
other: very sore	_			
Date of event 28/1 Describe event or		Date of rep	ort 10/2	8/2000
have had nits for ab lotion shampoo mou they are still there	ise nit comb	and even o		-
Relevant tests/labo	oratory data	I		
Other relevant his ashma,	tory, includ	ling preex	cisting con	dition

C. Suspect medication(s)					
Name: tea tree oil					
hairclean	123,clear,and	d all	the oth	er ones that are	
Dose, frequency,	, route use	The	rapy d	ates	
every week		10/0	0/02/00		
				to 28/10/00	
Diagnosis for us	e	ŀ	Event	abated after use	
head lice				d or dose reduced	
nead nee					
•	-		yes		
Lot #	Exp. date			reappeared after	
			reintro	oduction	
			yes		
NDC # -	-				
Concomitant me					
lyclear, clear/fullm					
shampoo/teatree c					
electronic nit com	b,plastic nit o	comb	metal	nit comb i've used	
D. Suspect med	lical device	•			
Brand name					
Type of device			-		
Manufacturer na	ame and add	iress	□ □ □ u	ator of device ealth professional ser facility istributor	
				ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
	returned	to m	anufact	urer <u>/_/</u>	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	pl	hone #	(781)449-6487	
The National Pe					
P.O. Box 610189	, Newton, M	1A. (02461		
Health professio	-	oatio	n	Also reported to manufacturer	
If you do NOT wa	nt your identi	ty		user facility	
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor	

	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
427	10/17/55		female	135	lbs
B. Adverse event	or produ	ict pr	oblem		
	Product	Prob	lem		
Outcomes attribut	_		vent		
death	∐disab	oility			
□ life-threatening			anomaly		
hospitalization		red in	terventior	l	
other: symptom	n return				
Date of event 06/9	99/	Date	of repor	t 10/27/2	2000
same spot. used lind rumeric now.	ane, elimi	te. try	ng to nd	using nee	m &
Relevant tests/labo	indiation y ad				

Triage Unit Sequence #

C. Suspect medication(s) Name: elimite 5% Dose, frequency, route use Therapy dates 30 g once a week 06/2000 to 10/2000Diagnosis for use Event abated after use stopped or dose reduced doctor said to apply then reapply again in 7 days no Lot # Exp. date Event reappeared after reintroduction 1003152 04-02 doesn't apply NDC # **Concomitant medical products** june 1999 eliomite which worked after 90g in three 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 # 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_{no} user facility If you do NOT want your identity distributor disclosed to the manufacturer, place an

A. Patient Informa	ation			
Patient Identifier	Date of birth	Sex	Weight	
426	10/28/91	female	80	lbs
B. Adverse event	or product p	roblem		
	Product Prob			
Outcomes attribut		event		
□ death	∐ disability			
□ life-threatening		-		
hospitalization		itervention		
other: FAMILY		_		
Date of event 10/1 Describe event or		e of report	10/27/20)00
WORKING.				
Relevant tests/labo	ratory data			

C. Suspect medication(s)					
Name: lindane					
IV'E TRIED EVERY	THI	NG			
Dose, frequency, route use	The	rapy d	ates		
ONCE A WEEK	10/1				
			to 10/27		
Diagnosis for use		Fvont	abated after use		
LICE AND NITS			d or dose reduced		
LICE AND NITS					
doesn't apply					
Lot # Exp. date Event reappeared after					
		reintro	oduction		
NDC #		doesn'	t apply		
Concomitant medical produ					
I HAVE TRIED EVERYTHI					
HAVE EVEN RESORTED T SHAMPOO BUT IT DON'T					
		KK EH	TIEK.TIEET I WI		
D. Suspect medical device	e				
Brand name					
Type of device Manufacturer name and add	drood	Oner	ator of device		
	ures				
			ealth professional ser facility		
			istributor		
//		Expi	ration date		
model		- If im	planted, give date		
catalog # serial #		-	p		
lot #		If ext	planted, give date		
other #			, 8		
Device available for evaluat	ion?				
□ _{yes} □ _{no} □ _{returned}	to m	anufact	urer _/_/		
Concomitant medical produ					
E. Reporter					
Name and address	r	hone #	(781)449-6487		
The National Pediculosis A			(101)++9-0+01		
P.O. Box 610189, Newton, N					
Health professional Occu			Also reported to		
\mathbf{V}_{yes} \mathbf{I}_{no}	Paul		manufacturer		
If you do NOT want your ident	itv		user facility		
	olace		distributor		

A. Patient Inform	ation				
Patient Identifier	Date of bir	th Se:	X	Weigh	t
422	03/05/94	fei	nale	58	lbs
B. Adverse even					
	Product P				
Outcomes attribu	ted to adver	se ever	nt		
⊔ death	∐ disabili	•			
☐ life-threatening			•		
hospitalization	•	d interv	vention		
other: missed s					
Date of event 10/		Date of	report	10/24	4/2000
effects of this We k Help - we are going school!! Relevant tests/lab e	crazy and sh	ne is mi			аррса
		ling nr	reexisti	ng con	

C. Suspect medication(s)				
Name: lindane				
over the	counter lice s	shamj	poos and gels	
Dose, frequency,	, route use	The	rapy dates	
lindane - 3 times,		10/1′		
time Gels - twice			to 10/24/00	
Diagnosis for us	e	 1	Event abated after use	
_			stopped or dose reduced	
school nurse and pharmacist				
T (11)	F 14		doesn't apply	
Lot #	Exp. date		Event reappeared after	
		1	reintroduction	
NDC # -	-		yes	
Concomitant me	dical produ	ots		
Conconntant me	uicai produ	cis		
D. Suspect med	lical device	5		
Brand name		, 		
Type of device				
Manufacturer na	me and add	lress	Operator of device	
			health professional	
			\square user facility	
			distributor	
			Expiration date	
model #				
catalog #			If implanted, give date	
serial #				
lot #			If explanted, give date	
lot # other #			If explanted, give date	
other # D <u>ev</u> ice av <u>ail</u> able	f <u>or</u> evaluat			
other # D <u>ev</u> ice av <u>ail</u> able	for evaluati	to ma	If explanted, give date	
other # Device available	for evaluati	to ma		
other # Device available	for evaluati	to ma		
other # Device available Uyes Ino Concomitant me	for evaluati returned dical produce	to ma cts		
other # Device available Uves no Concomitant me E. Reporter	for evaluati	to ma cts ph	anufacturer _ / /	
other # Device available yes no Concomitant me E. Reporter Name and addre	for evaluati returned dical produce ss diculosis A	to ma cts pł	anufacturer/_ / none # (781)449-6487 iation	
other # Device available yes no 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	to ma cts ph .ssoc 1A. 0	anufacturer/_/ none # (781)449-6487 iation 22461	
other # Device available yes no Concomitant me E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	for evaluati returned dical product ss diculosis A Newton, N nal Occup	to ma cts ph ssoc 1A. 0 patio	anufacturer/_/ none # (781)449-6487 iation 2461 n Also reported to	

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
417	2/17/90		female	60	lbs
B. Adverse event	or produ	lct p	roblem		
	Product	Prob	lem		
Outcomes attribut	ed to adv	erse e	event		
death	disat	oility			
Life-threatening		enital	anomaly		
hospitalization		ired ir	tervention		
other:					
Date of event 8/00)	Date	e of report	10/18/	2000
Describe event or	problem				
Treated hair once p	er week fo	r thre	e weeks wi	th RID N	JIX
and prescription Lir	ndane Con	nbed h	air with se	veral diff	ferent
styles of combs It is	s now mid	Octo	ber and we	had to the	reat
her hair with the res	st of the pr	escrip	tion tonigh	nt	
Relevant tests/labo	oratory da	nta			
	i utory ut				
Other relevant his	story, incl	uding	g preexisti	ng cond	ition

Triage Unit Sequence #

C. Suspect medication(s) Name: lindane NIX and RID Dose, frequency, route use Therapy dates 8/00 1 time per week for 3 weeks to Again every 2 weeks 10/00 Diagnosis for use Event abated after use stopped or dose reduced Itching first, then found lice no Lot # Exp. date Event reappeared after reintroduction yes NDC # **Concomitant medical products** everyone in the house has been treated again and again. everything washed in hot water, vacuumed etc. our house has always been very clean and we all shower every day, 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_{no} user facility If you do NOT want your identity distributor disclosed to the manufacturer, place an

	ation	a		
ent Identifier		Sex	Weight	
408	01/14/2000	male	48	lbs
iverse event	or product p Adverse Ev			
omes attribut	ed to adverse			
leath	disability	e vent		
ife-threatening		anomaly		
ospitalization	required in	-		
other:				
of event 08-3	30-00 Dat	e of report	10/10/2	2000
be event or	problem			
-	FEET AND HA	ANDS		
		11125		
rant tests/labo	ratory data			
yant tests/labo	ratory data			
ant tests/labo	ratory data			
7ant tests/labo	ratory data			
vant tests/labo	ratory data			
vant tests/labo	ratory data			
		g preexisti	ng condi	tion
		g preexisti	ng condi	tion
		g preexisti	ng condi	tion
evant tests/labo er relevant his		g preexisti	ng condi	tion
		g preexisti	ng condi	tion
		g preexisti	ng condi	tion
		g preexisti	ng condi	tion
		g preexisti	ng condi	tion

C. Suspect medication(s)					
Name: lindane					
1%					
Dose, frequency,	route use	The	rapy d	ates	
RUB ON BODY	RUB ON BODY 08-2		8-27-00		
				to 09-30-00	
Diagnosis for us	e	1	Event	abated after use	
SCABBIES	•			d or dose reduced	
SCADDIES			••		
			no		
Lot #	Exp. date			reappeared after	
		1	reintro	oduction	
		-	yes		
NDC # -	-		-		
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	
			\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			-		
□ _{yes} □ _{no}			anufact	urer _/_/	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addres	ss	pł	none #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, N	1A. 0	2461		
Health profession	nal Occuj	oatio	n	Also reported to	
\mathbf{V}_{yes} \square_{no}	-			manufacturer	
If you do NOT war	nt your identi	ity		user facility	
disclosed to the ma	5	-	an 🔲	distributor	

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
406	07-02-94	female	63 lbs
B. Adverse event	or product	problem	
	Product Pro	blem	
Outcomes attribut	ted to adverse	event	
death	disability	/	
□ life-threatening	$\Box_{\text{congenita}}$	al anomaly	
hospitalization	\Box required	intervention	
other:			
Date of event 5/20	000 Da	te of report	10/6/2000
Describe event or	problem		
cna't get rid of infes	tation of daugh	nter's head lie	ce
Relevant tests/labo	oratory data		
Other relevant his	story, includi	ng preexisti	ing condition
continued from abo			
infestation, we jum	-		
recommended may	•	•	•
least on our son, a w		-	
something so we m			
-	-		

C. Suspect med	C. Suspect medication(s)				
Name: lindane					
nix, clear, mayoniaise, generic lice shampoo & lice					
Dose, frequency, route use Therapy dates					
10 minutes on hea	d every 2	5/20	00		
days	•			to 10/2000	
Diagnosis for us	e]	Event	abated after use	
over the phone, sc		5	stoppe	d or dose reduced	
recommendation			doesn'	t apply	
Lot #	Exp. date	_			
L0t #	Exp. date		Event reappeared after reintroduction		
		ľ			
NDC # -	-		doesn	t apply	
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	
			Ē	ealth professional	
user facility					
				istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			_ If explanted, give date		
other #					
Device available for evaluation?					
Uyes Ino Ireturned to manufacturer _/_/					
Concomitant me	Concomitant medical products				
E. Reporter					
Name and addre	SS	pł	none #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189, Newton, MA. 02461					
	Health professional Occupation Also reported to				
\mathbf{V}_{yes} $\square_{\text{normalized}}$)			manufacturer	
If you do NOT want your identity					
disclosed to the manufacturer, place an 🔲 🔲 distributor					

A. Patient Informa	ation				
Patient Identifier	Date of b	irth	Sex	Weigh	t
399	10/08/19	97	female	31	lbs
B. Adverse event	or produ	ict p	roblem		
	Advers		-		
Outcomes attribut	ed to adv	erse e	event		
death	∐disat	•			
☐ life-threatening	<u> </u>		anomaly		
✓ hospitalization	□ requi	red ir	tervention		
other:					
Date of event 09/1	4/2000	Date	e of report	9/28	3/2000
Describe event or p My daughter was ru eyes irrigated follow Nice to Lice" which was diagnosed with	shed to the ving the us was labele chemical o	e of a ed as l conju	product correction product corrections and the product correction of t	alled "N	ot
Relevant tests/labo	oratory da	ita			
Other relevant his		uding	g preexisti	ing cond	lition
History not relevan	t.				

Triage Unit Sequence #

C. Suspect medication(s) Name: Not Nice to Lice Dose, frequency, route use Therapy dates 1 8 oz. bottle, one time 09/14/2000 to 09/14/2000 Diagnosis for use Event abated after use stopped or dose reduced Don't understand question. yes Lot # Exp. date Event reappeared after reintroduction doesn't apply NDC # **Concomitant medical products** An electronic lice comb was used on my daughter's dry hair prior to the use of this "non-toxic" produce. 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_{no} user facility If you do NOT want your identity

disclosed to the manufacturer, place an

distributor

tient Identifier	Date of birth	Sex	Weight	
398	6-29-89	female	87	lbs
Adverse event	or product p	roblem		
	Product Pro	blem		
tcomes attribut	ed to adverse	event		
death	disability			
life-threatening		l anomaly		
hospitalization	required i	ntervention		
other:				
te of event 9-1-	00 Dat	e of report	9/28/2	2000
evant tests/labo				

C. Suspect medication(s)					
Name: lindane					
1%					
Dose, frequency,	, route use	The	rapy d	ates	
shampoo twice 10) days apart	9/00			
				to 9/00	
Diagnosis for us	e]	Event	abated after use	
head lice		5	stoppe	d or dose reduced	
neuu nee			no		
Lot #	Exp. date		-		
LOI #	Exp. date			reappeared after	
		נ	reintroduction		
NDC # -	-		yes		
Concomitant me	dical produ	rts			
	uicai produ	5			
D. Suspect med	lical device	<u>.</u>			
Brand name		, 			
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			1 Â	ealth professional	
user facility					
				istributor	
			Ехріі	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
	ot #		If exp	planted, give date	
other #					
Device available for evaluation?					
yes no returned to manufacturer _/_/					
Concomitant medical products					
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occu	patio	n	Also reported to	
\mathbf{V}_{yes} $\square_{\text{normalized}}$)			manufacturer	
If you do NOT was	•	•		□user facility	
disclosed to the ma	nufacturer, p	lace a	an 🔲	distributor	

A. Patient Inform	ation			
Patient Identifier	Date of birtl	n Sex	Weigh	t
396	03/27/1991	male	60	lbs
B. Adverse event	or product	problem		
	Product Pr	oblem		
Outcomes attribut	ed to advers	e event		
death	∐ disabilit	•		
□ life-threatening		al anomaly		
hospitalization		interventio	n	
other:				
Date of event 06/0	07/2000 D a	ate of repo	rt 9/2'	7/2000
ages,9,8,6,3, got hea perscreption med.I children still have li rid of them. Relevant tests/labo	have returned ce.I have tried	to Arizona	and my	
Other relevant his	story, includi	ng preexis	ting con	dition

C. Suspect n	nedication(s)				
Name: lindar	ie				
Dose, frequen	cv, route use	Therapy d	ates		
used six times		6/07/2000			
used six times	since June	0/07/2000	to 09/27/2000		
Diagnosis for	use	Event	abated after use		
killing lice		stoppe	d or dose reduced		
		no	no		
Lot #	E-m data				
LOT #	Exp. date		reappeared after		
		reintro	oduction		
NDC #		yes			
	- modical nucl	ata			
	medical produ	CIS .			
Rid,A-200					
D. Suspect n	nedical device	ę			
Brand name					
Type of device					
Manufacture	name and add	iress Open	ator of device		
			ealth professional		
			iser facility		
		۵	listributor		
		Expi	ration date		
model #					
catalog #		If im	planted, give date		
serial #					
		If ex	planted, give date		
other #					
	ble f <u>or</u> evaluat				
\square_{yes} \square_{n}	o returned	to manufac	turer//		
Concomitant	medical produ	cts			
E. Reporter					
Name and add	lress	phone #	(781)449-6487		
The National	Pediculosis A	ssociation			
P.O. Box 610		A 00461			
	189, Newton, N	IA. 02461			
	sional Occuj	1A. 02461 pation	Also reported to		
Health profes			manufacturer		
	sional Occuj	pation			

Patient Identifier	ation Date of birth	Sex	Weight	
		~	_	
395	05/25/94	female	35	lbs
B. Adverse event				
	e Event & Pro		m	
Outcomes attribut	ed to adverse	event		
∐ death	∐ disability			
□ life-threatening		anomaly		
hospitalization	required in	ntervention		
other: difficulty	breathing			
Date of event 09/2	.5/00 Dat	e of report	9/27/2	.000
This was so strong t preathing, felt like v next day; still lice bi ungs also hurt, Blist numb.	omiting, very o ting into her he	lizzy. even ad. I also g	worse, the	y Y

Other relevant history, including preexisting condition we were pretty healthy before putting on the toxic shampoo that should have skull and cross bones on it.

Triage Unit Sequence #

C. Suspec	t medication(s)		
Name: R&	λC		
Ру	rethin 0.33%, Pipe	eronyl Bu	toxide Technical 3.0
Dose, frequ	iency, route use	Therap	y dates
about 30-40) mL per person	09/25/00	
	1 1		to 09/25/00
Diagnosis f	for use	Eve	nt abated after use
Head lice	tor use		oped or dose reduced
i leau lice		-	-
Lot#		yes	
Lot #	Exp. date		nt reappeared after
		rein	ntroduction
NDC #	I	doe	esn't apply
	nt modical and de-	lata	
	nt medical produ		
We are not	willing to try any o	other mec	lications for lice.
D. Suspec	t medical devic	e	
Brand nam			
Type of dev			
	rer name and ad	dress O	perator of device
			health professional
		Ī	$\exists_{\text{user facility}}$
		Ī	
		Ex	xpiration date
model #		If	implanted, give date
catalog # serial #		 **	piunceu, give udie
seriai # lot #		 Tf	explanted, give date
other #		11	capitanicu, give udle
Device eve	ilable for evaluat	ion?	
	\square_{no} $\square_{returned}$		facturer / /
	nt medical produ		Iaciulei//
Conconnta	nt meurear produ	115	
E. Reporte	er		
Name and	address	phon	e # (781)449-6487
The Nation	nal Pediculosis A	_	
	10189, Newton, N		
Health pro		pation	Also reported to
Ileann pro ∎ _{yes}		Pation	manufacturer
•		•	
	DT want your ident		
disclosed to	the manufacturer, j	place an	