A. Patient Inform	ation							
Patient Identifier	Date of birt	h S	ex	Weight				
1054	07/17/1998	f	emale	40	lbs			
B. Adverse event	or product	pro	blem					
Advers	e Event & P	rodu	ct Proble	m				
Outcomes attribut	Outcomes attributed to adverse event							
death disability								
☐ life-threatening ☐ congenital anomaly								
hospitalization			ervention					
other: scabs on								
Date of event 09/2			of report	1/6/2	2003			
Describe event or								
We have not been a	_	of th	e problen	n even wi	th			
numerous treatment	-		-					
scratches her head.				_				
hair and find severa				n her scal	p,			
and after 3 months	we are very c	once	rned.					
Relevant tests/labo	oratory data							
	·							
Other relevant his	tory includ	ina -	nroovisti	na aondi	tion			
NA	story, menu	ıng I	DI CEXISTI	ng conun	11011			
NA								

Triage Unit Sequence #	

	lication(s)				
Name: Rid					
Nix					
Dose, frequency, route use The			erapy dates		
1 box every 3-4 da	ays	09/20			
			to 12/2001		
Diagnosis for use			Event abated after use		
to repeat every 7	days	S	stopped or dose reduce		
			doesn't apply		
Lot#	Exp. date	ī	Event reappeared after		
na		1	reintroduction		
NDC# -		$\dashv$	yes		
	-				
Concomitant med	dical produ	cts			
D. Suspect med	lical device	9			
Brand name					
Type of device					
Manufacturer na	me and add	dress	Operator of device		
			health professional		
			user facility		
			distributor		
			Expiration date		
<b>3 3</b> 11					
			If implanted, give date		
catalog #			If implanted, give date		
model # catalog # serial # lot #					
catalog # serial # lot #			If implanted, give date		
catalog # serial # lot # other #		ion?			
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	for evaluat		If explanted, give date		
catalog # serial # lot # other # Device available yesno	for evaluati	to ma			
catalog # serial # lot # other # Device available	for evaluati	to ma	If explanted, give date		
catalog # serial # lot # other #  Device available yesno  Concomitant med	for evaluati	to ma	If explanted, give date		
catalog # serial # lot # other # Device available yesno Concomitant med	for evaluati	to ma	If explanted, give date		
catalog # serial # lot # other #  Device available	for evaluati	to ma	If explanted, give date anufacturer/_/ none # (781)449-6487		
catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	for evaluation returned dical productions see the diculosis A	cts  ph	If explanted, give date  anufacturer/ /  none # (781)449-6487  iation		
catalog #	for evaluati  returned dical products ss diculosis A , Newton, M	phassoc	If explanted, give date  anufacturer/_/  none # (781)449-6487  iation 2461		
catalog #	for evaluation returned dical products  ss diculosis A , Newton, M nal Occup	phassoc	If explanted, give date  anufacturer/_/  none # (781)449-6487  iation		
catalog #	for evaluation returned dical productions of the control of the co	phassoc MA. 0	If explanted, give date  anufacturer/_/  none # (781)449-6487  iation 2461  n Also reported to		

A. Patien	t Inform	ation						
Patient Id	lentifier	Date of birth	Sex	Weight				
	1044	02/25/97	female	45 1	bs			
B. Advers	se even	or product p	roblem					
		Product Prob	lem					
Outcomes	Outcomes attributed to adverse event							
death		disability						
	reatening		anomalı					
	_							
_	alization	required in	ntervention		_			
other:								
Date of ev	ent 12/2	25/02 <b>Date</b>	e of report	12/26/200	)2			
Describe (	event or	problem		<u> </u>				
	-	aughter for head						
		n still seeing live						
	rry but i ı	used lindane and	I they are st	ill alive~~~				
help~								
Relevant t	tests/labo	oratory data						
Other rel	evant his	story, including	g preexisti	ng conditio	n			

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Nix					
lindane					
Dose, frequency,	route use	The	rapy d	ates	
3 times			2/23/0		
	12/2		2,0	to 12/26/02	
D'			Event	abated after use	
Diagnosis for us	e		stopped or dose reduce		
head lice			stopped of dose reduced		
	1		no		
Lot#	Exp. date		Event 1	reappeared after	
			reintroduction		
ND C #			yes		
NDC# -	-				
Concomitant me	dical produ	cts			
D. Suspect med	dical device	)			
Brand name					
Type of device			T <sub>0</sub>		
Manufacturer na	ime and add	lress	1 —		
				ealth professional	
				ser facility istributor	
			_		
			Expir	ration date	
model #			If im	planted, give date	
catalog #			-   111 1111	pianteu, give date	
serial # lot #			If over	planted, give date	
other#			- III CAL	nanicu, give uaic	
Device available	for evaluati	ion?			
$\square_{\text{yes}} \square_{\text{no}}$				urer / /	
Concomitant me					
	_				
E Demostes					
E. Reporter					
Name and addre		Ĺ		(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
	Health professional Occupation Also reported t				
yes no manufacturer					
If you do NOT was	•	-		user facility distributor	
disclosed to the ma	ınufacturer, p	lace	an 🔳	-uisuidutor	

A. Patient Infor	mation							
Patient Identifi	er Date of	birth S	Sex	Weight				
1029	05/30/9	6	female	45	lbs			
B. Adverse eve	ent or proc	duct pro	oblem					
		t Probl						
Outcomes attributed to adverse event								
death disability								
	☐ life-threatening ☐ congenital anomaly							
□hospitalizatio	on □req	uired int	ervention					
other:								
Date of event 1	2/01/02	Date	of report	12/8/2	002			
Describe event o	or problem	1						
We've treated wit	th tea oil co	nditione	r and then	with				
malathion pestici			nd nymph	lice (as w	vell			
as nits) surviving	all treatme	nts.						
	_							
Relevant tests/laboratory data								
Other relevant	history, ind	cluding	preexisti	ng condit	ion			
o ther relevant		uuiiig	PI COMBIL	ng conun				

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: malathion					
Dose, frequency, route use The			erapy dates		
one dose (each: m	y child and	120	102		
I both treated, wi	-			to 120202	
Diagnosis for us	se.		Event	abated after use	
Use on dry hair.			stopped or dose reduced		
thoroughly, work	-	f			
L_: T 10	1.1		no		
Lot#	Exp. date			reappeared after	
			reintro	oduction	
NDC# -	<u>l</u>		doesn'	t apply	
	311	-4.			
Concomitant me	=				
We are also manu	-	_		-	
				Standard treatment	
for UK kids is to			oner or t	ea tree oil	
D. Suspect med	dical device	<del>)</del>			
Brand name					
Type of device			_		
Manufacturer n	ame and add	lress	Oper	ator of device	
				ealth professional	
			user facility		
			distributor		
			Expi	ration date	
model #			_		
catalog #			_ If implanted, give date		
serial #					
lot #			If explanted, give date		
other #					
Device available $\square_{ m yes} \ \square_{ m no}$				urer _ /_ /	
Concomitant me	dical produ	cts			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	ediculosis A	sso	ciation	_	
P.O. Box 610189	Newton, N	<b>ΙΑ</b> . (	02461		
				Also reported to	
·				manufacturer	
			user facility distributor		
disclosed to the m	anufacturer, p	lace	an 🔳	-uisurbutor	

	-						
A. Patient Inform	ation						
Patient Identifier	Date of b	irth	Sex	Weight	,		
1028	02/02/50		female	170	lbs		
B. Adverse event	or produ	ıct pı	oblem				
Product Problem							
Outcomes attribut	ed to adv	erse e	event				
□death	□disab	ility					
☐ life-threatening	_ `		anomaly				
hospitalization	□requi	red in	terventio	n			
other:							
Date of event 11/1	15/02	Date	of repor	t 12/4	/2002		
Describe event or	problem						
I have tried just abo Rx: doctors thought I went to a psychiat resistant lice do exi His experience with vasoline on the scal seemed to smother body hair needed to	I was nuts rist & disc st. a adolesent p with pla- the little cr be shaved	teens stic w itters	ause I stil ed I am no & resista rrap over . Howeve	I have the ot nuts & ant lice is it for 3 da er any oth	m, so that that		
Relevant tests/labo	oratory da	ta					
Other relevant his	tory, inch	udina	preexis	ting cond	lition		
I am IgG3 deficient	,		, r. Jemis				

C. Suspect med	lication(s)				
Name: Kwell					
Dose, frequency, route use The			erapy dates		
?		10/2	2002	to	
			to 11/2002		
Diagnosis for us	e		Event abated after use		
lice			stopped or dose reduced		
			doesn't apply		
Lot#	Exp. date		Event reappeared aft		
1			reintroduction		
"			yes		
NDC# -	-		-		
Concomitant me	=				
Rid, Nix, Lindane	, Mayonaise,	Oliv	ve Oil, (	Green tree oil,	
Acticin,					
D. Suspect med	lical device	•			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
			$\square_{\mathrm{h}}$	ealth professional	
			user facility		
			distributor		
			Expiration date		
model #					
catalog #			If implanted, give date		
serial #			-		
lot #			If exr	planted, give date	
other #				zazzea, gr e amee	
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}}  \square_{\mathrm{no}}$			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, MA. 02461					
Health professio	nal Occup	oatio	n	Also reported to	
✓ yes □no □ manufacture					
If you do NOT wa	nt your identi	ty		user facility	
disclosed to the manufacturer, place an distributor					

A. Patien	t Inform	ation				
Patient Id	lentifier	Date of bi	rth	Sex	Weight	
	1020	07/04/191	7	female	113	lbs
B. Adver	se event	or produ	ct p	roblem		
	Advers	e Event &	Prod	luct Probl	em	
Outcomes	s attribut	ted to adve	rse e	event		
death		□disabi	lity			
$\Box$ life-th	reatening	$\Box_{\mathrm{conge}}$	nital	anomaly		
$\square_{\mathrm{hospit}}$	alization	□ requir	ed ir	ntervention		
other:						
Date of ev	vent 11/0	05/1989	Date	of report	11/17/	2002
Describe	event or	problem				
		ested with h		_		
		beauty shop				
		l months ha	_	-		_
	•	rawling, itc narket so m	_	_		
		ing now. H				
	-	things? I ca				
scalp, but	she insist	ts they're st	ill th	ere. After	13 yars, i	t's a
		ost her mind			-	
		there We l				n
		man to spra What can y				
		rson can go				
1	•	C				
D -14	44 /1 - 1		-			
Relevant	tests/iab(	oratory dat	a			
			•			
	evant his	story, inclu	ıdinş	g preexisti	ing cond	ition
None						

Triage Unit Sequence #	

C. Suspect medication(s)						
Name: Nix						
Dose, frequency	, route use	The	rapy d	ates		
as instructed on b		199	0			
			to 2002			
Diagnosis for us	e		Event abated after use			
I don't understand	l the question	1	stopped or dose reduced			
here	1		no			
Lot #	Exp. date		Event.	mannaged often		
	Zarpv date			reappeared after oduction		
			i cillui (	ouut II OII		
NDC# -	-		yes			
Concomitant me	dical produ	cts				
Rid, same time pe	riod					
Hair Clean 2000-						
R & C between 1		0				
D. Suspect med	dical device	)				
Brand name						
Type of device						
Manufacturer na	ame and add	lress	Oper	ator of device		
				ealth professional		
				ser facility		
				istributor		
"			Expir	ration date		
model #			- If im	planted, give date		
catalog #			-   11 1111	pianteu, give uate		
serial #						
lot # other #			- III exp	planted, give date		
<b>Device available</b> $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$				urer / /		
Concomitant me						
Producto						
E. Reporter						
Name and addre	Name and address phone # (781)449-6487					
The National Pediculosis Association						
P.O. Box 610189	Newton, N	ΙΑ. (	02461			
Health professio	nal Occup	patio	n	Also reported to		
				manufacturer		
If you do NOT wa	nt your identi	ity		user facility		
disclosed to the ma			an 🔲	distributor		

A. Patient Information									
Patient Identifier	Date of b	irth	Sex	Weight					
1019	07-23-19	996	female	60	lbs				
B. Adverse event	B. Adverse event or product problem								
	Product	Prob	lem						
Outcomes attribut	ted to adv	erse e	event						
$\Box_{\text{death}}$									
☐ life-threatening	$\Box_{\mathrm{cong}}$	enital	anomaly						
hospitalization	_ `		tervention						
other:									
Date of event 11-0	02-2002	Date	of report	11/17/2	2002				
Describe event or		Date	or report	11/11//2	.002				
We have treated my	_	for the	e 6th time	I know sh	ne				
has had this for at le	-								
and NIX 4 times and									
her head when it wa	as still wet	after	using the co	omb and I					
would see live adult	lice walki	ing arc	ound, I calle	ed my doc	tor				
and he perscribed so		-							
an adult lice that wa	_	-	-	-					
moving. I need to ch					he				
perscription late las	t night. I a	am not	t sure if tha	it did it.					
Relevant tests/labo	oratory da	ata							
Other relevant his	story, incl	luding	g preexisti	ng condit	tion				

Triage Unit Sequence #	

C. Suspect med	lication(s)						
Name: Nix							
RID and Lindane prescription shampoo							
Dose, frequency,	route use	Therapy	dates				
RID 1 time NIX 4	times,	11-02-200	)2				
Lindane 1 time			to 11-16-2002				
Diagnosis for use	e	Event	abated after use				
shampoo was used		stopp	ed or dose reduced				
on box, leave on for			n't apply				
Lot #	Exp. date		***				
	Ехр. чан		reappeared after oduction				
not known							
NDC# -	-	does	n't apply				
Concomitant me	dical produ	cts					
	• "						
D. Suspect med	lical device	;					
Brand name							
Type of device							
Manufacturer na	me and add	lress Ope	rator of device				
			health professional				
			user facility				
			distributor				
		Exp	iration date				
nodel #		Te in	anlanted give date				
catalog # serial #		11 111	nplanted, give date				
ot #		If ex	xplanted, give date				
other #		11 €2	rpranicu, give uate				
Device available	for evaluati	ion?					
	returned		cturer/_/				
Concomitant me							
E. Reporter							
-	ss	nhone	# (781 <u>)44</u> 9_6487				
Name and address			# (781)449-6487				
E. Reporter Name and addres The National Pe	diculosis A	ssociation					
Name and address The National Pe P.O. Box 610189	diculosis A	ssociation IA. 02461	n				
Name and addres The National Pe P.O. Box 610189 Health profession	diculosis A , Newton, M nal Occup	ssociation IA. 02461	Also reported to				
Name and address The National Pe P.O. Box 610189	diculosis A , Newton, M nal Occup	ssociation IA. 02461 pation	n				

A. Patient Inform	ation						
Patient Identifier	Date of bir	th S	Sex	Weight			
1009	11/09/1990	) :	female	95	lbs		
B. Adverse even	t or produc	t pro	blem				
Advers	se Event & P	rodu	ct Proble	em			
Outcomes attribu	ted to adver	se ev	ent				
$\Box_{\text{death}}$	□disabil	ity					
☐ life-threatening	Congen	ital a	nomaly				
hospitalization	require	d inte	ervention				
other: vomiting	7						
Date of event 11/	02/2002 <b>I</b>	Date (	of report	11/3/2	2002		
Describe event or	problem						
Bugs keep coming				-			
says prevents reinfo			ys. It mad	le her sick	at		
her stomach with lo	ots of vomitin	ıg.					
Relevant tests/laboratory data							
Other relevant his	story, inclu	ding	preexisti	ng condi	tion		
none.							

Triage Unit Sequence #	

C. Suspect med	lication(s)	C. Suspect medication(s)					
Name: Nix	(-/						
	na sprav/ ocl	zard	hedding	r enrav			
rid bedding spray/ eckard bedding spray							
Dose, frequency,			rapy d				
Once a day shamp	•	10/2	29/2002	to			
Twice on the first	day.			11/03/2002			
Diagnosis for us	e		Event abated after use				
Head lice Live and	d nits. Bugs a	nd	stoppe	d or dose reduced			
nits are both white	e and brown		no				
Lot#	Exp. date		Event	reappeared after			
2e2024	•			duction			
20202-1			Cinti	duction			
NDC# -	-		yes				
Concomitant me	dical produc	cts					
Everday that I me	=		n todas	y Sunday			
Everday that I me	iitionea. we	u un	u touay	, Sunday.			
D. Suspect med	lical device						
	ilcai device						
Brand name							
Type of device Manufacturer na	me and add	Irocc	Oper	ator of device			
manufacturer na	inic and add	ii CS	l Â				
				ealth professional			
				ser facility istributor			
			_				
			Expi	ration date			
model #				1 ( 1 1 1 1 )			
catalog #			-  II IM]	planted, give date			
serial #							
lot #			_ If exp	olanted, give date			
other #			]				
Device available							
$\square_{\text{yes}} \square_{\text{no}}$	returned	to m	anufact	urer//			
Concomitant me	dical produ	cts					
E. Reporter							
Name and addre	Name and address phone # (781)449-6487						
The National Pe		ᆮ					
P.O. Box 610189	, Newton, M	IA. (	02461				
Health professio	nal Occup	oatio	n	Also reported to			
$ \mathbf{V}_{\text{yes}}  \square_{\text{no}}$	)			manufacturer			
If you do NOT want your identity user facility							
disclosed to the ma	-	-	an 🔲	distributor			

A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
1004	06/21/67	female	135	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Prod	luct Proble	em	
Outcomes attribut	ed to adverse e	event		
$\Box_{\text{death}}$	<b>✓</b> disability			
☐ life-threatening	□ congenital	anomaly		
hospitalization	required in			
other:				
Date of event 09/0	04/02 <b>Date</b>	of report	10/27/2	.002
Describe event or	problem			
R&C product in eye	=	resulted in	burns and	
holes in cornea - lon				
photophobia, eye pa			throbbing	,
and results in heada	che in behind ey	e.		
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condit	ion
NONE!!!!!!!		- <b>-</b>	Ü	

Triage Unit Sequence #	

C. Suspect medication(s)						
Name: R&C						
.33% pyrethrin, 3% piperonyl butoxide technical						
Dose, frequency,	route use	Thei	apy d	ates		
5 doasages, 2 dose	es 7 davs	08/0				
apart, June, July a	-			to 10/31/02		
Diagnosis for us	ρ.	h	Event abated after use			
Lice infestation	C		stopped or dose reduced			
Lice infestation						
	<b>.</b>	_	no			
Lot#	Exp. date			reappeared after		
C18266		1	eintro	oduction		
NDC# -		$\dashv$	yes			
Concomitant me	dical produc	ets				
nitial injury: diag	-		cal hu	m Prescribed:		
Voltaren anti-infla						
oatch.		г.,	, -2110	F, e, e		
D. Suspect med	lical device	<b>,</b>				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
			$\square_{\mathrm{h}}$	ealth professional		
				ser facility		
			$\square_{d}$	istributor		
			Expir	ration date		
nodel #						
catalog #			If im	planted, give date		
serial #						
ot #			If exp	planted, give date		
other #						
Device available yes no				, ,		
Concomitant me			ınuract	urer/_/		
Concomitant inc	aicai produ	CLO				
- Poporter						
E. Reporter		1	on a H	(791)//(0.6/197		
Name and addre The National Pe				(781)449-6487		
P.O. Box 610189						
Health profession			1	Also reported to		
$\mathbf{\nabla}_{\mathrm{yes}}  \square_{\mathrm{nc}}$	-	jau101	u	Also reported to manufacturer		
	f you do NOT want your identity user facility					
i you do NOT was			տ 🔲	distributor		

A. Patient Inform	ation				
Patient Identifier	Date of bir	th	Sex	Weight	
999	09/19/98		male	19	lbs
B. Adverse event	or produc	t pr	oblem		
	Adverse	Eve	ent		
Outcomes attribut	ted to adver	se e	event		
death	disabil	ity			
life-threatening	Conger	nital	anomaly		
hospitalization	□ require	ed in	tervention		
other:					
Date of event 10/0	06/01	Date	of report	10/18/2	2002
Describe event or	problem				
6 mo. old prescribed	d Kwell Loti	on f	for scabies.	Died fro	m
Lindane poisening.					
Relevant tests/labo	oratory data	a			
Other relevant his	tour inclu	dine	v munaviati	na sandi	tion.
none known	story, inclu	սուչ	g preexisu	ng conai	uon
none known					

Triage Unit Sequence #	

C. Suspect medication(s)						
Name: Kwell						
Dose, frequenc	y, route use	Ther	apy d	ates		
"bathe the child	and give it	10/02	2/01			
once a day for th			-,	to 10/05/02		
Mother missed of Diagnosis for u	no dow and	 	Twont	abated after use		
	.50		stopped or dose reduce			
Scabies						
	1		doesn'	t apply		
Lot#	Exp. date			nt reappeared after stroduction		
NDC# -			doesn'	t apply		
Concomitant m						
D. Suspect me	edical device	÷				
Brand name						
Type of device						
Manufacturer i	name and add	lress	□ <sub>h</sub>	ator of device ealth professional ser facility istributor		
			Expi	ration date		
model #			If im	planted, give date		
catalog # serial #			11 1111	pianicu, give uaic		
lot #			If over	olanted, give date		
other #			псх	nameu, give date		
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						
J	10		1	Also reported to		
If you do NOT w				user facility		
disclosed to the n	nanufacturer, p	lace a	ın 🔲	□distributor		

B. Adverse event or product prob  Adverse Event & Product  Outcomes attributed to adverse eve  ☐ death ☐ disability  ☑ life-threatening ☐ congenital and ☐ hospitalization ☐ required interesting other:	emale olem et Proble ent omaly	Weight 300	lbs
997 4-17-51 fe  B. Adverse event or product prob  Adverse Event & Product  Outcomes attributed to adverse eve  death disability  life-threatening congenital and hospitalization required inter-  other:	emale olem et Proble ent omaly	300	lbs
B. Adverse event or product prob  Adverse Event & Produce  Outcomes attributed to adverse eve  death disability  life-threatening congenital and hospitalization required inter-  other:	olem et Proble ent		lbs
Adverse Event & Produc  Outcomes attributed to adverse eve  ☐ death ☐ disability  ☑ life-threatening ☐ congenital and ☐ hospitalization ☐ required inter other:	t Proble nt omaly	m	
Outcomes attributed to adverse eve	ent omaly	m	
death disability  life-threatening congenital and hospitalization required inter	omaly		
☐ life-threatening ☐ congenital and ☐ hospitalization ☐ required interother:			
hospitalization required inter			
other:			
	vention		
D-4 - 6 4 6 20 02   D : 4			
Date of event 6-29-02 Date of	f report	10/14/2	002
Describe event or problem			
please help I have tried every shampood Ovide and Linadine. I have been to Drs Health Dept which located eggs. Three lice but I do. Daughter has cut my hair picked for nits, yet I find I am pulling trying to get rid of nits. Please contact ridesperate. 248-588-5512	s.x3 and e times the r short. Hout half	my local he Dr. saic Iusband	
Relevant tests/laboratory data			
Other relevant history, including p hypertension,MS,Depression, Vasculi Allergy			ion

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: A-200					
Kwell, Ovide, Nix, Pronto, Coconut shampoo, and					
Dose, frequency	, route use	The	rapy d	ates	
according to packa	ige	6-29	9-02	to	
				10-9-02	
Diagnosis for us	e		Event	abated after use	
head lice			stoppe	d or dose reduced	
			no		
Lot#	Exp. date		Event	reappeared after	
n/a				duction	
<b>ND</b> G #			doesn	t apply	
NDC# -	-				
Concomitant me	dical produ	cts			
all listed above					
D. Suspect med	dical device	<u>.</u>			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
			$\square_{\mathrm{h}}$	ealth professional	
			$\square_{\mathrm{u}}$	ser facility	
			$\square_{d}$	istributor	
			Expi	ration date	
model #			- Te :	ulantad aina data	
catalog #			-  II IM]	planted, give date	
serial # lot # _			If ex	olanted, give date	
other #			- In cap	Junica, give date	
Device av <u>ail</u> able					
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to m	anufact	urer/_/	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	ss	p	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189	, Newton, M	ΙΑ. (	02461		
Health professio		patio	n	Also reported to	
$\mathbf{V}_{\mathrm{yes}}$ $\square_{\mathrm{no}}$	)			manufacturer	
If you do NOT wa	•	•		user facility	
disclosed to the ma	anufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform					
Patient Identifier	Date of bi	rth	Sex	Weight	;
996	06/07/199		female	60	lbs
B. Adverse event	or produ	ct p	oblem		
	Advers	e Eve	ent		
Outcomes attribut	ed to adve	erse e	vent		
death	<b>✓</b> disab	ility			
life-threatening	Conge				
hospitalization	<b>∠</b> requi	red in	terventio	n	
other:					
Date of event 12/1	9/99	Date	of repor	<b>t</b> 10/11	/2002
Describe event or	problem				
	muane on i	ner ai	id 3 foste	r children	on a
at our house, they we wottle of Lindane an avever warned about	y 2 weeks vere full of a d I shampo possible si	vhen lice. poed d ide ef	the 3 wou Their doo everyone.	ctor sent a	back big
regular basis. Every at our house, they we bottle of Lindane an ever warned about Relevant tests/labout	y 2 weeks vere full of ad I shampe possible si	vhen llice. ooed d ide ef	the 3 wou Their doo everyone. fects.	ald arrive ctor sent a We were	back big

Triage Unit Sequence #	

C. Suspect i	medication(s)				
Name: linda	ne				
Dose, freque	ncy, route use	Therapy	dates		
1-2 times a m	onth	02/1999	2/1999 to		
shampooed			11/1999		
Diagnosis for	r use	Evei	nt abated after use		
headlice		stop	ped or dose reduced		
		no			
Lot#	Exp. date	Evei	nt reappeared after		
			troduction		
		doe	sn't apply		
NDC #					
	medical produ	cts			
NONE					
D. Cuencet	andical device				
	medical device	<del>)</del>			
Brand name Type of devic					
	r name and add	lress Or	erator of device		
.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	i iidiiic diid dac	ΙĒ	health professional		
			user facility		
			distributor		
		Ex	piration date		
model #			•		
catalog #		If i	mplanted, give date		
serial #					
lot #		If •	explanted, give date		
other #					
	ible for evaluati				
Concomitant	no returned medical produ	to manui cts	acturer/_/		
concomitant	medical produ	CUS			
E. Reporter		_	W (504) 440 5405		
Name and ad			e# (781)449-6487		
	The National Pediculosis Association				
	189, Newton, N	IA. 0246	1		
Health profe		oation	Also reported to		
✓ yes	lno l		manufacturer user facility		
-	want your identi e manufacturer, p		distributor		

A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
995	05/11/98	female	42	lbs
B. Adverse event	t or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse e	event		
$\Box_{\text{death}}$	disability			
□ life-threatening	□ congenital	anomaly		
hospitalization		ntervention		
other:				
Date of event 10/1	10/02 <b>Date</b>	of report	10/11/2	002
Describe event or				
treated head lice wit	=	e lice did n	ot die	
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condit	ion

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: Kwell					
Dose, frequency, route use Therapy dates					
1 1/2 oz X 1		10/1	10/02		
				to 10/10/02	
Diagnosis for us	e		Event	abated after use	
head lice	•			d or dose reduced	
nead nec					
T . 4 #	E . 1.4.			t apply	
Lot#	Exp. date			reappeared after	
			reintroduction		
NDC# -			doesn'	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	
			$\square_{\rm h}$	ealth professional	
				ser facility	
				istributor	
				ration date	
			LAPII	ation date	
model # catalog #			- If im	planted, give date	
catalog # serial #			-   '	, 8	
lot #			If ext	planted, give date	
other #				Junica, gree aute	
Device available	for evaluati	ion?	1		
yes $\square_{no}$				urer / /	
Concomitant me	dical produ	cts			
	<b>J</b>				
E Papartar					
E. Reporter Name and address phone # (781)449-6487					
		ഥ		(701)++7-0+07	
The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461					
				Algo wow and all 4	
Health professio  ✓ yes □ no	_	patic	)11	Also reported to manufacturer	
-				user facility	
If you do NOT wa				distributor	
disclosed to the ma	anutacturer, p	lace	an 🔳		

A. Patient Inform	ation							
Patient Identifier	Date of birth	Sex	Weight					
994	10/18/99	female	30	lbs				
B. Adverse event	or product p	roblem						
	Product Prob	lem						
Outcomes attribut	ted to adverse e	event						
death	□ death □ disability							
☐ life-threatening	Congenital	anomaly						
□hospitalization	☐required in	ntervention						
other: shaved h	ead							
Date of event 10/1	10/02 <b>Date</b>	e of report	10/10/2	2002				
Describe event or	problem							
My 4 children were which a Malathion were still prevalent, week the headlice vagain. After a furthe Yesterday they wer shaven off.	based product. A They were trea were still prevale or week the head	After 1 week ted again. A ent. They were again.	k the head After a fur ere treated gain prese	ther d ent.				
Relevant tests/labo		g preexisti	ng condi	tion				

C. Suspect med	C. Suspect medication(s)						
Name: malathion							
Dose, frequency, route use Therapy dates							
· · ·			3/02				
				to 10/10/02			
Diagnosis for use	2	h	Event abated after use				
_			stopped or dose reduced				
live headlice							
	<u>,                                      </u>			no			
Lot#	Exp. date	]	Event reappeared after				
		1	reintroduction				
NDC# -			yes				
	diaal x J	ot a					
Concomitant med	=						
Over the years 199							
used including LY PRIODERM, CO		AIK (	UND	HONEK,			
D. Suspect med							
-	iicai uevice	7					
Brand name Type of device							
Manufacturer na	me and add	lress	Oper	ator of device			
			ΙÀ	ealth professional			
				user facility			
			distributor				
			Expir	ration date			
model #							
model # catalog #			If implanted, give date				
serial #							
lot #			If exp	olanted, give date			
other #							
Device available							
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			nufact	urer/_/			
Concomitant med	dical produ	cts					
E. Reporter							
Name and addres	SS	ph	one #	(781)449-6487			
The National Pediculosis Association							
P.O. Box 610189, Newton, MA. 02461							
Health professional Occupation Also reported							
$\mathbf{V}_{\mathrm{yes}}$ $\square_{\mathrm{no}}$				manufacturer			
If you do NOT war	nt your identi	ty		user facility			
disclosed to the ma	nufacturer, p	lace a	ın 🔳	□distributor			

A. Patient Inform	A. Patient Information						
Patient Identifier	Patient Identifier Date of birth Sex Weight						
992	07/27-95		female	50	lbs		
B. Adverse event	or produ	ıct pr	oblem				
Advers	e Event &	Prod	uct Proble	m			
Outcomes attribut	ted to adv	erse e	vent				
$\Box_{\text{death}}$	$\Box_{\mathrm{disab}}$	oility					
☐ life-threatening	$\Box_{\mathrm{cong}}$	enital	anomaly				
hospitalization	_ ~		tervention				
other: loss of ha							
		D 4	• 4	10/0/0	2002		
Date of event 10-2		Date	of report	10/9/2	2002		
Describe event or	_		1 11	1	1		
I found headlice on	-						
her hair is now brea though we have trea	-	_					
because she still has		-			)1		
finding live bugs. It		-	-		ated		
the whole house inc							
dont know what els	_						
Relevant tests/labo	ratory de	ıta					
Refevant tests/labe	natory uz	ııa					
Other relevant his	story, incl	uding	g preexisti	ng condi	tion		

Triage Unit Sequence #	

C. Suspect medication(s)						
Name: lindane						
Dose, frequency,	route use	Thei	nerapy dates			
bottle every 2 w		10/0				
ice are gone				to 10/10/12		
			Event	abated after use		
Diagnosis for use			stopped or dose reduce			
reatent of head lic	ce			a or abscreaacea		
			no			
Lot#	Exp. date	1	Event reappeared afte			
		1	reintroduction			
AID C. II		$\dashv$	doesn'	t apply		
NDC # -	-			- ^ -		
Concomitant me	dical produ	cts				
D. Suspect med	lical device	)				
Brand name						
Type of device			1			
Manufacturer name and address Operator of device						
health professional						
user facility distributor						
				istributor		
			Expir	ration date		
nodel #						
catalog #			If im	planted, give date		
serial #						
ot # other #			If exp	planted, give date		
			<u> </u>			
Device available						
$\square_{ m yes} \square_{ m no}$			anufact	urer/_/		
Concomitant me	uicai pi ouu	CIS				
E. Reporter						
Name and addre	ss	ph	none #	(781)449-6487		
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health profession	nal Occuj	patio	n	Also reported to		
<b>✓</b> yes □ <sub>nc</sub>	,			manufacturer		
f you do NOT war	nt your identi	ity		user facility		
lisclosed to the ma			an 🔳	□distributor		

A. Patient Inform	ation							
Patient Identifier	Date of birth	Sex	Weight					
989	01/14/97	female	55.0	lbs				
B. Adverse event or product problem								
Advers	e Event & Prod	luct Proble	em					
Outcomes attribut	ted to adverse o	event						
$\Box_{\text{death}}$	death disability							
☐ life-threatening	□ congenital	anomaly						
$\square_{ m hospitalization}$	☐required in	ntervention						
other: caused lg	g red blotches an	d whelps a	bove & be	ehin				
Date of event 09/1	10/02 <b>Date</b>	of report	10/6/2	2002				
Describe event or	problem							
Child was treated w				sse				
for head lice.Advers Product did not get			reatment.					
r roduct did not get	nu or nee or mi	5						
Relevant tests/labo	oratory data							
Other relevant his	story, including	g preexisti	ng condi	tion				
none								

		lication(s)				
Name: generic lice shampoo						
rid mousse						
Dose, frequency, route use The				Therapy dates		
used 3-4	oz of pro	duct one	9-10	0-02	4-	
time repe	ated in 7	days with			to 9-17-02	
Diagnosis for use				Event	abated after use	
head lice					d or dose reduced	
nead nec	mesaur	)II				
Lot#		E 1-4-		no		
Lot #		Exp. date			reappeared after	
				reintroduction		
NDC #		_		doesn'	t apply	
	tont	dical prod	otc			
		dical produ				
		e and Pronto				
sucess, ai	so using	robicomb p	resei	my.		
D. Suco	oot mod	lical device				
		ilcai devic	7			
Brand na Type of d						
		me and add	dres	Oner	ator of device	
Manurac	turer me	inic and au	ai co			
					health professional user facility	
				distributor		
11//				Expii	ration date	
model # _ catalog #				- If im	planted, give date	
serial # _				-   '	· · · · · · , g · · · · · · · ·	
lot #				If ext	planted, give date	
other#_					, 8	
Device av	vailable	for evaluat	ion?			
$\square_{\mathrm{yes}}$	$\square_{\rm no}$	returned	to m	nanufact	turer/_/	
Concomi	tant me	dical produ	cts			
F Renoi	rter					
E. Reporter Name and address phone # (781)449-6487						
			ᆫ		(101)++9-0+01	
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
				Also reported to		
				manufacturer		
	f you do NOT want your identity				user facility distributor	
disclosed	to the ma	ınufacturer, p	lace	an 🔳	-uisuibutor	

		-		
A. Patient				
Patient Ide	entifier	Date of birth	Sex	Weight
	983	09/24/91	female	75 lbs
B. Advers	e event	or product p	roblem	
		Product Prob	lem	
Outcomes	attribut	ted to adverse	event	
$\Box_{\text{death}}$		disability		
□life-thre	eatening		anomaly	
hospita	_		ntervention	
other:	nzation	— required in	iter vention	
L				
Date of eve		i	e of report	9/25/2002
Describe e		=		
		first. Did not ki		
was prescrit	oed Lind	ane and still am	finding liv	e lice.
Relevant to	ests/labo	oratory data		
Other rele	vant his	story, includin	g preexisti	ng condition
				J

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: lindane					
nix					
Dose, frequency	, route use	The	Therapy dates		
used nix two time		7/14			
treatment one wee		,, .		to 9/20/02	
Usad lindana thra	•	ŀ	Event	abated after use	
Diagnosis for us				d or dose reduced	
Nix not effective a prescribed lindane		ľ	зторрс	a or dosc reduced	
	;. •		no		
Lot#	Exp. date	[	Event reappeared after reintroduction		
		]			
		_	yes		
NDC# -	-				
Concomitant me	dical produ	cts			
none					
D. Suspect med	dical device	)			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
			I □h	ealth professional	
user facility					
			Шd	istributor	
			Expi	ration date	
model #			. —		
catalog #			If im	planted, give date	
serial #					
lot # other #			If exp	planted, give date	
Device available				, ,	
□ <sub>yes</sub> □ <sub>no</sub>				urer//	
Concomitant me	aicai produ	cis			
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					
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$	_			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma			an 🔲	distributor	

Describe event or problem  I descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I phoned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck head and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
B. Adverse event or product problem  Adverse Event & Product Problem  Outcomes attributed to adverse event  death disability life-threatening congenital anomaly hospitalization required intervention other: skin rash  Date of event 09/17/02 Date of report 9/21/2002  Describe event or problem  I descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I phoned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck head and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
Adverse Event & Product Problem  Outcomes attributed to adverse event  death disability life-threatening congenital anomaly hospitalization required intervention other: skin rash  Date of event 09/17/02 Date of report 9/21/2002  Describe event or problem I descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I phoned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck head and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
Outcomes attributed to adverse event  death disability life-threatening congenital anomaly hospitalization required intervention other: skin rash  Date of event 09/17/02 Date of report 9/21/2002  Describe event or problem I descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I phoned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck head and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
Outcomes attributed to adverse event  death disability life-threatening congenital anomaly hospitalization required intervention other: skin rash  Date of event 09/17/02 Date of report 9/21/2002  Describe event or problem descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I phoned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck nead and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
death disability congenital anomaly congenital anomaly hospitalization required intervention other: skin rash  Date of event 09/17/02 Date of report 9/21/2002  Describe event or problem  descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I choned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck nead and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
life-threatening congenital anomaly hospitalization required intervention other: skin rash  Date of event 09/17/02 Date of report 9/21/2002  Describe event or problem I descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I phoned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck head and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
hospitalization required intervention other: skin rash  Date of event 09/17/02 Date of report 9/21/2002  Describe event or problem  I descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I choned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck nead and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
Oate of event 09/17/02 Date of report 9/21/2002  Describe event or problem  I descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I phoned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck nead and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
Date of event 09/17/02 Date of report 9/21/2002 Describe event or problem I descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I choned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck need and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
Describe event or problem descovered I had lice after noticing it on some children at thurch. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I phoned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck nead and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit emoval comb everyday. On 09/17/02 I found live lice. I choned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck need and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live
critter from my head. I am at my witts end. I have not gone anywhere to avoid infesting others. The two children were neverly infested. I have been told they have been treated and are back to school and church. I don't know what else to do. Thank you.

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: Kwell				
Dose, frequency,	route use	Ther	apy d	ates
1 time		09/17	7/02	
				to 09/17/02
Diagnosis for us	e	I	Event	abated after use
Lice		s	toppe	d or dose reduced
			doesn'	t apply
Lot#	Exp. date	I	Event 1	reappeared after
				duction
		_	doesn'	t apply
NDC# -	-		200011	rr-y
Concomitant me	dical produ	cts		
Nix 09/14/02 did 1	not work			
D. Cuspertur	liaal davi			
D. Suspect med	lical device	;		
Brand name Type of device				
<u> 1 ype of device</u> Manufacturer na	me and add	lress	Oper	ator of device
			آ ا	ealth professional
				ser facility
				istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
ot # other #			If exp	olanted, give date
Device available $\square_{\text{yes}} \ \square_{\text{no}}$			nufact	urar / /
Concomitant me			uiuiaci	uici//
	arear produ			
E. Reporter				(504) 446 - 1105
Name and addre		<u> </u>		(781)449-6487
The National Pe				
P.O. Box 610189	, Newton, M	<b>1A.</b> 0	2461	
Health profession was yes and make the second secon	_	pation	n	Also reported to manufacturer
If you do NOT was		itv		user facility
disclosed to the ma	-		ın 🔲	distributor

A. Patient				
Patient Id	entifier	Date of birth	Sex	Weight
	972	01/20/93	female	80 lbs
B. Advers	se event	or product p	roblem	
		Product Prol	olem	
Outcomes	attribut	ted to adverse	event	
$\Box_{\text{death}}$		disability		
	eatening		anomaly	
	·		-	
· •	alization	□ required i	ntervention	
other:				
Date of ev	ent 05/0	)2/ <b>Dat</b>	e of report	9/16/2002
Describe e	event or	problem		
	_	with lice since	-	
•		only for them t		
		ger but the still		
		nes and even Ma	alath1on. I a	m not quite
sur what to	o do anyi	nore		
Relevant t	ests/laha	oratory data		
Kelevalit	CStS/1ab(	natory uata		
Other rele	evant his	story, includin	g preexisti	ng condition

Triage Unit Sequence #	

				·
C. Suspect med	dication(s)			
Name: Nix				
Rid and	Malathion			
Dose, frequency	, route use	Ther	apy d	ates
unknown		5/02		
				to 09/02
Diagnosis for us	e	E	vent	abated after use
head lice		st	toppe	d or dose reduced
			loesn	t apply
Lot#	Exp. date	_		
unknown	2			reappeared after oduction
unknown				
NDC# -	-		doesn	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
				ser facility
			□d	istributor
			Expi	ration date
model #			те •	1 ( 1 . 1 .
catalog #			II im	planted, give date
serial # lot #			T£	
other #			m exp	planted, give date
Device available	for evaluati	ion?		
	returned		nufact	turer / /
Concomitant me				
E. Reporter				
Name and addre	agg.	nh	ono#	(781)///0.6/87
				(781)449-6487
The National Pe				
P.O. Box 610189				
Health professio  ✓ yes □ no		pation	1	Also reported to
•				manufacturer user facility
If you do NOT wa disclosed to the ma	-	-	n 🔳	distributor
miscrosca to the Illi	αιαςιαι <b>σ</b> ι, μ	race al		

A. Patient Inform	ation						
Patient Identifier	Date of birth	Sex	Weight				
970	06/24/2000	female	30	lbs			
B. Adverse event	or product p	roblem					
	Product Prob	lem					
Outcomes attribut	ed to adverse	event					
death	disability						
life-threatening	Congenital	anomaly					
hospitalization	required in	ntervention					
other:							
Date of event 09/1	14/2002 <b>Date</b>	e of report	9/14/2	2002			
Describe event or	problem						
After Two attempts	-						
Pediatrician Rx Lind out fast moving live			I have pull	led			
out fast moving five	fice from the ci	mus nan.					
Relevant tests/labo	oratory data						
Other relevant his	story, including	g preexisti	ng condi	tion			

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name: lindane						
Permethi	rin					
Dose, frequency, route use The			rapy d	ates		
OTC dosages Lind	lane x3	9-2-	-02			
Permethrin Nix x1				to 9-14-02		
Diagnosis for us	e		Event	abated after use		
Lice infestation	-			d or dose reduced		
Lice illestation						
			doesn	t apply		
Lot#	Exp. date			reappeared after		
			reintroduction			
NDC #			doesn't apply			
NDC# -	-					
Concomitant me	dical produ	cts				
D. Suspect med	lical device	•				
Brand name						
Type of device						
Manufacturer na	Manufacturer name and address Operator of device					
health professional						
				ser facility		
distributor						
			Expi	ration date		
model #						
catalog #			If im	planted, give date		
serial #			. L			
lot #			_ If exp	planted, give date		
other #						
	Device available for evaluation?  yes no returned to manufacturer // /					
Concomitant me	dical produ	cts				
•						
E. Reporter						
Name and address phone # (781)449-6487						
The National Pe						
P.O. Box 610189	, Newton, M	<b>ΙΑ.</b> (	02461			
				Also reported to		
$\mathbf{V}_{\mathrm{yes}}$ $\square_{\mathrm{no}}$	no manufacture					
If you do NOT wa	you do NOT want your identity user facility			· ·		
disclosed to the manufacturer, place an distributor				□distributor		

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
968	12/23/1976	female	180 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Prod	luct Proble	em
Outcomes attribut	ed to adverse	event	
$\Box_{\text{death}}$	disability		
☐ life-threatening	□ congenital	anomaly	
$\square_{ m hospitalization}$	required in	ntervention	
other: difficulty	breathing		
Date of event 8/8/	2002 <b>Date</b>	of report	9/13/2002
Describe event or	problem		
each time I have tre			
or over the counter			
breathing for a few			-
breathing from the t MOST RECENT ex		eII. 8/8/200	2 is only the
MOST RECEIVT 6	vent		
Relevant tests/labo	oratory data		
Other relevant his	story, including	g preexisti	ng condition
My 6 yr old son has	been diagnose	d with asth	ma.

Cuanast mas	liantinu/a)				
C. Suspect medication(s)					
Name: Ovide					
Kwell, Lindane, Nix, Rid, Generic, Permethrin					
Dose, frequency,	route use	Ther	apy d	ates	
Suggested dose on		1996		to	
prescription. Use				2002	
Diagnosis for us		I	Event	abated after use	
Head Lice		s	toppe	d or dose reduced	
			doesn'	t apply	
Lot#	Exp. date	Ī	Event	reappeared after	
		r	eintro	duction	
		_	yes		
NDC# -	-		, 55		
Concomitant me	dical produ	cts			
D. Suspect med	lical device	<b>)</b>			
Brand name					
Type of device					
Manufacturer name and address Operator of device					
health professional					
				ser facility	
				istributor	
			Expir	ration date	
nodel #					
catalog #			If im	planted, give date	
serial #					
ot #			If exp	olanted, give date	
other #				·	
Device available for evaluation?					
$\square_{\mathrm{yes}}  \square_{\mathrm{no}}$			nufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter	E. Reporter				
Name and addre	SS	ph	one#	(781)449-6487	
The National Pe					
P.O. Box 610189		1A. 0	2461		
				Also reported to	
yes no manufacturer					
f you do NOT want your identity					
lisclosed to the ma	nufacturer, p	lace a	ın 🔲	□distributor	

A. Patient Inform	ation					
Patient Identifier	Date of birth	Sex	Weight			
966	06/05/88	female	180	lbs		
B. Adverse event	or product p	roblem				
	Product Prob	lem				
Outcomes attribut	ted to adverse o	event				
$\Box_{\text{death}}$	disability					
☐ life-threatening	□ congenital	anomaly				
hospitalization	required ir	ntervention				
other:						
Date of event 7/5/	02 <b>Date</b>	of report	9/9/2	2002		
Describe event or	problem					
i havehad lice for 5	months i have to	ried everyth	ning			
Relevant tests/laboratory data						
Other relevant his	story, including	g preexisti	ng condi	tion		

Triage Unit Sequence #	

C. Suspect me	dication(s)				
Name: Nix					
rid					
Dose, frequency	, route use	Ther	herapy dates		
nix every 2 weeks	s for 3	0000			
weeks and rid wa				to 0000	
does and it some l Diagnosis for us	hoole in O	l IF	Event	abated after use	
0000			stopped or dose reduce		
0000			no		
Lot#	E do4o				
Lot #	Exp. date			reappeared after	
		r	reintroduction		
NDC# -	_		yes		
Concomitant me	dical produ	cts			
Conconntant me 0000	uicai produ	cis			
0000					
D. Suspect med	dical device	<i>3</i>			
Brand name	aroar dovioc				
Type of device					
Manufacturer n	ame and add	iress	Oper	ator of device	
				ealth professional	
				ser facility	
			distributor		
				ration date	
d -1 #			Expii	auon uate	
model # catalog #			If im	planted, give date	
serial #			•	. , ,	
lot #			If exp	planted, give date	
other #			_	. , ,	
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}}  \square_{\mathrm{no}}$			nufact	urer/_/	
Concomitant me	edical produ	cts			
E. Reporter					
Name and addre	ess	ph	one #	(781)449-6487	
The National Pe		<u> </u>		. ,	
P.O. Box 610189					
Health profession		-		Also reported to	
$\mathbf{\nabla}_{\mathrm{yes}}$			-	manufacturer	
If you do NOT wa		itv		user facility	
disclosed to the m			n 🔲	distributor	

	nt Inform			
Patient I	dentifier	Date of birth	Sex	Weight
	963	05/20/1993	female	47 lbs
B. Adver	rse event	or product p	roblem	
		Product Prob	lem	
Outcome	s attribut	ted to adverse	event	
$\Box_{\text{death}}$		disability		
$\Box_{\text{life-th}}$	nreatening	□ congenital	anomaly	
$\square_{\text{hospi}}$	talization		ntervention	
other		1		
Date of e	vent 04/0	00/ <b>Date</b>	e of report	9/3/2002
Describe	event or			
		is problem for 2	2 yrs. now.	i have tried
everything	g to get ric	l of this. i am ge		
keeping h	er out of s	chool.		
Relevant	tests/labo	oratory data		
Other re	levant his	story, including	g preexisti	ng condition

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: Kwell					
Dose, frequency, route use Therapy dates					
she has used nix, a	and rid	2000	)		
ŕ				to 2002	
Diagnosis for us	<u> </u>	l I	Event :	abated after use	
she still has lice			stopped or dose reduced		
sile still has nee			no		
Lot #	Erm data				
Lot#	Exp. date			reappeared after	
		]	reintroduction		
NDC# -	_	$\dashv$	yes		
Concomitant me	dical nrodu	rte			
Concomitant me	uicai prouu	CLS			
D. G	liant davia				
D. Suspect med	dical device	)			
Brand name					
Type of device					
Manufacturer na	ame and add	iress	_	ator of device	
				ealth professional	
				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					
$\square_{\text{yes}} \square_{\text{no}}$				turer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	pł	one#	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
$\mathbf{V}_{\text{yes}}$ $\square_{\text{no}}$	_			manufacturer	
-				_	
If you do NOT wa	nt your ident	ity		user facility	

A. Patient Inform	ation						
Patient Identifier	Date of birth	Sex	Weight				
950	12/17/1997	female	35	lbs			
B. Adverse event	or product p	roblem					
	Product Prob	lem					
Outcomes attribut	ed to adverse o	event					
$\Box_{\text{death}}$	death disability						
☐ life-threatening	□ congenital	anomaly					
$\square_{ m hospitalization}$	required in	ntervention					
other:							
Date of event 08/2	27/02 <b>Date</b>	e of report	8/28/2	2002			
Describe event or	problem						
there was really no							
work - I do not wan head	t to use more ch	emicals on	her little				
nead							
Relevant tests/laboratory data							
Other relevant his	story, including	g preexisti	ng condi	tion			

C. Suspect medication(s)						
Name: lindane						
Happy Harry's Lice Products						
Dose, frequency, route use The			rapy d	ates		
I have used the Li	ndane	8/11	/02			
every 5 days along	g with			to 8/27/02		
Diagnosis for us	e		Event	abated after use		
0				d or dose reduce		
live bugs and thou the scalp and hair	isands of fins	111				
			doesn	t apply		
Lot #	Exp. date		Event 1	reappeared after		
			reintro	duction		
NDC #			doesn'	t apply		
NDC# -	-					
Concomitant me	dical produ	cts				
D. Suspect med	dical device	•				
Brand name						
Type of device			_			
Manufacturer na	me and add	lress	Oper	ator of device		
health professional						
user facility						
			distributor			
			Expir	ration date		
model #						
catalog #			_ If implanted, give date			
serial #						
lot #			_ If exp	olanted, give date		
other #						
Device available  yes no						
				urer/_/		
Concomitant medical products						
E Benerter						
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			
If you do NOT want your identity user facility						
disclosed to the manufacturer, place an distributor						
	7 F					

	nt Inform							
Patient I	dentifier	Date of birth	Sex	Weight				
	949	04/14/94	female	50	lbs			
B. Adver	se event	t or product p	roblem					
	Advers	e Event & Pro	duct Proble	em				
Outcome	s attribut	ted to adverse	event					
$\Box_{\text{death}}$	death disability							
$\Box_{\text{life-th}}$	nreatening	□ congenita	l anomaly					
$\square_{\mathrm{hospi}}$	talization	required i	ntervention					
other:	:							
Date of e	vent 01/0	00/ <b>Da</b> t	te of report	8/27/2	2002			
Describe	event or							
		thing perscribe	d and unpr	escribed a	nd			
_		. We have done						
	_	ibed. I have fiv						
_		tried everythin	-					
_	-	llows and all.H eople. Thank y		-	;			
way we a	re cream po	copic. Thank y	ou for your	time.				
Relevant tests/laboratory data								
Other re	levant his	story, includin	g preexisti	ng condi	tion			
None								

Triage Unit Sequence #	

				-
C. Suspect me	edication(s)			
Name: Kwell				
NixF	Rid123Ro	obbio	e comb,	etc.
Dose, frequenc			rapy d	
weeky. Dosage	-	08/0		
weeky. Dosage	ulikilow.	06/0	,0	to
<b>5</b>			<b>.</b>	08/02
Diagnosis for u				abated after use
still living (little	bastards)		stoppe	d or dose reduced
			no	
Lot#	Exp. date		Event	reappeared after
			reintro	oduction
			yes	
NDC# -	-		<i>y</i> cs	
Concomitant m	edical produ	cts		
Every weekI			-	s head several
times and I can r	ot get rid of th	ne lic	e.	
D. Suspect me	edical device	)		
Brand name				
Type of device				
Manufacturer i	name and add	lress	1 -	ator of device
				ealth professional
			u	ser facility
				istributor
			Expi	ration date
model #			- If im	planted, give date
catalog # serial #			-   111 1111	pianicu, give uaic
lot #			If evi	olanted, give date
other #				Janteu, give date
Device availabl	e for evaluati	ion?		
	returned			turer//
Concomitant m				<u> </u>
E Domostos				
E. Reporter			• "	(701) 440 6407
Name and addr		Ē		(781)449-6487
The National F				
P.O. Box 61018	9, Newton, M	ΙΑ. (	02461	
Health professi	onal Occup	patio	n	Also reported to
	10			manufacturer
If you do NOT w	•	•		user facility
disclosed to the n	nanufacturer, p	lace	an 🔳	□distributor

		•					
A. Patier							
Patient I	dentifier	Date of birth	Sex	Weight			
	943	10/09/1942	female	160 ll	bs		
B. Adver	se event	or product p	oroblem				
	Advers	e Event & Pro	duct Proble	em			
Outcome	s attribut	ted to adverse	event				
$\Box_{\text{death}}$		disability					
life-threatening congenital anomaly							
hospitalization required intervention							
other:		104					
Date of e	vent 10/2	20/02 <b>Da</b>	te of report	8/22/200	<u> </u>		
Describe	event or						
		suspected to ca	ancer, or pre	cancer on			
breast. Do	-	w that is sttribu	_				
mention.							
	_	roducts such R cticin, pronto a			,		
illidalie sii	iampoo, a	cticiii, pronto a	nd they all i	ancu.			
Relevant	tests/labo	oratory data					
Other rel	levant his	story, includir	ng preexisti	ng conditio	n		
none							

Triage Unit Sequence #	

C. Susp	ect med	licati	on(s)			
Name:	lindane					
	mayo. vii	negar	&mine	ral o	il.	
Dose, fro	equency,	rout	e use	The	rapy d	ates
multiple	times ove	er 4 ye	ears.	199	8	to 2002
Diagnos	is for us	e			Event	abated after use
scabies and lice were dx by			stoppe	d or dose reduced		
doctor an			-	of	doesn'	t apply
Lot#		Exp.	date			reappeared after oduction
NDC #			_		doesn'	t apply
Concom	itant me	dical	produ	cts		
D. Susp Brand na		lical	device	<del>)</del>		
Type of						
Manufac	cturer na	ime a	nd add	lres	□h □u □d	ator of device ealth professional ser facility istributor ration date
model #					Expii	auon uate
moder# catalog#					If im	planted, give date
serial # _						
lot #					If exp	planted, give date
other # _						
$\square_{\mathrm{yes}}$	Device available for evaluation?  yes no returned to manufacturer / / Concomitant medical products					
E. Reporter						
Name an	nd addre	SS		p	hone #	(781)449-6487
The Nat	ional Pe	dicul	osis A	SSO	ciation	
P.O. Box	k 610189	, New	ton, N	IA.	02461	
Health p  ✓ yes	orofession no		Оссиј	oatio	n	Also reported to manufacturer
If you do		•		•		user facility
disclosed	to the ma	nufac	turer, p	lace	an 🔳	□distributor

A Battant Inform	- CC - C						
A. Patient Inform		47	a	***			
Patient Identifier		rth	Sex	Weight			
937	05/01/52		female	125	lbs		
B. Adverse event							
	Adverse						
Outcomes attribut			event				
☐ death ☐ disability							
☐ life-threatening ☐ congenital anomaly							
hospitalization required intervention							
other: long tern	n affects						
Date of event 6/86	5-7/86	Date	of repor	t 8/17/	2002		
Describe event or	problem						
Three months prega	nant and gi	ven I	Lindane fo	r scabies.			
Weight problems,no	_		_	severe			
stomach problems,	-		ms,				
incontience both uri	me and bow	ei,					
Dalamant tasts/lab.s	4						
Relevant tests/labo	ratory dat	a					
		1.	•	•			
Other relevant his							
Was 3 months preg Not sure if I really		usea	for suppo	sily scable	es.		
Not sure if I really	nau man						

C. Suspect	medicati	on(s)			
Name: lind	ane				
sulf	a based oir	itment,	sini	lar	
Dose, freque	ency, rout	e use	The	rapy d	ates
Lindane one time. From neck 6/8		6/86	5	4	
to soles of fe					to 7/86
Also applied Diagnosis fo		d		Event :	abated after use
Scabies				stoppe	d or dose reduced
20000				yes	
Lot #	Exp.	doto			
LOI#	Exp.	uate			reappeared after
				reintro	oduction
NDC #		-		no	
Concomitan	t medical	produ	cts		
Lindane 5/92		-	- 0.5		
Linuane 3/92	ioi neaulic	٠.			
D. Suspect	medical	device			
Brand name					
Type of devi					
Manufactur		nd add	lress	Oper	ator of device
				I —	ealth professional
					ser facility
					istributor
				_	ration date
model #				Expii	ation date
model # catalog #				If im	planted, give date
serial #				-   '	, , ,
lot #				If ext	planted, give date
other #					, , ,
Device avail					urer / /
Concomitant medical products					
E. Reporter					
Name and a	ddress		p	hone #	(781)449-6487
The Nationa	al Pedicul	osis A	sso	ciation	
P.O. Box 61	0189, Nev	vton, N	IA.	02461	
Health prof	essional	Occup	oatio	n	Also reported to
<b>✓</b> yes	$\square_{\mathrm{no}}$				manufacturer
If you do NO	T want you	r identi	ty		user facility
disclosed to tl				an 🔲	□distributor

A. Patien							
Patient Id	lentifier	Date of birth	Sex	Weight			
	936	01/21/87	female	90 lbs			
B. Adver	se event	or product p					
		Adverse Ev	ent				
Outcomes attributed to adverse event							
death disability							
☐ life-threatening ☐ congenital anomaly							
•	alization						
other:	Profound	l Mental Retard	lation				
Date of ev	vent 6/86	5 Dat	e of report	8/17/2002			
Describe	event or	problem					
impaired,0 sensory di both urine growth,che Abnormal	Severe M.R. with mulitple disabilities. Enlarged liver, vison impaired,G.I. tract damage, no speech, motor disability, sensory disability, short in stature, low weight,incontience both urine and bowel, flat back head, excessive hair growth,chewing problems, hormone problems, allergies, Abnormal MRI's, C-T scans and EEG's with abnormal seizure activity						
Relevant	tests/labo	oratory data					
		story, includin Mother used wh					

Triage Unit Sequence #	

C Suc	noot mod	lication(c)			
		lication(s)			
Name:	lindane				
	sulfur ba	sed ointmen	t, sin	ilar	
Dose, fi	requency	route use	The	rapy d	ates
Used on	ice		6/86	5	4
					to 7/86
Diagno	sis for us	e		Event	abated after use
Scabies	515 TOT <b>U</b> 5				d or dose reduced
Scables					
		1		yes	
Lot#		Exp. date		Event	reappeared after
				reintro	duction
				no	
NDC#	-	-			
Concon	nitant me	dical produ	cts		
Lindane	5/92 for h	eadlice			
D. Sus	pect med	lical device	)		
Brand r					
Type of					
		me and ado	lress	Oper	ator of device
				$\square_{h}$	ealth professional
					ser facility
					istributor
				Expi	ration date
model #	#			2	
	#			If im	planted, give date
_	"			-   '	, , ,
lot#				If exi	planted, give date
other #					,, <b>g</b>
Device	availahle	for evaluat	ion?		
		returned			urer / /
Concon	nitant me	dical produ	cts		
		-			
_					
Name a	nd addre				(781)449-6487
Name a	nd addre	ss diculosis A			(781)449-6487
The Na	nd addre		ssoc	ciation	(781)449-6487
Name a The Na P.O. Bo	nd addre ational Pe ox 610189	diculosis A	ssoc IA. (	ciation 02461	(781)449-6487  Also reported to
Name a The Na P.O. Bo	nd addre	diculosis A , Newton, N  nal Occup	ssoc IA. (	ciation 02461	
Name a The Na P.O. Bo Health yes	nd addre ational Pe ox 610189 professio	diculosis A , Newton, N  nal Occup	SSOO IA. (	ciation 02461	Also reported to

	-					
A. Patient Inform						
Patient Identifier	Date of birth	Sex	Weight			
934	05/31/1961	female	136 lbs			
B. Adverse event	or product p	roblem				
Adverse Event & Product Problem						
Outcomes attribut	ted to adverse o	event				
$\Box_{\text{death}}$	disability					
☐ life-threatening	Congenital	anomaly				
hospitalization required intervention						
	ical problemsu		1			
Date of event 04/0		e of report	8/14/2002			
Describe event or		or report	0/14/2002			
Since within a few of	=	application	I have			
exhibited neurologic	-					
emmented mean oroga	our prooreins une					
Relevant tests/labo	ratory data					
Refevant tests/lab	natory data					
Other relevant his	story, including	g preexisti	ng condition			
none						

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: lindane				
Dose, frequency	route use	The	rapy d	ates
Applied from nec		04/0		accs
and left on for 12		04/0	1/02	to
wools loter was no	narihad			04/15/02
Diagnosis for us	e			abated after use
Scabies		1	stoppe	d or dose reduced
			no	
Lot#	Exp. date		Event	reappeared after
				duction
			doesn'	t apply
NDC# -	-		doesii	с аррту
Concomitant me	dical produ	cts		
D. Suspect med	lical device			
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
				ealth professional
				ser facility
			Шd	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot # other #			If exp	planted, give date
Device available $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$			£4	
Concomitant me	returned		anuracı	urer//
Concomitant inc	dicai produ	cus		
E. Reporter				
Name and addre	SS	pl	hone #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	<b>1</b> A. 0	)2461	
Health professio	· · · · · ·			Also reported to
$ \mathbf{V}_{\text{yes}}  \square_{\text{no}} $	)		_	manufacturer
If you do NOT wa		ty		user facility
disclosed to the ma	•	•	an 🔲	distributor

Patient Identifier	Date of birth	Sex	Weigh	t
932	06/29/1971	female	140	lbs
B. Adverse event	or product p	roblem		
	Product Pro	blem		
Outcomes attribut	ed to adverse	event		
death	disability			
☐ life-threatening	□ congenita	l anomaly		
hospitalization	required i	nterventio	on	
other:				
Date of event 8/1/	2002 <b>Da</b> t	e of repo	rt 8/13	3/2002
Describe event or	problem			
already sprayed my all clothing and bed all heads repeately- now as i am writing saturated in mayona	dind in the hou adleast 7 times all my children	se! we has piece by and have	ve went the piece. right our hair	rough ht
all clothing and bed all heads repeately- now as i am writing	dind in the hou adleast 7 times all my children is as well as with a shower cat-raged at the fast time, we even in from the hair or can help my and this lice here sitting for hotemoval of bott	se! we have and have our hair rate. i am be act that not family. was become urs each of a control of the contro	ve went the piece. right our hair apped in pleecoming verteatment noving all we at a loss we are not ea huge day and se	rough tht lastic ery thas nits and dirty

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: lindane					
Dose, frequency	, route use	The	rapy d	ates	
used 2oz per per person. 8/1		8/1/2	8/1/2002		
also used nix			to 8/13/2002		
Diagnosis for use			Event abated after use		
head lice-no posit	ive results, st	till	stoppe	d or dose reduced	
have lice	,		no		
Lot#	Exp. date	_		1 6	
	Lap. date			reappeared after oduction	
		•	i emu (	duction	
NDC# -	-		yes		
Concomitant me	dical produ	cts			
lindane 8/1/02,nix	=		ouse sn	raved with rid 3	
times, all clothing			_	-	
olive oil and now					
D. Suspect med	dical device				
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
			ے ا	ealth professional	
				ser facility	
			distributor		
				ration date	
model#			Expii	ation date	
model			If im	planted, give date	
serial #			·	, , ,	
lot #			If ext	olanted, give date	
other #				granicou, granic	
Device available	for evaluati	on?			
$\square_{\mathrm{yes}}  \square_{\mathrm{no}}$	returned	to m	anufact	urer/_/	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	pl	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	<b>I</b> A. (	)2461		
Health professio	nal Occup	atio	n	Also reported to	
$ \mathbf{v}_{\text{yes}} $	_			manufacturer	
If you do NOT wa	nt your identi	ty		user facility	
disclosed to the ma	-	-	an 🔲	distributor	

A. Patient Inform	ation		
Patient Identifier		Sex	Weight
929	05/06/71	female	188 lbs
B. Adverse even	t or product p	roblem	
	Product Prob	lem	
Outcomes attribut	ted to adverse o	event	
$\Box_{\text{death}}$	disability		
☐ life-threatening	Congenital	anomaly	
hospitalization	required ir	ntervention	
other:			
Date of event 05/0	02/ <b>Date</b>	of report	8/11/2002
Describe event or	problem		
I had an original lic	e outbreak in M	ay and clea	red it up then
in end of June and r		-	
I have used NIX the			-
infestation i bought used it , not every (			
during infestations,			
am 31 yrs old . you			
several times			C
Relevant tests/labo	oratory data		
041413			
Other relevant his	story, including	g preexisti	ng condition

Triage Unit Sequence #	

or odopoor illoa	lication(s)				
Name: Nix					
Oose, frequency, route use Therapy dates					
bose, mequency,	Toute use			ates	
L		05/0	2	to	
				05/02	
Diagnosis for use	e		Event abated after use		
Κ			stoppe	d or dose reduced	
			doesn'	t apply	
Lot#	Exp. date		Event	reappeared after	
				oduction	
			doesn'	t apply	
NDC# -	<u>-</u>		uoesii	т аррту	
Concomitant med	dical produ	cts			
D. Suspect med	lical device	,			
Brand name					
Type of device					
	me and add	lress	Oper	ator of device	
Manufacturer name and address Operator of device					
				ealth professional	
			□ <sub>h</sub>	ealth professional	
			$\square_{\mathrm{u}}$	ser facility	
				ser facility istributor	
				ser facility	
model #			Expin	ser facility istributor ration date	
catalog #			Expin	ser facility istributor	
catalog # serial #			Expin	ser facility istributor ration date planted, give date	
catalog # serial # ot #			Expin	ser facility istributor ration date	
catalog # serial # ot # other #			Expin	ser facility istributor ration date planted, give date	
catalog # serial # ot # other # Device available	for evaluati		Expin  If imp	ser facility istributor ration date planted, give date planted, give date	
catalog # serial # ot # other # Device available  yes  no	for evaluati	to m	Expin  If implements the second secon	ser facility istributor ration date planted, give date planted, give date	
catalog # serial # ot # other # Device available	for evaluati	to m	Expin  If implements the second secon	ser facility istributor ration date planted, give date planted, give date	
catalog # serial # ot # other # Device available  yes  no	for evaluati	to m	Expin  If implements the second secon	ser facility istributor ration date planted, give date planted, give date	
catalog # serial # ot # other # Device available  yes  no	for evaluati	to m	Expin  If implements the second secon	ser facility istributor ration date planted, give date planted, give date	
eatalog # serial # ot # other # Device available	for evaluati returned dical produce	to m	Expin  If implements the second secon	ser facility istributor ration date planted, give date planted, give date	
catalog # serial # ot # other # Device available	for evaluati	to markets	Expire If impartments If expenses anufact	ser facility istributor ration date planted, give date planted, give date	
eatalog # serial # ot # other # Device available	for evaluation returned dical products	to ma	Expired If implementation If explanation	ser facility istributor ration date planted, give date planted, give date	
eatalog # serial # ot # other # Device available	for evaluation of the second second production of the second seco	plassoc	Expired to the state of the sta	ser facility istributor ration date planted, give date planted, give date	
eatalog # serial # ot # other # Device available	for evaluating returned dical productions of the control of the co	plassoc	Expired to the state of the sta	ser facility istributor ration date planted, give date planted, give date currer// (781)449-6487	
eatalog # serial # ot # other # Device available	for evaluation returned dical productions of the control of the co	pl sssoc IA. (	Expired to the state of the sta	ser facility istributor ration date planted, give date planted, give date currer _/_/ (781)449-6487	

A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
925	3/9/65	female	120	lbs
B. Adverse event	or product p	roblem		
	Adverse Ev	ent		
Outcomes attribut	ted to adverse o	event		
$\Box_{\text{death}}$	disability			
☐ life-threatening		anomaly		
hospitalization		ntervention		
other: allergic of		ner vention		
			0.17.10	
Date of event 05/0		e of report	8/5/2	002
Describe event or	=			
After applying shar				
developed a headac				r
Started within 1/2 h		sted most of	the day.	l
felt very drowsy to	0.			
Relevant tests/labo	oratory data			
	·			
Other relevant his			ng condit	ion
I have no allergies of	r medical proble	ems.		

Triage Unit Sequence #	

C Sugnast mas	lication(s)				
C. Suspect med	ilcation(5)				
Name: lindane					
1% solut	ion shampoo	)			
Dose, frequency, route use 1			Therapy dates		
1% Lindane sham	poo used	05/0	8/02	to	
once for 10 or 15	minutes.			05/08/02	
Diagnosis for us	e		Event a	abated after use	
Head lice			stoppe	d or dose reduced	
			yes		
 Lot #	Exp. date	_			
	Ехр. часе			reappeared after	
DIN 00703605			reintro	duction	
NDC# -	_		doesn'	t apply	
Concomitant me	dical produ	rts			
None	arem produ				
None					
D. Suspect med	lical device				
	iloai acvice				
Brand name Type of device					
<u>Hype of device</u> Manufacturer na	me and add	lress	Oner	ator of device	
vianulacial ci ni	inic ana aac	055			
			_	ealth professional ser facility	
				istributor	
"			Expir	ration date	
model #			If im	planted, give date	
catalog # serial #			.	prantica, grie aute	
seriar # lot #			If evr	planted, give date	
other #			III CAL	Julicu, give unic	
Device available	for evaluati	ion?	1		
$\square_{\text{yes}} \square_{\text{no}}$			anufact	rurer//	
Concomitant me					
E. Reporter					
Name and addre	SS	n	hone #	(781)449-6487	
The National Pe		_		(701)++7-0+07	
P.O. Box 610189					
Health professio				Also reported to	
$\mathbf{V}_{\text{yes}}$	_	oat10	·11	manufacturer	
If you do NOT was		tv		user facility	
disclosed to the ma	-	-	an 🔳	distributor	
and the same and	p				

A. Patient Inform	ation					
Patient Identifier	Date of birt	h Sex	Weight	t		
924	4/14/92	female	65	lbs		
B. Adverse even	t or product	problem				
	Product Problem					
Outcomes attribut	ted to advers	se event				
death	□disabili	ty				
☐ life-threatening	☐ life-threatening ☐ congenital anomaly					
hospitalization	require	d interventio	n			
other:						
Date of event 3/20	0/02 <b>D</b>	ate of repoi	rt 8/5	5/2002		
Describe event or	problem					
my children came h		-	-			
full time sitters. (I h	-	_	-			
infected from school When I realized wh						
the generic lice trea		•				
comb provided - bu						
slipped right over the						
repeated this 10 day						
vacuumed, bagged,	1 5	-	0 5			
in contact with.In a so I did this all agai						
separate Nix applica	_					
vacuuming/bagging.		-				
don't know what to	do. It has been	en 5 tiring m	onths!			
Relevant tests/lab	anatany data					
Relevant tests/labo	oratory data					
Other relevant his	story, includ	ing preevis	ting cand	lition		
other relevant m	, meiu	ing preexis	ting conc	1111011		

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: Nix				
also gene	ric lice medi	cation	1	
Dose, frequency,	route use	The	rapy d	ates
5 applications		3/24	/02	
11				to 8/5/02
Diagnosis for us	e	l l	Event	abated after use
don't understand				d or dose reduced
don't understand				t apply
Lot#	Erm dota	_		
LOI #	Exp. date			reappeared after
		]	reintro	duction
NDC# -	_		doesn'	t apply
Concomitant me	dical produc	cts		
	uicai prouu	CLS		
D. Suspect med	lical device	<b>,</b>		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			$\square_{\mathrm{h}}$	ealth professional
			$\square_{\mathrm{u}}$	ser facility
			$\square_{\mathrm{d}}$	istributor
			Expi	ration date
nodel #				
catalog #			If im	planted, give date
serial #				
ot # other #			If exp	planted, give date
	C			
Device available yes no	for evaluati		anufact	urer / /
Concomitant me			ununaci	uici/_ /
	Proud			
E. Reporter				(504) 440 5105
Name and addre				(781)449-6487
The National Pe				
P.O. Box 610189	, Newton, M	<b>1A</b> . 0	2461	
Health profession		oatio	n	Also reported to
$ \mathbf{V}_{\text{yes}}  \square_{\text{no}} $	)			manufacturer
f you do NOT war	-	-		user facility
lisclosed to the ma	ınufacturer, p	lace a	an 🔲	□distributor

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
922	05/18/94	female	42	lbs
B. Adverse event	or product p	roblem		
	e Event & Prod		em	
Outcomes attribut	ted to adverse e	event		
$\Box_{\text{death}}$	disability			
☐ life-threatening		anomaly		
hospitalization		ntervention		
	— required in	itei veiitioii		_
other: RASH				
Date of event 05/1	15/02 <b>Date</b>	of report	8/3/2	2002
Describe event or	=			
MY DAUGHTER				
BOUGHT ALL TY				TO
GET RID OF IT				210
TREATMENT TH				NG
AND I STILL SEE				A NT
EVERY PRODUC' YOU PLEASE HE				
AFFORD THESE I				NI
AFFORD THESE I	rkoducis Al	VI LONG	EK	
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condi	tion
N/A				

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name: Rid						
AC200 AND MANY MORE						
Oose, frequency, route use Therapy dates						
EVERY 7 DAYS		05/15				
MONTHS	TORS	03/10	702	to 08/03/02		
Diagnosis for us	0	ı	Twont	abated after use		
_			stopped or dose reduce			
STILL COMING DOESN'T STOP				a or dose reduced		
	T		no			
Lot#	Exp. date			reappeared after		
N/A		r	eintro	duction		
NDC# -		$\dashv$	yes			
Concomitant me	dical produc	ote				
	uicai produ	LIS				
0						
D. Suspect med	lical device	ž				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
			_	ealth professional		
				ser facility		
				distributor		
			Expir	ration date		
model #						
catalog #			If im	planted, give date		
serial #						
lot #			If exp	explanted, give date		
other #						
Device available	_		C	, .		
$\square_{ m yes} \square_{ m no}$ Concomitant me			ınufact	urer/_/		
Concomitant me	uicai proud(	LIS				
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}_{\text{yes}}  \square_{\text{no}} $	)			manufacturer		
If you do NOT was	nt your identi	ity		user facility		
disclosed to the ma	nufacturer, p	lace a	ın 🔲	□distributor		

A. Patient Inform	otion					
		a g	***	1.4		
Patient Identifier			Weig			
919	1/21/90	femal		lbs		
B. Adverse event	or produ	ct probler	n			
Advers	e Event &	Product Pr	oblem			
Outcomes attribut	ed to adve	rse event				
$\Box_{\text{death}}$	□disabi	lity				
□ life-threatening	$\Box_{\text{conge}}$	nital anoma	ly			
hospitalization	□ <sub>requir</sub>	ed interven	tion			
other:						
		D		2 < /2 0 0 2		
Date of event 7/26 Describe event or		Date of rep	ort 7/	26/2002		
after shampooing with product when I did the combing stage of treatment. Child insisted on shower cap due to episode of Arthur seen that day dealing with lice. The next morning child complained of burning sensation to scalp, immediately washed hair with regular shampoo and consulted internet for more info on lice.						
Relevant tests/labo	oratory dat	a				
Other relevant his						
Sensitive to nickel,	_		all result ir	contact		
dermetitus when contact is made. Has seasonal allergies. Grass Pollen is only known one due						
to U of Iowa Ped St			-	me due		
		Pro II				

Triage Unit Sequence #	

				-
C. Suspect med	dication(s)			
Name: generic l	ice shampoo			
Equate (	compare to F	RID)		
Dose, frequency	, route use	The	rapy d	ates
6-8oz once then a	gain 7-10	7/26	/02	
days later				to 8/2/02
Diagnosis for us	e	l l	Event	abated after use
Actual sighting of				d or dose reduced
and OTC treatme			yes	
Lot #	Exp. date			
Lot #	Ехр. чан			reappeared after
				oduction
NDC# -	_		doesn'	t apply
Concomitant me	dical produc	cts		
Plan on doing mar			owing a	child to continue
wearing shower ca			_	
8	1 1 1			
D. Suspect med	dical device	)		
Brand name				
Type of device				
Manufacturer na	ame and add	lress	Oper	ator of device
			$\square_{\mathrm{h}}$	ealth professional
				ser facility
			$\square_{\mathrm{d}}$	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot # other #			If exp	olanted, give date
Device available $\square_{ m yes} \ \square_{ m no}$	returned		onufoot	uror / /
Concomitant me			anuraci	urer//
	ureur produ			
E. Reporter				
Name and addre		드		(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
<b>V</b> yes □no	)			manufacturer
If you do NOT wa	-	-		user facility
disclosed to the ma	anufacturer, p	lace	an 🔲	□distributor

A. Patient Informa	ation					
Patient Identifier		irth Sex	W	eight		
914	10/23/73	male		_	bs	
B. Adverse event	or produ	ct proble	em			
	Advers	e Event				
Outcomes attribut	ed to adv	erse event				
□death	$\Box_{\text{disab}}$	oility				
☑ life-threatening	$\Box_{\mathrm{conge}}$	enital anom	aly			
□hospitalization	$\square_{\text{requi}}$	red interve	ntion			
other: servere b	reathing p	roblems				
Date of event 7/13	3/2002	Date of re	eport	7/21/200	)2	
Describe event or	problem					
purchase the spray for the furniture and bedding, and i did. The problem is that my husband has severe sarcoidosis which is a lund diease and also attacks all the organs. We didnt think being so upset from the whole instance, we sprayed it, and washed all of our hair in the Nix. That night my husband had a bad breathing spelling and coughing attack and got so sick that he could hardly even sit up. Well I guess we know now and this product will never be used in our household again						
Relevant tests/laboratory data  Other relevant history, including preexisting condition						
Severe Sarcoidosis v mg. of Prednisone a marrow involvemen Sarcoidosis.	with treatn day. Lung	nent of Me involveme	thotraxat ent and B	te and 60 Sone		

Triage Unit Sequence #	

· · · · · · · · · · · · · · · · · · ·				•	
C. Suspect med	lication(s)				
Name: Nix					
na					
Dose, frequency,	, route use	Ther	apy d	ates	
one time		07-13	3-2002		
				to 07-13-2002	
Diagnosis for us	e	I	Event	abated after use	
child that brought		s	toppe	d or dose reduced	
C			doesn'	t apply	
Lot#	Exp. date	_			
na	<b>1</b>			reappeared after duction	
NDC# -	-		doesn'	t apply	
Concomitant me	dical produ	cts			
na					
D. Suspect med	dical device	<del>)</del>			
Brand name					
Type of device	1 1				
Manufacturer na	ime and add	iress		ator of device	
			□h	ealth professional ser facility	
				istributor	
			$\vdash$	ration date	
model #			Lapii	ation tate	
catalog #			If im	planted, give date	
serial #					
lot #			If exp	olanted, give date	
other #					
Device available					
	returned		nufact	urer/_/	
Concomitant me	aicai produ	cts			
E. Reporter					
Name and addre	ss	ph	one#	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189	, Newton, M	<b>1</b> A. 0	2461		
Health profession		pation	n	Also reported to	
	)			manufacturer	
If you do NOT war	-	-		user facility	
disclosed to the ma	nufacturer, p	lace a	ın 🔳	□distributor	

A. Patient Inform	ation		
Patient Identifier		Sex	Weight
910	10/20/94	female	40 lbs
,10			40 108
B. Adverse event	Product Prob		
0-4		-	
Outcomes attribut	_	event	
□death	□disability		
☐ life-threatening			
hospitalization	☐ required in	ntervention	
other: excessive	absence from s	chool	
Date of event 09/1	15/00 <b>Date</b>	e of report	7/18/2002
Describe event or	problem		
I have been battling	-	_	
has been a recurring	-		-
daughters age 6 and		-	
shampoo, spray, gel and toys, washed be			_
temperature, vaccur	-		
done everything I co	-		
instructions of the s		-	
their solutions. I've	put mayonaise	on my girls	' hair, used
dog shampoo (whic	h after reviewin	g this webs	site, I now
know is a no-no), ha			-
their hair. Also, who			
prescribed Lindane			
They have missed s reported to the Scho			
Relevant tests/labo		icy Divisio	n. r don t
11010 ( 11110 100 10) 1110	rates y amou		
Other relevant his	story, including	g preexisti	ng condition

Triage Unit Sequence #	

-				-	
C. Suspect med	lication(s)				
Name:					
Rid, Nix, Pronto, Lindane, and generic brand					
Dose, frequency,	route use	The	rapy d	ates	
Follwed the instru	ctions.	09/1	5/00		
Have been using o	n a weekly			to 07/18/02	
Diagnosis for us		-	Event	abated after use	
Pediculosis				d or dose reduced	
calculosis			no		
Lot#	F Jo4o		no		
LOT #	Exp. date			reappeared after	
		]	reintro	oduction	
NDC# -	_	$\dashv$	yes		
Concomitant me	dical produ	ete			
Sonconntant me	uicai piouu	LIS			
D. Suspect med	lical device				
Brand name	ilour do vioc				
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			1 —	ealth professional	
			$\square_{\mathrm{u}}$	ser facility	
			$\square_{\mathrm{d}}$	istributor	
			Expi	ration date	
nodel #					
catalog #			If im	planted, give date	
erial #					
ot #			If explanted, give date		
other #					
Device available					
	returned		anufact	urer/_/	
Concomitant me	aicai produ	cts			
E. Reporter					
Name and addre	ss	pl	none #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health profession				Also reported to	
✓ yes □no				manufacturer	
f you do NOT war	nt your identi	ity		user facility	
lisclosed to the ma	-	-	an 🔲	distributor	

	_				
A. Patient I					
		Date of birth		Weigh	
	908	1-19-95	female		lbs
B. Adverse	event	or product	problem		
		Product Pro	blem		
	ttribut	ed to adverse			
death		disability	y		
☐ life-threa	tening	Congenit	al anomal	y	
$\square_{\mathrm{hospitali}}$	zation	required	interventi	ion	
other:					
Date of even	t 7/02	2 <b>D</b> a	te of repo	ort 7/17	7/2002
Describe eve	ent or				
		ears to kill al	l live lice	on pt, but	
several days t	to a we	ek later, crawl	ing lice ar	re present a	-
_		ment 3x, after	-		
		hild has been			
now. I have doing someth		hecking regula	rly for nit	ts, but obvi	ously
doing someth	ing wi	ong.			
Relevant tes	ts/labo	oratory data			
Other releve	ant his	story, includi	ng nreevi	isting can	dition
other releva	ant me	, tory, includi	ng preex	isting con	uition

Triage Unit Sequence #	

C. Suspect medication(s)						
Name: Kwell						
Dose, frequency	route use	The	erapy dates			
shampoo - every 10 days.			6/02			
repeated 3x.				to 7/02		
Diagnosis for us			Event abated after use			
pediculosis capitu			stopped or dose redu			
pediculosis capitu	18					
T 4 11	D 14			t apply		
Lot #	Exp. date			reappeared after		
			reintro	duction		
NDC# -	_		doesn'	t apply		
	- 	-4				
Concomitant me	aicai proau	cts				
D. Cuanast mas	liaal davia					
D. Suspect med	ilcai device	<del>)</del>				
Brand name						
Type of device	me and add	lmag	Onor	ator of device		
Manufacturer na	ime and add	ires				
	III   III	health professional user facility				
			distributor			
			$\bot$			
			Expiration date			
model # catalog #			If implanted, give date			
serial #			_			
lot #			If explanted, give date			
other #				, <b>g</b>		
Device available						
$\square_{\text{yes}} \square_{\text{no}}$						
Concomitant me	aicai produ	cts				
E. Reporter						
Name and address phone # (781)449-6487						
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health professio	_	patio	n	Also reported to		
				manufacturer user facility		
If you do NOT wa	•	•		distributor		
disclosed to the ma	inufacturer, p	an 🔳				

Patient Identifier	Date of h	irth	Sex	Weigh	ıf.
906	19/20/	11 (11	male	150	lbs
3. Adverse even	or produ	ıct pı			
	Advers				
Outcomes attribut	ted to adv	erse e	vent		
death	$\Box_{ ext{disat}}$	oility			
□ life-threatening	$\Box_{\mathrm{cong}}$	enital	anomaly	7	
✓ hospitalization	<b>✓</b> requi				
other:					
Date of event 7/12	2/2002	Date	of repo	rt 7/1	6/2002
Describe event or	problem				
Coumadin. About 1 oubled up the dose					
Glucosamine, and to Following that experience of Following that experience of Following broad sease his big list of other culprits are the Glucother than the following broad sease his big list of other received discontinuation of such the following the f	ook some I osure, pati arch for po therapy, we cosamine/C ntly increasuch and then short per noted a poddin (Nexitoratory dassettory, incl	Nexiu: ent's l essible re con Chond chond of l l of l of	m in a print in a prin	rn basis.  It up tp 12  ions between the manifate, who in to  tion between to  tion between to  sting con	een ain ich prompt een and and

Triage Unit Sequence #	

C. Suspect medication(s)						
Name:						
Glucosamine and Chondroitin Sulfate						
Dose, frequency,	route use	The	erapy dates			
lose was doubled	; qd	1990	)	to		
				to 7/11/02		
Diagnosis for us	e		Event abated after use			
osteoarthritis		:	stopped or dose reduced			
			yes			
Lot #	Exp. date			1 0		
?	Exp. date			reappeared after oduction		
!		ľ	remire	duction		
NDC# -	_		doesn'	t apply		
Concomitant me	dical produc	cts				
Coumadin, 1-2mg	=					
Nexium, 20mg PC						
GARLIC caps, 1c						
D. Suspect med						
Brand name						
Type of device						
Manufacturer na	me and add	lress	$\square_{\mathrm{h}}$	ator of device ealth professional ser facility istributor		
			Expi	ration date		
nodel #						
catalog #			If im	planted, give date		
serial #						
ot #			_ If explanted, give date			
other #						
Device available $\square_{\mathrm{yes}}  \square_{\mathrm{no}}$	returned	to m	anufact	urer _ / _ /		
Concomitant me	dical produ	cts				
E. Reporter						
Name and addre	ss	pl	none #	(781)449-6487		
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health professional Occupation  yes  no			n	Also reported to manufacturer		
f you do NOT want your identity				user facility		
lisclosed to the manufacturer, place an				□distributor		

A. Patient	Inform	etion						
			12					
Patient Ide		Date of birth	Sex	Weight				
D. Advers	897	12/13/99	female	35 lbs				
B. Advers	e even	t or product p						
0. 1	44 *1							
_	Outcomes attributed to adverse event							
☐ death		□ disability	•					
□ life-thre								
hospita	lization	required in	ntervention					
other:								
Date of eve			e of report	7/10/2002				
Describe e								
		ons. Products ju	ist can't see	m to kill and				
provide resi	stance t	o reinfestation						
Relevant tests/laboratory data								
Other rele	vant his	story, includin	g preexisti	ng condition				

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name: Nix						
Rdi						
Dose, frequency,	route use	Ther	erapy dates			
			6/30/02			
directions closely.	-	0/30/	02	to 7/10/02		
at racommanded i	atomiol .	 	34			
Diagnosis for us	e	Event abated after use stopped or dose reduc				
visible adult lice						
		-	doesn'	t apply		
Lot#	Exp. date	F	Event 1	reappeared after		
		r	eintro	duction		
			doesn'	t apply		
NDC# -	-					
Concomitant me	dical produ	cts				
D. Suspect med	lical device	<b>)</b>				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
			$\square_{\mathrm{h}}$	ealth professional		
			user facility			
				distributor		
			Expir	ation date		
model #			Z.Ap.i.	auton dute		
catalog #			If im	planted, give date		
serial #				. , ,		
lot #			If ext	planted, give date		
other #			1	7.6		
Device available	for evaluati	ion?				
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			nufact	urer//		
Concomitant me	dical produ	cts				
E. Reporter						
Name and addre	99	nh	one #	(791)440 6497		
		Ĺ	one #	(781)449-6487		
The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461						
$\mathbf{\nabla}_{\text{yes}}  \mathbf{\square}_{\text{no}}$	-	Jaulul	•	Also reported to manufacturer		
· I I				user facility		
disclosed to the manufacturer, place an distributor						

A. Patient Inform								
Patient Identifier	Date of birth	Sex	Weight					
892	08/12/74	female	132	lbs				
B. Adverse event	or product p	roblem						
	Product Prol	olem						
Outcomes attribut	Outcomes attributed to adverse event							
$\Box_{\text{death}}$	disability							
☐ life-threatening	congenital	anomaly						
hospitalization	_							
other: diffiulty								
Date of event 07/0		e of report	7/8/2	2002				
		c or report	77072	.002				
<b>Describe event or</b> I took Lindane shap	=	in koraa n	leace hale					
i took Emdane shap	illoo twice liefe	ти когеар	iease neip					
Relevant tests/laho	Relevant tests/laboratory data							
Kelevant tests/labe	natory data							
Other relevant his	story, includin	g preexisti	ng condi	tion				
anxiety, shakyness								

Triage Unit Sequence #	

C. Suspect me	dication(s)					
Name: lindane						
Dose, frequency	, route use	The	erapy dates			
2wic on for 5 min	1	343	424			
				to 45374		
Diagnosis for u	se	l	Event :	abated after use		
fd			stopped or dose redu			
			doesn'	t apply		
Lot#	Exp. date		Event	reappeared after		
fa			reintro	oduction		
NDC# -	<u> </u>		yes			
Concomitant me	edical produ	cts				
fd	carear produ					
ıu						
D. Suspect me	dical device	•				
Brand name						
Type of device						
Manufacturer n	ame and add	lress	Oper	ator of device		
			health professional			
				user facility distributor		
			ша	istributor		
			Expi	ration date		
model #			- If im	planted, give date		
catalog #			-   11 1111	pianteu, give uate		
serial # lot #			Tf over	planted, give date		
other #			- In ext	nameu, give uate		
Device available	e for evaluat	ion?				
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				urer/_/		
Concomitant m						
E. Reporter						
Name and addr	ess	p	hone #	(781)449-6487		
The National P	ediculosis A	sso	ciation			
P.O. Box 610189, Newton, MA. 02461						
				Also reported to		
	0			manufacturer		
If you do NOT w	ant your ident	ity		user facility		
disclosed to the m			an 🔲	distributor		

	nt Inform								
Patient I	dentifier	Date of birth	Sex	Weight					
	884	11/16/97	female	32 lbs					
B. Adve	rse event	or product p	roblem						
		Product Prob	lem						
Outcome	es attribut	ted to adverse o	event						
death									
_	hreatening	Congenital	anomaly						
_	italization	_	-						
•		required if	ntervention						
other	:								
Date of e	event 6/17	7/02 <b>Date</b>	e of report	6/28/2002					
Describe	event or	problem							
		e, her cousin had							
		nd with her. Or							
	_	aution. Used the	_						
		ions did not say		_					
		st checked it by							
	-	th actual lice un							
-		one small just ha							
		d. Nix was used	-						
	_	macy told me it		-					
		ycare discovere							
	-	t should have ki							
		nair used the Nix	-						
		problem with li ctor prescribed							
-		nb on the childs							
			nead. The	products do					
Relevant tests/laboratory data									
Otherra	lovort k	story, including	a nuocuici	ng oonditie-					
Otner re	ievant nis	story, including	g preexisti	ng condition					

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name:					
Walgreen	ns Brand				
Dose, frequency, route use The			erapy dates		
Used once- covere	ed entire	6/11/	02	to	
head- shampoo st	ayed on for			to 6/11/02	
Diagnosis for us	e e	]	Event	abated after use	
nead lice exposure		s	toppe	d or dose reduced	
1			no		
 Lot #	Exp. date	_			
201 11	Lap. date			reappeared after oduction	
		ľ	emu	duction	
NDC# -	-		yes		
Concomitant me	dical produ	cts			
6/17/02 Walgreens	=		000		
5/19/02 wargreen 5/19/02 used an el		_		aution, did not	
find any live lice				,	
D. Suspect med	lical device	<b>,</b>			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			_	ealth professional	
				ser facility	
			distributor		
			Expii	ration date	
model #					
catalog			11111	pianicu, give uaic	
seriai # lot #			If are	alantad circ data	
other #			_ If explanted, give date		
Device available	for avaluati	ior?			
yes $\square_{no}$			nufact	urer / /	
Concomitant me					
	-				
E. Reporter					
Name and addre	22	nh	one #	(781)449-6487	
		<u> </u>		(101) 112-0101	
Γhe National Pediculosis Association P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
V <sub>yes</sub> □ <sub>no</sub> Cccupation Asso reported □ <sub>manufacture</sub>					
				user facility	
If you do NOT want your identity disclosed to the manufacturer, place an distribut					
nsciosed to the ma	muracturer, p	тасе а	ш	- 41541104101	

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
881	08/26/91	male	74 lbs
B. Adverse event	or product p	roblem	
	Adverse Ev	ent	
Outcomes attribut	ed to adverse	event	
death	$\Box_{disability}$		
☐ life-threatening	Congenital	anomaly	
hospitalization	required in	ntervention	1
other: vitiligo			
Date of event 12/0	00/01 <b>Dat</b>	e of repor	t 6/18/2002
		or repor	0/10/2002
Describe event or Probable misdiag of brown & white blots prescribed products couldn't do this but	scabies & tx w/ ches over body by derm who s until this he had	& face. ha	s since been dane/kwell
Other relevant his previous to the rash problems with his s	story, including	and neve	

Triage Unit Sequence #	

C. Suspect m	edication(s)			
Name: Kwell				
Dose, frequen	cv. route use	Ther	rapy d	ates
			0/01	ares
to use until gon	-	12/00	3/01	to
				12/04/01
Diagnosis for	use			abated after use
Skin rash		S	toppe	d or dose reduced
			no	
Lot#	Exp. date	1	Event	reappeared after
				oduction
				. 1
NDC# -	-		doesn	t apply
Concomitant r	nedical produ	cts		
Since then he ha	as had hydroco	rtison	e crem	e. elidel which
caused another	-			
			-	
D. Suspect m	edical device	•		
Brand name				
Type of device				
Manufacturer	name and add	lress	Oper	ator of device
			$\Box_{\mathrm{h}}$	ealth professional
				ser facility
			$\square_{\mathrm{d}}$	istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device availab				
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to ma	anufact	turer/_/
Concomitant r	nedical produ	cts		
E. Reporter				
Name and add	ress	nh	one #	(781)449-6487
The National		드		(101)-17-0-101
P.O. Box 6101				
Health profess		patio	n	Also reported to
-	no			manufacturer
If you do NOT	-	-		user facility
disclosed to the	manufacturer, p	lace a	ın 🔳	□distributor

A. Patient Inf								
Patient Identi	ifier	Date of bi	rth	Sex	Weight			
88	30	08/29/47		female	265	lbs		
B. Adverse e	vent	or produ	ct pı	oblem				
		Advers	e Eve	ent				
Outcomes attr	ribut	ed to adve	rse e	vent				
death		□disabi	ility					
☐ life-threate	□ life-threatening □ congenital anomaly							
hospitaliza	_			tervention				
other:		requi						
<u> </u>	20/6	20./	D-4-	- C	6/17/0	1002		
Date of event			Date	of report	6/17/2	2002		
Describe even		_	_1_:	1 ·	. 41	0_		
Years ago, beg	-		-	_				
between some just @ night.bl	_			_				
& sweaty. oint						пос		
a sweary. one	1110111	s seem to n	iiuico	it itell illor	<i>.</i>			
Relevant tests/laboratory data								
Other relevan	ıt hic	tory inch	ıdin	nreevisti	ng condi	tion		
I have allergies								
have scabies by		-	-					
		pro derma						

Triage Unit Sequence #	

C. Suspect m	edication(s)		
Name: lindane	)		
cortiso	ne creams		
Dose, frequenc	cy, route use	Therapy d	ates
don't remember		2000-	
			to 2002
Diagnosis for t	use	Event	abated after use
atopic dermatiti			d or dose reduced
atopie dermani	o ce seubles	yes	
 Lot #	Exp. date		7 0
Lot #	Exp. date		reappeared after oduction
		remire	duction
NDC# -	-	yes	
Concomitant n	nedical produ	cts	
cortisone cream	=		enadryl
			•
D. Suspect m	edical device	<b>;</b>	
Brand name			
Type of device		1	
Manufacturer	name and add	ــــ ا	ator of device
			ealth professional
			ser facility
			istributor
		Expi	ration date
model #		Te:	nlantad aiva data
catalog # serial #		11 1111	planted, give date
seriai # lot #		If ev	olanted, give date
other #		II (A)	planted, give date
Device availab	le for evaluati	ion?	
	$\square_{\text{returned}}$		turer//
Concomitant n	nedical produ	cts	
E. Reporter			
Name and add	ress	phone #	(781)449-6487
The National 1			
P.O. Box 6101			
Health profess			Also reported to
w <sub>yes</sub> □		e a livii	manufacturer
If you do NOT v		itv	user facility
disclosed to the	-		distributor

21200211								
A. Patient Inform								
Patient Identifier	Date of b	irth	Sex	Weight				
879	12/05/19:	55	female	120	lbs			
B. Adverse event	or produ	ıct pı	roblem					
	Advers	se Eve	ent					
	Outcomes attributed to adverse event							
□ death	∐disab	oility						
☐ life-threatening	□conge	enital	anomaly					
hospitalization	□requi	red ir	itervention					
other:								
Date of event 10/1	19/97	Date	of report	6/16/2	2002			
Describe event or	problem							
diagnosed with scal								
developed rash/blist			•	•	,			
dermotology patien later told I never had	-	ears a	as a result	of this. W	as			
iatei tolu i nevel nat	1 scables							
Relevant tests/labo	oratory da	ıta						
Other relevant his								
Car accident in 199								
broken pelvis, tibia, a patient in ICU. W								
a patient in ICO. w treated for scabies.	as told I w	as cie	ear of this t	before I w	as			
ireated for scapies.								

Triage Unit Sequence #	

C. Suspect medication(s)						
Name: lindane						
LyClear						
Dose, frequency,	route use	Ther	erapy dates			
Quellada left over			997			
night.LyClear left	24 hours			to 10/1997		
Diagnosis for us	e	l l	Event	abated after use		
_				d or dose reduced		
Blisters fingers,ras	sii oii aiiii,					
			no			
Lot #	Exp. date	1	Event	reappeared after		
		1	eintro	duction		
NIDC #			doesn'	t apply		
NDC# -		$\perp$				
Concomitant me	=					
From October 199						
prednasone and v				-		
-			as also	given Augmentan		
D. Suspect med	lical device	<del>)</del>				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
	ealth professional					
			user facility			
			distributor			
			Expi	ration date		
model #						
catalog #			_ If implanted, give date			
serial #						
lot #			_ If explanted, give date			
other #						
Device available						
	returned		nufact	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						
				user facility		
disclosed to the manufacturer, place an distributor						

A. Dationt Inf		-(!				
A. Patient Info			- 1	a	***	
Patient Identi			rth	Sex	Weight	11
87 B. A.I.	~	1-16-78	-	female	125	lbs
B. Adverse ev	/ent					
		Advers				
Outcomes attr	ibut	_		event		
death		□disab	ility			
☐ life-threater	ning	□conge	enital	anomaly		
□hospitalizat	tion	□requii	red in	tervention		
other: flu-li	ike s	ymptoms,	saliv	ation		
Date of event	6-15	5-02	Date	of report	6/16/2	2002
Describe event	tor	problem				
Used Lindane a						
I started salivati					ptoms suc	h
as dizziness, we	eakn	ess, and na	usea	followed.		
Relevant tests/	labo	ratory dat	ta			
	244.00	20025 000				
Other relevan	t bio	tory inch	ıdin	ı nraevisti	na condi	lion
Other relevan	t IIIS	tory, men	ıuııış	g pi cexisti	ng condi	1011

C. Suspect med	dication(s)			
Name: lindane				
shampoo	1%			
Dose, frequency	, route use	The	rapy d	ates
1/3 of bottle		6-13		
-,				to 6-15-02
Diagnosis for us	Δ		Event	abated after use
scabies	•			d or dose reduced
scables				
<b>*</b> . "	n 1.			t apply
Lot#	Exp. date			reappeared after
			reintro	duction
NDC# -			doesn'	t apply
	diaal residen	ot c		
Concomitant me	=		cc	
Do not yet know i	if application	ı wa	s effect	ive.
D. Suomost mas	lical davias			
D. Suspect med	ilcai device	<del>,</del>		
Brand name				
Type of device Manufacturer na	me and add	Irocc	Oper	ator of device
Manufacturer na	iiic anu auc	11 688		
				ealth professional ser facility
				istributor
			Expii	ration date
model # catalog #			If im	planted, give date
serial #			-	p gr / c umic
lot #			If ext	planted, give date
other #			III CA	Junica, give dute
Device available	for evaluati	ion?		
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			anufact	rurer//
Concomitant me				
E. Reporter				
Name and addre			4	(701)440 (407
		ᆮ		(781)449-6487
The National Pe				
P.O. Box 610189		1A. (	)2461	
Health professio	_	patio	n	Also reported to
$\mathbf{V}_{\mathrm{yes}}  \mathbf{\square}_{\mathrm{no}}$	)			manufacturer
If you do NOT wa				user facility
disclosed to the ma	anufacturer, p	lace	an 🔲	□distributor

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
875	20/00/	male	35	lbs
B. Adverse event	t or product p	roblem		
	Product Pro			
Outcomes attribut	ted to adverse	event		
□death	disability			
☐ life-threatening	Congenital	anomaly		
□hospitalization	☐ required i	ntervention		
other:				
Date of event 06/0	02/ <b>Dat</b>	e of report	6/12/20	002
Describe event or				
Treated 3 kids ages				_
prescription pediatr				
work. After ealized children under 6 bu				OII
children under 0 bu	it the doctor pre	scribed it a	ny way.	
Relevant tests/labo	ratory data			
recevant tests/iab	natory data			
Other relevant his	story includin	g nreevisti	ng conditi	ion
Other relevant his	story, includin	g pi cexisti	ng conun	ion

Triage Unit Sequence #	

se				
ced				
4				
ter				
e				
Manufacturer name and address Operator of device				
nal				
late				
iaic				
ate				
7				
37				
37				
d to				

A. Patient Inform	ation				
Patient Identifier	Date of birt	h Sex	Weight		
873	05/16/1994	female	50	lbs	
B. Adverse event	or produc	problem			
Advers	e Event & P	roduct Pro	blem		
Outcomes attribut	ed to adver	se event			
$\Box_{\text{death}}$	death disability				
☐ life-threatening	☐ life-threatening ☐ congenital anomaly				
$\square_{ m hospitalization}$	require	d interventi	on		
other:					
Date of event 06/0	08/2002 E	ate of repo	ort 6/11/20	002	
Describe event or		ate of Tepo	0/11/20	702	
used the rid three tin	_	aughter's h	ead lice Non	e	
of the medications v		-			
huge patches of her					
white maybe like da			-	J	
		•			
Relevant tests/labo	ratory data				
Other relevant his					
i brushed her about				is	
falling out. it was e	nough to be i	noticable wl	nen her hiar		
dried.					

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: Kwell				
Dose, frequency,	route use	The	rapy d	ates
1 - twice the amou	ınt of	0608	32202	
shampoo a persor	would use			to 06082002
Diagnosis for us	e		Event :	abated after use
head lice				d or dose reduced
nedd nee			doesn'	t apply
Lot #	Exp. date	_		
LOC#	Exp. date			reappeared after
		]	reintro	oduction
NDC# -	-		doesn'	t apply
Concomitant me	dical produc	cts		
	<b>F</b>			
D. Suspect med	lical device	)		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			$\square_{\mathrm{h}}$	ealth professional
				ser facility
				istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial # lot #			TC .	.14.1
other #			n exp	planted, give date
Device available	for evaluati	ion?		
	returned		anufact	curer / /
Concomitant me				
E. Reporter				
Name and addre	aa	nl	one#	(781)449-6487
- 100 00		드		(781)449-0487
The National Pe				
P.O. Box 610189	<del> </del>			
<b>Health professio ✓</b> yes □no	nal Occuj	patio	n	Also reported to
•		.,		manufacturer user facility
If you do NOT was disclosed to the ma	•	•	an 🔳	distributor

A Detient Inform	-tion		
A. Patient Inform		~	
Patient Identifier		Sex	Weight
872	05/06/91	female	75 lbs
B. Adverse event	e Event & Prod		m
Outcomes attribut			:111
death	disability	event	
life-threatening	_	anomaly	
hospitalization		ntervention	
other:	— required in	iter vention	
Date of event 05/2	20/02 <b>Date</b>	e of report	6/7/2002
Describe event or		or report	0/1/2002
Nix ineffective and	=	hild (7) nau	sea each
treatment.	gave youngest e	illia (7) ilaa	sea each
Relevant tests/labo	ratory data		
Kele vant tests/lab	natory data		
Other relevant his	tory, including	preexisti	ng condition
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	, F	

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: Nix	ilcation(s)			
THE TAIN				
Dose, frequency,	route use	The	rapy d	ates
			13/02	
within 3 week per		03/1	13/02	to
			<b>T</b>	/6/03/02
J		Event abated after use stopped or dose reduce		
Lice		stoppe	a or aose reaucea	
			yes	
Lot #	Exp. date		Event	reappeared after
				duction
			****	
NDC# -	-		yes	
Concomitant me	dical produ	cts		
D. Suspect med	lical device	,		
Brand name				
Type of device				
Manufacturer na	me and add	Irece	Oner	ator of device
manufacturer ne	inic and add	II CS		
				ealth professional
				ser facility istributor
			Expi	ration date
model #			- 10.	1 4 1 1 1 4
catalog #			-  If im	planted, give date
serial #			-	
lot #			_ If exp	planted, give date
other #				
<b>Device available</b> $\square_{\text{yes}} \square_{\text{no}}$				turer / /
Concomitant me				
	• "			
E. Reporter				
Name and addre	ss	p	hone #	(781)449-6487
The National Pe	diculosis A	sso	ciation	
P.O. Box 610189	, Newton, M	1A. (	02461	
Health professio	nal Occup	patio	n	Also reported to
$\mathbf{v}_{\mathrm{yes}}$ $\mathbf{v}_{\mathrm{no}}$	1 -			manufacturer
If you do NOT was	nt your identi	ity		user facility
disclosed to the ma			an 🔲	distributor

2120671		'	
A. Patient Inform			_
Patient Identifier	Date of birth	Sex	Weight
871	4/3/1999	female	30 lbs
B. Adverse event	or product p	oroblem	
	e Event & Pro		lem
Outcomes attribut	_		
□death	□disability		
☐ life-threatening	Congenita	l anomaly	
hospitalization		ntervention	n
other: burn - ha	ir loss		
Date of event 6/3/	2002 <b>Da</b> t	te of repor	t 6/6/2002
Describe event or	_		
Treated - her with			
failure again treated head with possible l			
devistated - plus it		oon to ten.	1 4111
•			
Relevant tests/labo	oratory data		
Other relevant his			
Even after the 10 m	in application I	found LIV	E Lice.

Triage Unit Sequence #	

				-
C. Suspect med	lication(s)			
Name: Nix				
Dose, frequency,	route use	The	rapy d	ates
2 treatment - first		5/10	/02	to
second only 10 mi	in			6/3/02
Diagnosis for us	e		Event	abated after use
lice		ĺ	stoppe	d or dose reduced
			no	
Lot#	Exp. date		Event	reappeared after
	_			duction
			VOC	
NDC# -	-		yes	
Concomitant me	dical produ	cts		
TODAY 6/6 Olive	e Oil treatme	ent -	trying t	o drown them i
guess - nit picking				•
have any info on t			air loss	5 ??
D. Suspect med	lical device	9		
Brand name				
Type of device			10	
Manufacturer na	ime and add	iress	1 -	
			l III	ealth professional
				ser facility istributor
			_	ration date
			Expi	ation date
model			If im	planted, give date
serial #			`	, ,
lot #			If exp	planted, give date
other #				
Device available				
	returned		anufact	turer//
Concomitant me	dical produ	cts		
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 profession				Also reported to
$ \mathbf{V}_{\text{yes}} $				manufacturer
If you do NOT war	nt your ident	ity		user facility
disclosed to the ma	-	-	an 🔲	□distributor

A Detient Inform	etion .			
A. Patient Inform		~		
Patient Identifier 866	Date of birth 4-15-52	Sex male	Weight 150	lbs
B. Adverse event			130	108
b. Adverse eveni	Adverse Eve			
Outcomes attribut				
Outcomes attribut  death		event		
	☐ disability	1		
☐ life-threatening				
hospitalization		ntervention		
other: skin cand	•			
Date of event 1/3		of report	6/2/2	.002
Describe event or		,		
misdiagnosed scabio		and skin ca	ıncer had	
been popping up ev	er since.			
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condit	ion
hiv positive				

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: lindane				
Dose, frequency,	Dose, frequency, route use Therapy dates			
kept reapplying:	no	1/31/	01	
dicertions were giv		.,		to 2/3/02
Diagnosis for us	e			abated after use
scabies		s	toppe	d or dose reduced
			doesn'	t apply
Lot#	Exp. date	I	Event 1	reappeared after
05439 169280				oduction
NDC# -	-		doesn'	t apply
Concomitant med	dical produ	cts		
	<b>F</b>			
D. Suspect med	lical device	•		
Brand name				
Type of device			ı	
Manufacturer na	me and add	lress	Oper	ator of device
			$\square_{\mathrm{h}}$	ealth professional
user facility				ser facility
				istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #			'	· · · · · · / · · · · · · · · · · · · ·
lot #			If ovr	planted, give date
other #			псл	nanicu, give date
Device available	for evaluati	ion?	1	
$\square_{\text{yes}} \square_{\text{no}}$			nufact	urer / /
Concomitant me				
	I			
E. Reporter				
Name and addres	ss	ph	one#	(781)449-6487
The National Pe	diculosis A	ssoci	iation	
P.O. Box 610189	, Newton, M	<b>1A</b> . 0	2461	
Health profession	nal Occup	oatio	n	Also reported to
$\mathbf{v}_{\mathrm{yes}}$ $\mathbf{v}_{\mathrm{no}}$	,			□ manufacturer
✓ yes □ no		itv		manufacturer user facility

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
865	12-11-72	2	female	158	lbs
B. Adverse even	t or produ	uct pi	roblem		
Advers	se Event &	Prod	luct Proble	em	
Outcomes attribu	ted to adv	erse e	event		
death	$\Box_{\mathrm{disal}}$	oility			
□ life-threatening	□ cong	enital	anomaly		
hospitalization	□requ	ired in	ntervention		
other: persistar				pants aft	er us
Date of event 10/	01-1/02	Date	of report	6/1/	2002
Describe event or	problem				
I was teaching at ch	_	ed. ni	ghts when I	I noticed	lice.
My husband and I			_		
on. I never saw the	m in my 8	yr old	daughters	hair. I q	ıit
teaching and still co	ontinued w	ith the	e problem f	or month	ıs.
D alamant tanta/lab	4 J	.4			
Relevant tests/lab	oratory da	ııa			
Other relevant hi	story, incl	uding	g preexisti	ng cond	ition

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix	(0)				
Tunio.					
Dose, frequency, route use Therapy dates					
1/2 conditioner pe		10/0			
for 4 mth.(avg)	1 2 WCCKS	10/0	,2	to	
			<b>.</b>	1/02	
Diagnosis for us			Event abated after use stopped or dose reduce		
found lice in my h	air		stoppe	u or dose reduced	
			no		
Lot#	Exp. date		Event	reappeared after	
				duction	
			20		
NDC# -	-		no		
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	
				ser facility	
				istributor	
			Expii	ration date	
model #			- If im	nlantad aira data	
catalog #			-   111 11111	planted, give date	
serial #					
lot # other #			_ If exp	planted, give date	
<b>Device available</b> $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$				urer / /	
Concomitant me					
	-				
E. Reporter					
Name and addre	SS	р	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occuj	oatio	n	Also reported to	
$\mathbf{v}_{\mathrm{yes}}$ $\mathbf{v}_{\mathrm{ne}}$	-			manufacturer	
If you do NOT want your identity user facility					
disclosed to the ma			an 🔲	distributor	

	-			
A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
862	10-01-93	female	83	lbs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse 6	event		
death	disability			
	_			
☐ life-threatening				
hospitalization	□ required in	tervention		
other:				
Date of event 52/9	90/2 <b>Date</b>	of report	5/31/2	002
Describe event or	problem			
nothing is working				
Relevant tests/labo	oratory data			
	•			
Other relevant his	story, including	g preexisti	ng condit	ion
none				

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name:				
rid nix li	ndane			
Dose, frequency	, route use	The	rapy d	ates
once aweek		5-05	5	
				to 5-31
Diagnosis for us	e		Event	abated after use
don't understand	•			d or dose reduced
don't understand				t apply
 Lot #	Exp. date			** *
Lot #	Ехр. чан			reappeared after
			reintro	oduction
NDC# -	_		yes	
Concomitant me	dical produ	cts		
5-30 lindane, 5-28	=		5 22-:	a 5 20 rid
5-30 findane, 5-28	oimaane 5-25	mx	3-23IIIX	s 5-20 na
D. Suspect med	dical device	)		
Brand name				
Type of device				
Manufacturer na	ame and add	lress		ator of device
			□ l	ealth professional
			<u>□</u> u	ser facility
			$\square_{\mathrm{d}}$	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	olanted, give date
other #				, , ,
Device available	for evaluati	ion?		
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				urer//
Concomitant me				
	-			
E. Reporter				
Name and addre	ss	n	hone #	(781)449-6487
		ᆮ		(,01)112 0107
The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461				
$\mathbf{V}_{\text{yes}}$	_	Jau (	711	Also reported to manufacturer
		.,		user facility
If you do NOT wa				distributor
disclosed to the ma	anuracturer, p	ıace	an 🔳	—uisuibutoi

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
861	10/25/94	female	50	lbs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ed to adverse	event		
$\Box_{\text{death}}$	disability			
□ life-threatening	Congenital	anomaly		
hospitalization		ntervention		
other:	1			
Date of event 05/0	05/02 <b>Date</b>	e of report	5/30/2	2002
Describe event or				
I USED RID, NIX,	_	NDANE.		
EVERYTHING.NO			ERED A	
PRODUCT CALLI				
BASICALLY LOO	SENS THE GL	UE AND Y	OU CAN	1
WASH THEM OU				
ANYTHING. I W			EMICALS	I
AM EXPOSING M	IY CHILD TO.			
Relevant tests/labo	oratory data			
041 1 411		•	711	
Other relevant his	story, including	g preexisti	ng condit	tion

Triage Unit Sequence #	

<u> </u>			•		
C. Suspect med	lication(s)				
Name: Rid					
NIX, GENERIC LICE SHAMPOO					
Dose, frequency, route use Therapy dates					
IX WK X 3		050502	to		
WKS.ENOUGH			052902		
CATUDATE HAI Diagnosis for use		Event	abated after use		
HEAD LICE INF	ESTATION	stoppe	d or dose reduced		
		no			
Lot#	Exp. date	Event	reanneared often		
	1		reappeared after oduction		
			oude tivii		
NDC# -	-	yes			
Concomitant me	dical produ	ets			
D. Suspect med	lical device	;			
Brand name					
Type of device		ī			
Manufacturer na	me and add	1 -	ator of device		
			ealth professional		
		u	ser facility		
			listributor		
"		Expi	ration date		
nodel #		 If im	planted, give date		
catalog # serial #			planted, give date		
ot #		If ex	planted, give date		
other #			r		
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}}  \square_{\mathrm{no}}$			turer//		
Concomitant med	dical produ	ets			
E. Reporter					
Name and address	SS	phone #	(781)449-6487		
Γhe National Pediculosis Association P.O. Box 610189, Newton, MA. 02461					
			Also may seed 3.4		
Health profession  yes  no		oation	Also reported to manufacturer		
		tv	user facility		
f you do NOT war	n your identi		distributor		

		-			
A. Patien					
Patient Id	entifier	Date of birth	Sex	Weight	
	859	6/16/93	female	105	lbs
B. Advers	se event	t or product p	roblem		
		Product Prob	lem		
Outcomes	attribut	ted to adverse	event		
□death		disability			
	eatening		anomaly		
	alization		ntervention		
other:	anzanon	— required in	iter vention		
Date of ev			e of report	5/22/2	002
Describe e		_			
		L OVER THE			
		HAVE HAD N OCTOR AND			
		OCTOR AND OO, I HAVE US			м
		OUT KNITS. I			IVI
		HAS BEEN A			
Relevant t	ests/labo	oratory data			
041		.4	~• •		•
Otner rele	evant his	story, including	g preexisti	ng condit	ion

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: Kwell					
Dose, frequency, route use The			rapy d	ates	
USED ONCE		5/20	0/02		
				to 5/20/02	
Diagnosis for us	<u> </u>		Event	abated after use	
STILL FINDING				d or dose reduced	
STILLTHOMAG	LOGS				
T . 4 #	E . 1.4.		no		
Lot #	Exp. date			reappeared after	
			reintro	oduction	
NDC# -	_		yes		
Concomitant me	dical produ	cte			
Concomitant inc	uicai produ	cis			
D. Suspect med	lical device	,			
Brand name					
Type of device					
	me and add	lress	Oper	ator of device	
Manufacturer name and address Operator of device health professional					
			user facility		
			distributor		
			Expi	ration date	
model #					
catalog #		If implanted, give date			
serial #			-		
lot #			_ If explanted, give date		
other #					
<b>Device available</b> $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$				urer//	
Concomitant me					
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				Also reported to	
				manufacturer	
If you do NOT want your identity					
disclosed to the manufacturer, place an distributor					

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
857	9-23-98	female	35 lbs
B. Adverse event	t or product p	roblem	
	Adverse Ev	ent	
Outcomes attribut	ted to adverse o	event	
$\Box_{\text{death}}$	disability		
☑ life-threatening	Congenital	anomaly	
hospitalization	_		
other:	1		
Date of event 9/00	)/01 <b>D</b> ate	e of report	5/14/2002
		or report	3/14/2002
<b>Describe event or</b> I have written to yo		is ago abou	t my daughter
, she developed con			
and 10 doctors later	-		
prednisone			
Relevant tests/labo	oratory data		
	•		
Other relevant his	story includes	a proprieti	ng condition
no prexisting condit		g pi cexisti	ng condition
no prexisting condi-	lions		

Triage Unit Sequence #	

C. Suspect me	dication(s)				
Name: lindane					
Dose, frequency, route use Therapy dates					
totalof four times		9/00	0/01		
				to 10/00/01	
Diagnosis for us	se .		Event	abated after use	
doctor never saw		t in			
doctor never suv	as ne canca i		no		
 Lot #	Exp. date				
Lot #	Exp. date			reappeared after oduction	
			1 emu (	duction	
NDC# -	-		doesn'	t apply	
Concomitant me	dical produ	cts	I		
	•				
D. Suspect med	dical device	•			
Brand name					
Type of device					
Manufacturer n	ame and add	lres	s Oper	ator of device	
				ealth professional	
user facility			ser facility		
				istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	olanted, give date	
other #				<u>-</u>	
Device available					
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to m	nanufact	urer/_/	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	ess	р	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189	, Newton, M	ſΑ.	02461		
Health professio	nal Occup	oatio	n	Also reported to	
$\mathbf{V}_{\mathrm{yes}}$ $\square_{\mathrm{ne}}$	_			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the m			an 🔲	distributor	

A. Patient Inform	ation					
Patient Identifier	Date of bir	th	Sex	Weight		
855	11/25/1970	0	female	125	lbs	
B. Adverse event	or produc	ct pi	roblem			
	Product P	Prob	lem			
Outcomes attribut	ed to adve	rse e	event			
death	∐ disabil	lity				
life-threatening	Conger	nital	anomaly			
□hospitalization	□require	ed in	ntervention			
other:						
Date of event 07/1	12/2001	Date	of report	5/11/2	2002	
Describe event or	problem					
nothing works docto			_	ave me		
prescription shamo	poo. i used e	every	ything else			
Relevant tests/laboratory data						
Other relevant his	story, inclu	ding	g preexisti	ng condi	tion	

Triage Unit Sequence #	

C Suppost modication(s)					
	C. Suspect medication(s)				
Name: lindane					
Dose, frequency,	route use		rapy d	ates	
once in a week		000	000	to	
				000000	
Diagnosis for us	e		Event	abated after use	
00000			stoppe	d or dose reduced	
			doesn'	t apply	
Lot #	Exp. date				
Lot "	Enpi dute			reappeared after oduction	
			i cillur(	ouucuon	
NDC# -	-		doesn'	t apply	
Concomitant me	dical produc	rts			
concomitant me	aicai produ				
D. Suspect med	lical davice				
	ilcai uevice	,			
Brand name					
Type of device Manufacturer na	me and add	lwood	Onor	ator of device	
Manufacturer na	illic allu aud	II CS	I —		
				health professional user facility	
			distributor		
			Expii	ration date	
model #			- If im	planted, give date	
catalog #			-   111 1111	pianicu, give uate	
serial # lot #			If over	olanted, give date	
other #			- In ext	nameu, give uate	
Device available	for avaluet	or?			
yes $\square_{no}$				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 profession	nal Occup	oatio	n	Also reported to	
$\mathbf{V}_{\mathrm{yes}}$ $\square_{\mathrm{no}}$	)			manufacturer	
If you do NOT want your identity user facility					
disclosed to the manufacturer, place an distributor					

	nt Inform		Ļ	
Patient 1	Identifier	Date of birth	Sex	Weight
	849	6-5-63	male	154 lbs
B. Adve	rse event	or product	problem	
	Advers	e Event & Pro	duct Proble	em
Outcom	es attribut	ed to adverse	event	
<b>∠</b> deatl	h	disability disability	1	
$\Box_{\text{life-t}}$	hreatening	Congenita	al anomaly	
	italization		intervention	
other				
Date of	event 7-10	)-98 <b>Da</b>	te of report	4/30/2002
Describe	e event or	problem		
disability		•		
Dalaman	4 4 a = 4 = /1 a la a	4		
Kelevalli	i tests/iabc	oratory data		
0.0		, , , , ,,	• . •	70.0
	elevant his	story, includii	ng preexisti	ng condition
None				

Triage Unit Sequence #	

C Suspect medication(s)					
C. Suspect medication(s)					
Name: lindane					
Dose, frequency,	route use	The	rapy d	ates	
weekly		11/9	93		
·				to 11/93	
Diagnosis for us	t		Event abated after use stopped or dose reduced		
Head Lice			stopped of dose reduced		
			no		
Lot #	Exp. date		Event 1	reappeared after	
				duction	
NDC# -	-		doesn'	t apply	
Concomitant me	dical produ	cts			
	<b>.</b>				
D. Cuanast mas	liaal davias				
D. Suspect med	ilcai device	<del>)</del>			
Brand name					
Type of device			1_		
Manufacturer name and address Operator of device					
				ealth professional	
				ser facility	
			$\square_d$	istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	olanted, give date	
other #			1	, , ,	
Device available	for evaluati	on?			
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					
Health professio	nal Occuj	oatio	n	Also reported to	
$ \mathbf{V}_{\text{yes}}  \square_{\text{no}}$	,			manufacturer	
If you do NOT want your identity user facility			user facility		
disclosed to the ma			an 🔲	distributor	

	000011		
A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
848	5-92	female	685 lbs
B. Adverse event	or product p	roblem	
	Adverse Ev	ent	
Outcomes attribut		event	
□death	disability		
☐ life-threatening		anomaly	
hospitalization	☐ required in	nterventior	1
other:			
Date of event 7-98	B Dat	e of repor	t 4/27/2002
Describe event or	problem		
My daughter stsrted	d to have seisur	es at home	was the first
one,then at school			
	4 1 4		
Relevant tests/labo	oratory data		
Other relevant his	story includin	g nreevist	ing condition
now she has special	= '		_
•	C		•

Triage Unit Sequence #	

C. Suspect medication(s)				
Name: Nix				
Dose, frequency, route use Therapy dates				
half a bottle		199		
nuir u bottie		1//	O	to 2001
D'	_		E4	
Diagnosis for us				abated after use d or dose reduced
alot of nits and lic	e in hair		stoppe	u or dose reduced
			yes	
Lot#	Exp. date		Event	reappeared after
			reintro	duction
			no	
NDC# -	-		no	
Concomitant me	dical produ	cts		
to many to say				
D. Suspect med	dical device	•		
Brand name				
Type of device				
Manufacturer name and address Operator of device				
health professional				
			$\square_{\mathrm{u}}$	ser facility
			$\square_{\mathrm{d}}$	istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			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 Pediculosis Association				
P.O. Box 610189, Newton, MA. 02461				
Health professional Occupation Also reported to			Also reported to	
$\mathbf{v}_{\mathrm{yes}}  \square_{\mathrm{no}}$	)			manufacturer
If you do NOT want your identity user facility				
disclosed to the manufacturer, place an distributor				

	000011		
A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
841	6-13-68	female	110 lbs
B. Adverse event	or product p	roblem	
	Adverse Ev	ent	
Outcomes attribut	ted to adverse o	event	
death	disability		
☐ life-threatening	□ congenital	anomaly	
hospitalization	required in	ntervention	1
other:			
Date of event 4-14	4-96 <b>Date</b>	e of report	t 4/5/2002
Describe event or			
Treated for scabies	_	eveloped i	multiple
chemical sensitivity		-	re been
disabled with MCS	since using lind	ane.	
Relevant tests/labo	oratory data		
	•		
Other relevant his	story, including	g preexist	ing condition
Had bout with ulcer			
been in remission for	or 7 years when	exposed to	Lindane
(onset of MCS).			

Triage Unit Sequence #	

Dose, frequency, route use 2 applications, 2 days 4-14-96 to 4-16-96  Diagnosis for use Scabies. Event abated after use stopped or dose reduced no  Lot # Exp. date Event reappeared after reintroduction doesn't apply  Concomitant medical products  D. Suspect medical device Brand name Type of device   health professional   user facility   distributor   Expiration date   Expiration date   If implanted, give date   If explanted, give	C. Suspect medication(s)				
2 applications, 2 days  Diagnosis for use Scabies.  Event abated after use stopped or dose reduced no  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  Manufacturer name and address  Device available for evaluation?  yes no returned to manufacturer / / Concomitant medical products  Event abated after use stopped or dose reduced no  Devent reappeared after reintroduction  doesn't apply  Operator of device  health professional user facility distributor  Expiration date  If implanted, give date  If explanted, give date	Name: lindane				
2 applications, 2 days  Diagnosis for use Scabies.  Event abated after use stopped or dose reduced no  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  Manufacturer name and address  Device available for evaluation?  yes no returned to manufacturer / / Concomitant medical products  Event abated after use stopped or dose reduced no  Devent reappeared after reintroduction  doesn't apply  Operator of device  health professional user facility distributor  Expiration date  If implanted, give date  If explanted, give date					
Diagnosis for use Scabies.  Event abated after use stopped or dose reduced no  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  Manufacturer name and address  Departor of device health professional user facility distributor  Expiration date  model # Exp. date Event reappeared after reintroduction  doesn't apply  Coperator of device health professional user facility distributor  Expiration date  If implanted, give date  other # If explanted, give date  Concomitant medical products  E. Reporter	Dose, frequency,	route use	The	rapy da	ates
Diagnosis for use Scabies.  Event abated after use stopped or dose reduced no  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 Manufacturer name and address  Device available for evaluation?	2 applications, 2 of	lays	4-14	-96	to
Scabies.  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  Device available for evaluation?					
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 health professional user facility distributor  Expiration date  If implanted, give date serial # If explanted, give date  Device available for evaluation?  yes no returned to manufacturer / / /  Concomitant medical products  E. Reporter	Diagnosis for us	e	]	Event a	abated after use
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  Manufacturer name and address  Coperator of device health professional user facility distributor  Expiration date  If implanted, give date serial # If explanted, give date other # If explanted, give date  Device available for evaluation?  Types no returned to manufacturer / / /  Concomitant medical products  E. Reporter	Scabies.		:	stoppe	d or dose reduced
Event reappeared after reintroduction doesn't apply  Concomitant medical products  D. Suspect medical device  Brand name Type of device  Manufacturer name and address  Manufacturer name and address  Coperator of device  health professional user facility distributor  Expiration date  If implanted, give date serial # lot # If explanted, give date  Operator of device  If implanted, give date  If explanted, give date  Types no returned to manufacturer / / /  Concomitant medical products  E. Reporter				no	
NDC # Concomitant medical products  D. Suspect medical device Brand name Type of device Manufacturer name and address  Manufacturer name and address  Device at a legistry and a legis	T of #	Evn doto			
NDC # doesn't apply  Concomitant medical products  D. Suspect medical device Brand name Type of device Manufacturer name and address Manufacturer name and address  Department of device health professional user facility distributor  Expiration date  If implanted, give date serial # lot #	LOI #	Exp. date			
Concomitant medical products  D. Suspect medical device Brand name Type of device Manufacturer name and address  Manufacturer name and address  Device available for evaluation?				reintro	duction
D. Suspect medical device  Brand name  Type of device  Manufacturer name and address  Manufacturer name and address  Device available for evaluation?  yes no returned to manufacturer  Concomitant medical products  Device available for evaluation?  Type of device health professional user facility distributor  Expiration date  If implanted, give date  If explanted, give date	NDC # -	_		doesn'	t apply
D. Suspect medical device  Brand name  Type of device  Manufacturer name and address  Operator of device  health professional user facility distributor  Expiration date  If implanted, give date  serial # lot # other #  Device available for evaluation?  yes no returned to manufacturer / / Concomitant medical products  E. Reporter		diaal ruad	otc		
Brand name Type of device  Manufacturer name and address  Manufacturer name and address  Device available for evaluation?	Concomitant me	uicai produ	cis		
Brand name Type of device  Manufacturer name and address  Manufacturer name and address  Device available for evaluation?					
Brand name Type of device  Manufacturer name and address  Manufacturer name and address  Device available for evaluation?					
Brand name Type of device  Manufacturer name and address  Manufacturer name and address  Device available for evaluation?	D. Suspect med	lical davice			
Type of device  Manufacturer name and address  Device available for evaluation?		lical device	<i>;</i>		
Manufacturer name and address  Operator of device  health professional user facility distributor  Expiration date  If implanted, give date  serial # lot # other #  Device available for evaluation?  yes no returned to manufacturer / / Concomitant medical products  E. Reporter					
model #		me and add	Irocc	Oper	ator of dovice
model #	Manufacturer na	illic allu auc	11 633	ı -	
model #					
Expiration date  model #					
model #				_	
catalog #   If implanted, give date serial #   lot #   If explanted, give date other #    Device available for evaluation?				Expii	ation date
serial # If explanted, give date other #				If im	olanted, give date
lot # If explanted, give date other #  Device available for evaluation?	_				prantica, gry c auto
other #  Device available for evaluation?  yes no returned to manufacturer / /  Concomitant medical products  E. Reporter	lot #			If exr	lanted, give date
yes no returned to manufacturer /_/ Concomitant medical products  E. Reporter	other #				amazeu, grae umee
yes no returned to manufacturer /_/ Concomitant medical products  E. Reporter	Device available	for evaluati	ion?		
Concomitant medical products  E. Reporter				anufact	urer//
	-				
	F Reporter				
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
✓ yes □no □manufacturer		_	,u110	••	
If you do NOT want your identity			itv		
disclosed to the manufacturer, place an distributor	-	-	-	an 🔲	

		'		
A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
840	19/48/	female	128	lbs
B. Adverse event	or product p	oroblem		
	Adverse Ev	ent		
Outcomes attribut	ted to adverse	event		
death	disability			
☐ life-threatening	□ congenita	l anomaly		
hospitalization	required i	intervention	n	
other: Dizzines	SS			
Date of event 3/12	2/02 <b>Dat</b>	te of repor	t 4/5/	/2002
Describe event or				
On 3/12, I suffered	_	ual spinnin	g. I still	
experience occasion				
close to my taking t	he lindane, I a	m suspect t	that it may	be be
related.				
Relevant tests/labo	oratory data			
Other relevant his	= '		_	
I suffer from migrai	nes but had no	migraine w	when I suff	ered
the spinning room.				

Triage Unit Sequence #	

C. Suspect me	edication(s)			
Name: lindane				
Dose, frequenc	v route use	Ther	apy d	ates
	-			ates
Full body applic hours.	ation for 12	2/26/	02	to
				2/28/02
Diagnosis for u	ise			abated after use
scabies		s	toppe	d or dose reduced
			doesn	t apply
Lot#	Exp. date	F	Event	reappeared after
				oduction
		]	no	
NDC# -	-			
Concomitant m	edical produ	cts		
D. Suspect me	edical device	•		
Brand name				
Type of device				
Manufacturer 1	name and add	dress	Oper	ator of device
			$\square_{\mathrm{h}}$	ealth professional
				ser facility
			$\Box_{d}$	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device availabl				
	returned		nufact	turer/_/
Concomitant m	ieaicai proau	cts		
E. Reporter				
Name and addi	ess	ph	one#	(781)449-6487
The National F	Pediculosis A	ssoci	ation	
P.O. Box 61018	89, Newton, M	<b>1A.</b> 0	2461	
Health professi	onal Occu	pation	1	Also reported to
<b>✓</b> yes □				manufacturer
If you do NOT w	ant your ident	ity		user facility
disclosed to the r	-	-	n 🔳	distributor

A. Patient Identifier   Date of birth   Sex   Weight   130   Ibs    B. Adverse event or product problem   Adverse Event    Outcomes attributed to adverse event   disability   Iife-threatening   congenital anomaly   hospitalization   required intervention   other:   Date of event   1/02   Date of report   3/30/2002    Describe event or problem   The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months, they tell me to keep using lindane even though am 4 months pregnant .  Relevant tests/laboratory data  Other relevant history, including preexisting condition   kids have asthma. i have diabetes and pregnant. kids range from 14 to 2					
B. Adverse event or product problem  Adverse Event  Outcomes attributed to adverse event    death					
Adverse Event  Outcomes attributed to adverse event  death disability hospitalization required intervention other:  Date of event 1/02 Date of report 3/30/2002  Describe event or problem  The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.  Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range	Patient 1			Sex	Ŭ
Adverse Event  Outcomes attributed to adverse event   death					130 lbs
Outcomes attributed to adverse event   death	B. Adve	rse event	or product p	roblem	
death disability life-threatening congenital anomaly hospitalization required intervention other:  Date of event 1/02 Date of report 3/30/2002  Describe event or problem  The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.			Adverse Ev	ent	
life-threatening congenital anomaly hospitalization required intervention other:  Date of event 1/02 Date of report 3/30/2002  Describe event or problem  The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.	Outcom	es attribut	ed to adverse	event	
hospitalization required intervention other:  Date of event 1/02 Date of report 3/30/2002  Describe event or problem  The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.  Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range	death	h	disability		
hospitalization required intervention other:  Date of event 1/02 Date of report 3/30/2002  Describe event or problem  The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.  Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range	$\Box_{\text{life-t}}$	hreatening	Congenital	anomaly	
Date of event 1/02 Date of report 3/30/2002  Describe event or problem  The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.  Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range	$\square_{\text{hosp}}$	italization	required i	ntervention	
Describe event or problem  The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.  Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range	other	r:			
Describe event or problem The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.  Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range	Date of e	event 1/02	2 Dat	e of report	3/30/2002
The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.  Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range	Describe	event or		<b>F</b>	
product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.  Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range			=	on me usi	ng this
they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant.  Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range					
Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range	-				
Relevant tests/laboratory data  Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range				g lindane ev	ven though
Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range	am 4 moi	nths pregna	ant .		
Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range					
Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range					
Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range					
Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range					
Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range					
Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range					
Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range					
Other relevant history, including preexisting condition kids have asthma. i have diabetes and pregnant. kids range					
kids have asthma. i have diabetes and pregnant. kids range	Relevant	t tests/labo	oratory data		
kids have asthma. i have diabetes and pregnant. kids range					
kids have asthma. i have diabetes and pregnant. kids range					
kids have asthma. i have diabetes and pregnant. kids range					
kids have asthma. i have diabetes and pregnant. kids range					
kids have asthma. i have diabetes and pregnant. kids range					
kids have asthma. i have diabetes and pregnant. kids range	Other re	elevant his	tory, includin	g preexisti	ng condition
				. 1 . 8	

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: lindane					
Dose, frequency,	route use	The	rapy d	ates	
once a week		1/02			
once a week		1, 02	-	to 3/02	
D'			E4		
Diagnosis for use	e			abated after use d or dose reduced	
headlice			stoppe	u of dose feduced	
			no		
Lot #	Exp. date		Event	reappeared after	
			reintro	oduction	
			doesn'	t apply	
NDC# -	-		aoesii	t apply	
Concomitant med	dical produ	cts			
D. Suspect med	lical device	,			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
			$\Box_{d}^{u}$	istributor	
			$\bot$	ration date	
			Expii	ation date	
model #			If im	planted, give date	
catalog # serial #			-	prantedu, grije dance	
lot #			If evr	planted, give date	
other #			III CA	nanteu, give date	
Device available	for evaluat	ion?			
$\square_{\text{yes}} \square_{\text{no}}$				turer / /	
Concomitant med	dical produ	cts			
	-				
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health profession	nal Occuj	oatio	n	Also reported to	
$\mathbf{v}_{\mathrm{yes}}$ $\square_{\mathrm{no}}$	-			manufacturer	
If you do NOT want your identity user facility				user facility	
disclosed to the ma				distributor	

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
837	5/95	female	50 lbs
B. Adverse event	or product p	roblem	
	Adverse Eve	ent	
Outcomes attribut	ted to adverse e	event	
death	disability		
☐life-threatening	□ congenital	anomaly	
hospitalization	☐required in	ntervention	
other: sores all			
Date of event 3/15	5/02 <b>Date</b>	e of report	3/27/2002
Describe event or			
I was called from th		y daughter l	had lice. I
went and bought the	e Nix brand. W	hen I went	to do the 10
day follow up i didi	n't. The sores or	n her head	were to bad.
Relevant tests/labo	oratory data		
Other relevant his	story, including	g preexisti	ng condition
	, , , , , , , ,	<b>, r</b>	6

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: Nix				
Dose, frequency,	, route use	The	rapy d	ates
only the one time		3/13	3/02	
				to 3/22/02
Diagnosis for us	e		Event :	abated after use
lice			stoppe	d or dose reduced
			no	
 Lot #	Exp. date			1 64
	LAp. date			reappeared after oduction
no			remurc	duction
NDC# -	-		doesn'	t apply
Concomitant me	dical produ	cts	1	
Rid 3/26	-			
Mayo 3/26				
Tea tree oil 3/27				
D. Suspect med	dical device	•		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
				ealth professional
				ser facility
				istributor
				ration date
model#			Expii	ation date
model # catalog #			If im	planted, give date
serial #			-   '	. , ,
lot #			If ext	olanted, give date
other #			'	, , , , , , , , , , , , , , , , , , , ,
Device available				
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				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 professio	nal Occup	atio	n	Also reported to
$\bigvee_{\mathrm{yes}}$ $\square_{\mathrm{no}}$	_			manufacturer
If you do NOT wa	nt your identi	ty		user facility
disclosed to the ma			an 🔲	distributor

A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
834	12/9/96	female	40	lbs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse o	event		
$\Box_{\text{death}}$	disability			
□ life-threatening	Congenital	anomaly		
hospitalization	_			
other:	1			
Date of event 3/18	R/02 <b>Date</b>	e of report	3/18/20	02
		or report	3/10/20	
Describe event or kwell does not work		v danohter	has school	ı
principal and nurse	-	_		L
was cleaned of lice				
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng conditi	on

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: Kwell					
Dose, frequenc	Dose, frequency, route use The			ates	
shampoo every	5 days	3/16	5	to	
				3/18	
Diagnosis for <b>u</b>	ıse		Event	abated after use	
headlice			stoppe	d or dose reduced	
			no		
Lot #	Exp. date		Event	reappeared after	
				duction	
NDC# -	-		doesn	t apply	
Concomitant n	nedical produ	cts			
olive oil					
RID					
NIX					
D. Suspect me	edical device	•			
Brand name					
Type of device					
Manufacturer	name and add	lres	Oper	ator of device	
			$\square_{\mathrm{h}}$	ealth professional	
				ser facility	
				istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			_ If exp	planted, give date	
other #					
<b>Device availab</b> □ <sub>yes</sub> □ <sub>no</sub>				urer / /	
Concomitant n	nedical produ	cts			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health profess	ional Occuj	patio	n	Also reported to	
	no			manufacturer	
If you do NOT want your identity user facility					
disclosed to the manufacturer, place an distributor					

	-			
A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
826	05/10/59	male	235	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Prod	luct Proble	m	
Outcomes attribut	ted to adverse e	event		
$\Box_{\mathrm{death}}$	disability			
☐ life-threatening		anomaly		
hospitalization		ntervention		
other:	— required in	iter vention		$\neg$
Date of event 02/2	20/02 <b>Date</b>	of report	3/5/20	)02
Describe event or	=		_	
Full body case of sa				
treatment failed to c	control. Lindane	has caused	shortness	of
breath, tiredness.				
Relevant tests/labo	oratory data			
Other relevant his	story, including	p preexisti	ng conditi	on
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	, p		.011

Triage Unit Sequence #	

C. Suspect medication(s)				
Name: lindane	Name: lindane			
Dose, frequenc	cy, route use	The	rapy d	ates
1% lotion.		12/2	2/01	4
				to 12/9/01
Diagnosis for t	use		Event	abated after use
Repeated in Fel	oruary.		stoppe	d or dose reduced
			doesn	t apply
Lot#	Exp. date		Event	reappeared after
				duction
NIDC #			doesn	t apply
NDC# -	-			
Concomitant n	nedical produ	cts		
D. Suspect m	edical device	е		
Brand name				
Type of device				
Manufacturer	name and add	dress	Oper	ator of device
				ealth professional
				ser facility
				istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If ex	olanted, give date
other #			'	, ,
Device availab	le for evaluat	ion?		
$\square_{\mathrm{yes}}  \square_{\mathrm{no}}$	returned	to m	anufact	urer/_/
Concomitant n	nedical produ	cts		
	_			
E. Reporter				
Name and address phone # (781)449-6487				
The National Pediculosis Association				
P.O. Box 610189, Newton, MA. 02461				
Health profess	ional Occu	patio	n	Also reported to
	no			manufacturer
If you do NOT v	vant vour ident	itv		user facility
disclosed to the			an 🔳	distributor
arserosea to tile.		,1uCC	wii 🔲	

A. Patient Inform				
Patient Identifier		Sex	Weight	
821	11/28/60	female	115	lbs
B. Adverse even				
	Adverse Eve			
Outcomes attribut	ted to adverse e	event		
death	disability			
☐ life-threatening	☐ congenital	anomaly		
hospitalization	required in	ntervention		
other: skin read	ction			
Date of event 2/02	2 Date	of report	3/1/2	002
Describe event or				
Itchy red skin bliste	_	neck & fin	igers	
Relevant tests/lab	oratory data			
Other relevant his	story, including	g preexisti	ng condit	ion

Triage Unit Sequence #	

C. Suspect m	edication(s)			
Name: generi	c lice shampoo			
C	•			
Dogo fuccion	wouto was	Thomany	datas	
Dose, frequen		Therapy	aates	
5 treatments in	2 mths	12/27	to	
			2/22	
Diagnosis for	use	Ever	t abated after use	
Reuse Rid and l	nave	stop	ped or dose reduced	
dermatologist m	nanage reaction	does	sn't apply	
Lot #	Exp. date			
	Lap. date		t reappeared after	
		reini	roduction	
NDC# -		does	sn't apply	
	nodical			
Concomitant r	neaicai produc	cis		
D. Suspect m	edical device	•		
Brand name				
Type of device		1		
Manufacturer	name and add	lress Op	erator of device	
			health professional	
user facility				
			distributor	
Expiration date			piration date	
model #				
catalog #		If i	mplanted, give date	
serial #				
lot #		If e	explanted, give date	
other #				
Device availab	le for evaluati	ion?		
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to manufa	acturer//	
Concomitant r	nedical produ	ets		
E Donortor				
E. Reporter				
Name and add			# (781)449-6487	
The National	Pediculosis A	ssociatio	on	
P.O. Box 6101	89, Newton, M	IA. 0246	1	
Health professional Occupation Also reported to				
	no cear	<del>-</del>	manufacturer	
If you do NOT		tv	user facility	
•	manufacturer, p		distributor	

	-		
A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
820	10/30/91	female	75 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Prod	luct Proble	m
Outcomes attribut	ted to adverse e	event	
□death	disability		
□ life-threatening		anomaly	
hospitalization		ntervention	
other:	— required in	iter vention	
Date of event 02/0		of report	2/27/2002
Describe event or	=		
child has became sid	ck with headach	s,stomach a	achs and not
hungry			
Relevant tests/labo	oratory data		
Other relevant his	story, including	g preexisti	ng condition

Triage Unit Sequence #	

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
815	12/01/45	female	125 lbs
B. Adverse event	or product p	roblem	
	Adverse Eve	ent	
Outcomes attribut	ted to adverse o	event	
death	disability		
☑ life-threatening	Congenital	anomaly	
$\square_{ m hospitalization}$	required ir	ntervention	
other:			
Date of event 02/2	20/02 <b>Date</b>	e of report	2/20/2002
Describe event or			
recurrance of precar		CI) in left l	oreast. Rt
breast mastectomy			
Relevant tests/labo	ratory data		
Refevant tests/lab	nawiy uata		
Oth on male and 1.		•.	
Other relevant his update on report of		g preexisti	ng condition
update on report or	02/19/02		

Triage Unit Sequence #	

C. Suspect medication(s)				
Name: lindane				
Dose, frequency	, route use	The	rapy d	ates
2-3 times full stre		01/9		
	C		to 02/98	
Diagnosis for us	se			abated after use
scabies, misdiagn	osis	5	stopped or dose reduce	
			no	
Lot#	Exp. date	Ī	Event reappeared after reintroduction	
NDC# -			doesn'	t apply
	-	$-\!$		
Concomitant me		cts		
see report of 02/1	.9/02			
D. Suspect me	dical device	9		
Brand name				
Type of device				
Manufacturer n	ame and add	lress	Oper	ator of device
			$\square_{\rm h}$	ealth professional
user facility				
distributor				istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	olanted, give date
other #				<u>-</u>
Device available				
$\square_{\text{yes}} \square_{\text{no}}$				urer//
Concomitant medical products				
E. Reporter				
Name and address phone # (781)449-6487				
The National Po	ediculosis A			
P.O. Box 610189, Newton, MA. 02461				
	9, Newton, M	1A. U	2401	
Health profession				Also reported to
Health profession ✓ Ves □ n	onal Occuj			Also reported to manufacturer
	onal Occup	patio		Also reported to  manufacturer  user facility

A. Patier				
Patient I	dentifier	Date of birtl	h Sex	Weight
	814	11/17/66	female	150 lbs
B. Adver	se even	t or product	problem	
		Adverse E	Event	
Outcome	s attribut	ted to advers	e event	
$\Box_{\text{death}}$		□disabilit	у	
$\square_{\text{life-th}}$	reatening	Congenit	al anomaly	
$\square_{\text{hospi}}$	talization	<b>✓</b> required	interventio	n
other:		•		
Date of e	vent 01/	20/02	ate of repor	rt 2/20/2002
			ate of repor	.t 2/20/2002
Describe		_	ild and my	self and became
	_	-	-	completely and
		elt nauseous, l		
Was sick	for severa	l days followi	ng.	
Relevant	tests/labo	oratory data		
Other re	levant his	story, includi	ing preexis	ting condition
				ever mentioned
any risks i	from linda	ane.		

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: lindane	Name: lindane				
Mort wa	s in the name	1%	generic		
Dose, frequency	, route use	The	rapy d	ates	
Used only once		01/0	01/02	to	
				to 02/20/02	
Diagnosis for us	se		Event	abated after use	
Lice not killed by	NIX		stopped or dose reduce		
-			no		
Lot#	Exp. date		Event	reappeared after	
	1			duction	
			docom	t amply	
NDC# -	-		uoesn	t apply	
Concomitant me	edical produ	cts			
I also sprayed wi	th NIX spray	pre	vious to	using the	
lindane.					
D. Suspect med	dical device	)			
Brand name					
Type of device Manufacturer n	ama and add	Irace	Oper	ator of device	
manufacturer in	ame and add	II CS	ı Â		
health professional user facility					
distributor			istributor		
				ration date	
model #			23.2		
catalog #			If im	planted, give date	
serial #			-		
lot #			_ If exp	planted, give date	
other #					
Device available				, ,	
yes no returned to manufacturer / /					
Concomitant medical products					
E. Reporter					
Name and addre	ess	р	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occuj	oatio	n	Also reported to	
				manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the m	anufacturer, p	lace	an 🔳	□distributor	

A. Patient Inform	ation				
Patient Identifier	Date of bi	irth	Sex	Weight	
812	12/01/45		female	125	lbs
B. Adverse event	or produ	ict pi	roblem		
	Advers	e Eve	ent		
Outcomes attribut	ted to adve	erse e	event		
death	<b>✓</b> disab	ility			
☐ life-threatening	$\Box_{\mathrm{conge}}$	enital	anomaly		
	□ requi	red ir	itervention	1	
other:					
Date of event 2/98	8-2/02	Date	of repor	f 2/19/	2002
Describe event or		Dan	оттерог	2/17/	2002
Skin lesions, breast	_	e prol	olems, ioir	nt pain	
, , , , , , , , , , , , , , , , , , , ,		- F		F	
Relevant tests/labo	ratory da	ta			
	natory da	···			
Other relevant his	story, inch	uding	nreexist	ing condi	ition
allergies: airborn a					
and in skin. Occasi				, ,	

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name: lindane						
Dose, frequency.	route use	The	rapy da	ates		
Shampoo full stre		01/0				
entire body.	aigui oii	01/0	3/70	to		
•		1	-	2/02		
Diagnosis for us	e		Event abated after use			
lice/scabies			stopped or dose reduced			
			no			
Lot#	Exp. date		Event 1	reappeared after		
				duction		
			doosn'	t ammly		
NDC # -	-		doesn	t apply		
Concomitant me	dical produ	cts				
Numerous antibio	tics, Numero	ous c	ortison	e preparations,		
diflucan	,			,		
D. Suspect med	lical device	,				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
			1 —	ealth professional		
				ser facility		
				istributor		
				ration date		
			Expii	ation date		
model # catalog #			If im	planted, give date		
serial #			1 '	,, <b>,</b>		
lot #			If exr	planted, give date		
other #				Junicea, give aute		
Device available	for evaluati	ion?				
$\square_{\text{yes}} \square_{\text{no}}$			anufact	urer//		
Concomitant me						
E. Reporter						
Name and addre	ss	pl	hone #	(781)449-6487		
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health professio	-	oatio	n	Also reported to manufacturer		
If you do NOT was		tv		user facility		
disclosed to the ma	-	-	an 🔲	distributor		

A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
804	01/04/79	female	110	lbs
B. Adverse event	or product p	roblem		
	Adverse Eve	ent		
Outcomes attribut	ted to adverse o	event		
□death	disability			
□ life-threatening		anomaly		
$\square$ hospitalization		ntervention		
other:	— required ii	iter vention		
Date of event 01/2	25/99 <b>Date</b>	e of report	1/26/20	02
Describe event or	=			
Prescribed elimite c				
AM.Was in ER 10 o	-			
back of my head dis				
stinging feeling in n diagnosis:cervical ca		is Left side	worse Rece	nt
diagnosis:cervicai ca	ancer			
Relevant tests/labo	ratory data			
	oratory and			
Other relevant his				on
I never had any maj	or illnesses prio	r to taking	this drug.	

Triage Unit Sequence #	

C. Suspect med	dication(s)					
Name:						
Elimite(permethrin) Topical Cream						
Dose, frequency, route use Therapy dates						
Several nights For			15/99			
12hr, wash off		01/1		to 01/25/99		
AM@DB advice Diagnosis for us	10		Event	abated after use		
<u> </u>				d or dose reduced		
a misdiagnosis of	scables			a or aose reader		
			no			
Lot#	Exp. date			reappeared after		
			reintro	oduction		
NDC# -	_		doesn	t apply		
	dical nucdu	o <b>t</b> a				
Concomitant me	=		:	a		
I am currently see neuropathy	ang two neur	olog	ist for d	nagnosed		
neuropaury						
D. Suspect med	dical device	,				
Brand name	alcal acvice					
Type of device						
Manufacturer n	ame and add	lress	Oper	ator of device		
			1 -	ealth professional		
				ser facility		
			$\square_{\mathrm{d}}$	istributor		
				ration date		
model #						
catalog #			If im	planted, give date		
serial #						
lot #			If exp	If explanted, give date		
other #						
Device available						
	returned		anufact	turer//		
Concomitant me	edical produ	cts				
E. Reporter						
Name and addre	ess	р	hone #	(781)449-6487		
The National Pediculosis Association						
P.O. Box 610189						
Health professio				Also reported to		
$\mathbf{v}_{\mathrm{yes}}$	0			manufacturer		
If you do NOT wa	nt your identi	ity		user facility		
disclosed to the m	•	•	an 🔲	distributor		

A. Patient	Inform	ation				
Patient Ide	ntifier	Date of b	oirth	Sex	Weight	
	800	6-5-96		male	45	lbs
B. Adverse	e event	or prod	uct pi	roblem		
	Advers	e Event &	k Prod	luct Proble	em	
Outcomes a	attribut	ed to adv	erse e	event		
death		∐disa	bility			
☐ life-thre	atening	□cong	genital	anomaly		
□hospital	ization	□requ	ired in	ntervention		
other:						
Date of eve	nt 1-12	2-02	Date	of report	1/22/2	2002
Describe ev	ent or	problem				
Used Kwell					caused	
headaches, o	dizzines	s, diahrea	, and f	atique		
Relevant tests/laboratory data						
Other relev	zant hic	tory inc	ludina	ı nraavisti	na condit	tion
Other refer	ant ms	otory, mc	iuuiiiş	g pi cexisti	ng condi	1011

Triage Unit Sequence #	

C. Suspect med	dication(s)				
	ilcation(s)				
Name: Kwell					
RID					
Dose, frequency	, route use	The	rapy d	ates	
RID two times an		1-15	5-02	to	
(one oz.) two time	es			1-19-02	
Diagnosis for us	e		Event	abated after use	
head lice			stopped or dose reduce		
			no		
 Lot #	Exp. date				
Lot #	Ехр. чан			reappeared after	
			reintro	duction	
NDC# -	_		doesn'	t apply	
Concomitant me	dical prod	ota			
Concomitant me	aicai produ	cis			
D. Suspect med	dical device	)			
Brand name					
Type of device			To		
Manufacturer na	ame and add	iress		ator of device	
				ealth professional	
				ser facility	
			Ша	istributor	
			Expi	ration date	
model #					
catalog #			- If im	planted, give date	
serial #			-		
lot #			- If exp	planted, give date	
other #					
Device available for evaluation?  yes no returned to manufacturer/_/					
Concomitant me	dical produ	cts			
	•				
E. Reporter					
Name and addre	SS	p	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189	, Newton, M	ΙΑ. (	02461		
Health professio	nal Occuj	patio	n	Also reported to	
$\mathbf{V}_{\mathrm{yes}}$	)			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma			an 🔲	□distributor	

A. Patient Inform				
Patient Identifier		Sex	Weight	
799	5-28-70	female	125	lbs
B. Adverse event				
	e Event & Prod		em	
Outcomes attribut	ted to adverse e	event		
$\Box_{\text{death}}$	disability			
☐ life-threatening	Congenital	anomaly		
□ hospitalization	required in	ntervention		
other:				
Date of event 1-12	2-02 <b>Date</b>	of report	1/22/2	002
Describe event or				
Used Kwell two tim	=	nd a friend.	, both have	e
headaches, dizzines	-			
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condit	ion
			9	

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: Kwell				
Dose, frequency	, route use	The	rapy d	ates
two ounces in two	o days	1-16	5-02	
	•			to 1-19-02
Diagnosis for us	<u>е</u>		Event :	abated after use
head lice				d or dose reduced
nedd nee			no	
Lot#	Exp. date			
Lot#	Exp. date			reappeared after
			reintro	duction
NDC# -	<u> </u>		doesn'	t apply
Concomitant me	dical produ	cts		
Concomitant inc	dicai produ	Cus		
D. Suspect med	dical device	,		
Brand name	arour do vro			
Type of device				
Manufacturer na	ame and add	lrese	Oper	ator of device
		00.		ealth professional
				ser facility
				istributor
				ration date
			Expii	auon uate
model # catalog #			- If im	planted, give date
serial #			-   '	, ,
lot #			If ext	planted, give date
other #				, <b>g</b>
Device available	for evaluat	ion?		
$\square_{\mathrm{yes}}  \square_{\mathrm{no}}$	returned	to m	anufact	urer/_/
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	ss	n	hone #	(781)449-6487
The National Pe				(701)115 0107
P.O. Box 610189				
Health professio				Also reported to
yes $\square_{nc}$	_	Jau	711	manufacturer
If you do NOT wa		itv		user facility
disclosed to the ma				distributor

A. Budinat Inform					
A. Patient Inform			~		
Patient Identifie			Sex	Weight	
797	11/22/99		female	31	lbs
B. Adverse ever					
	rse Event &			m	
Outcomes attribu	ited to adv	erse ev	vent		
$\Box$ death	$\Box_{\text{disa}}$	bility			
☐ life-threatenin	$_{\rm g}$ $\square_{\rm cong}$	genital a	anomaly		
hospitalization	n □requ	ired int	tervention		
other:					
Date of event 01	/19/2002	Date	of report	1/19/2	002
Describe event of			<b>F</b>	-,-,,-	
WE can not get ric	_	all in l	nousehold	are infecte	ed,
some of us even h					,
	-				
Relevant tests/lal	oratory d	ata			
					_
Other relevant h	istory, inc	luding	preexisti	ng condit	ion
NA					

Triage Unit Sequence #	

<u> </u>				
C. Suspect me	edication(s)			
Name: Rid				
Dose, frequenc	v. route use	The	rapy d	ates
Shampoo every		10/3		
comb out every		10/3	1	to
-				01/19
Diagnosis for <b>u</b>	ise			abated after use
Lice		ŀ	stoppe	d or dose reduced
			no	
Lot#	Exp. date		Event	reappeared after
NA				duction
			MOC	
NDC# -	-		yes	
Concomitant n	nedical produ	cts		
Nix; twice				
D. Suspect m	edical device	9		
Brand name				
Type of device				
Manufacturer	name and add	lress	Oper	ator of device
			$\square_{\mathrm{h}}$	ealth professional
				ser facility
			$\Box_{d}$	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device availab				
	returned		anutaci	turer//
Concomitant n	ieaicai produ	cis		
E. Reporter				
Name and add	ress	pl	hone #	(781)449-6487
The National I	Pediculosis A	ssoc	iation	
P.O. Box 61018	89, Newton. M	1A. (	)2461	
Health profess				Also reported to
✓ yes		patio	**	manufacturer
If you do NOT w		itv		user facility
disclosed to the	•	•	an 🔲	distributor

A. Patient					
Patient Ide	ntifier	Date of birth	Sex	Weight	
	793	04/09/1978	female	150	lbs
B. Adverse	e event	or product	oroblem		
		Product Pro	blem		
Outcomes a	attribut	ed to adverse	event		
$\Box_{\text{death}}$		disability	7		
$\square_{ ext{life-thre}}$	atening	Congenita	ıl anomaly		
$\square_{ m hospital}$	ization	required	intervention		
other: c	an't get	rid of them			
Date of eve	nt 01/1	15/2002 <b>Da</b>	te of report	1/15/2	002
Describe ev	ent or		· · · · · · · · · · · · · · · · · · ·		
		WELL shamp	oos, and car	nnot GET	
RID OF TH			,		
Relevant te	sts/labo	ratory data			
Other relev	ant his	story, includii	ng preexisti	ng condit	ion

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Rid					
Dose, frequency,	, route use	The	rapy d	ates	
Extra Strength, us			2001		
used 4oz each tim				to 1/15/2002	
Diagnosis for us	0		Event	abated after use	
_	C		stopped or dose reduce		
Head lice			вторрс	a or aose readeed	
			no		
Lot #	Exp. date		Event	reappeared after	
			reintro	duction	
			yes		
NDC# -	-		700		
Concomitant me	dical produ	ets			
Kwell					
D. Suspect med	lical device				
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
			□d	istributor	
			Expi	ration date	
model #					
catalog #			- If im	planted, give date	
serial #					
lot # other #			- If exp	olanted, give date	
Device available $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$				urer//	
Concomitant me					
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to   ✓ yes □ no □ manufacturer					
If you do NOT want your identity user facility					
If you do NOT was disclosed to the ma	•	•	an 🔲	distributor	
arserosea to the III8	muraciurer, p	iace	a11 🔲	alsa loutoi	

A Detient Inform	attan					
A. Patient Informatient Identifier		٠4	G	TT/oight		
	2-2-56	ırtn	Sex	Weight 290		
791		tot ni	male	290	lbs	
B. Adverse event	Advers					
Outcomes attribut						
death	✓ disab		vent			
life-threatening	_		anomaly	,		
hospitalization	_ `		iterventi			
other: prirectal						
Date of event 19/9	)2/	Date	of repo	rt 1/14	/2002	
Describe event or	problem					
In severce in 1975/7		ime h	e was tre	ated for sc	abies	
for 8 months. In 199					auah	
buttox because of t a long time might th					sucn	
Relevant tests/laboratory data						
Refevant tests/fabo	oratory da	ııa				
Other relevant his	tory, incl	uding	g preexi	sting cond	lition	
secondary disabilitie				J		

Triage Unit Sequence #	

C. Suspect me	dication(s)				
Name: Kwell					
Dose, frequency	, route use	The	rapy d	ates	
every day for 8 r	nonths	11/7	75		
				to 6/76	
Diagnosis for u	Se Se		Event	abated after use	
scaibies				d or dose reduced	
scaroics				't apply	
Lot#	Erm doto				
Lot#	Exp. date			reappeared after	
			reintro	oduction	
NDC# -	-		yes		
Concomitant m	edical produ	cts			
	-	- 13			
perianal cancer 1	992				
D. Suspect me	dical device				
Brand name	dicai device	•			
Type of device					
Manufacturer n	ame and add	lress	Oner	ator of device	
1,141141141Ctu1Ct	uni unu uu	ar Co.		ealth professional	
				ser facility	
				istributor	
3.1//			Expi	ration date	
model #			- If im	planted, give date	
catalog # serial #			-	piuricu, grie uuic	
lot #			If ov	planted, give date	
other #			- III CAJ	nanteu, give uate	
Device available	for evaluat	ion?			
$\square_{\text{yes}} \square_{\text{no}}$				turer / /	
Concomitant m					
	-				
E. Reporter					
Name and addr	oaa	n	hone #	(781)449-6487	
		ᆮ		(101)+12-0401	
The National Pediculosis Association  P.O. Boy 610180 Noveton MA 02461					
P.O. Box 610189, Newton, MA. 02461					
Health profession	_	patio	n	Also reported to	
	0	_		manufacturer	
If you do NOT wa				user facility distributor	
disclosed to the m	anufacturer, p	lace	an 🔳	iii aistributor	

A. Patient Identifier   Date of birth   Sex   Weight   787   4/8/96   female   39   lbs    B. Adverse event or product problem   Adverse Event & Product Problem      Adverse Event & Product Problem						
B. Adverse event or product problem  Adverse Event & Product Problem  Outcomes attributed to adverse event    death						
Adverse Event & Product Problem  Adverse Event & Product Problem  Outcomes attributed to adverse event    death	Patient Identifier	Date of birth	Sex	Weight		
Adverse Event & Product Problem  Outcomes attributed to adverse event   death	,	., 0, , 0		39 lbs		
Outcomes attributed to adverse event death disability life-threatening congenital anomaly hospitalization required intervention other:  Date of event 09/01/ Date of report 1/10/2002  Describe event or problem MY DAUGHTER, AGE 5 1/2 YRS, ATTENDS KINDERGARTEN.WE HAVE BEEN SUFFERING THRU REPEATED OUTBREAKS OF HEAD LICE SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT COMES BACK(2 OTHER CHILDREN IN THE CLASS HAVE ALSO BEEN AFFECTED).I AM VERY DESPARATE.  Relevant tests/laboratory data  Other relevant history, including preexisting condition MY DAUGHTER & I BOTH HAVE ASTHMA - THE PRODUCTS AGGRAVATE IT.ALSO, I AM PREGNANT & VERY CONCERNED IF THESE PRODUCTS COULD HAVE ADVERSE EFFECT ON	B. Adverse event	or product p	oblem			
death disability congenital anomaly hospitalization required intervention other:  Date of event 09/01/ Date of report 1/10/2002  Describe event or problem MY DAUGHTER, AGE 5 1/2 YRS, ATTENDS KINDERGARTEN.WE HAVE BEEN SUFFERING THRU REPEATED OUTBREAKS OF HEAD LICE SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT COMES BACK(2 OTHER CHILDREN IN THE CLASS HAVE ALSO BEEN AFFECTED).I AM VERY DESPARATE.  PROBUCTS AGGRAVATE IT.ALSO, I AM PREGNANT & VERY CONCERNED IF THESE PRODUCTS COULD HAVE ADVERSE EFFECT ON	Advers	e Event & Prod	uct Proble	em		
□ life-threatening □ congenital anomaly □ hospitalization □ required intervention other: □ Date of event 09/01/ □ Date of report 1/10/2002  Describe event or problem  MY DAUGHTER,AGE 5 1/2 YRS, ATTENDS  KINDERGARTEN.WE HAVE BEEN SUFFERING  THRU REPEATED OUTBREAKS OF HEAD LICE  SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT  COMES BACK(2 OTHER CHILDREN IN THE CLASS HAVE ALSO BEEN AFFECTED). I AM VERY  DESPARATE.   Other relevant history, including preexisting condition  MY DAUGHTER & I BOTH HAVE ASTHMA - THE  PRODUCTS AGGRAVATE IT.ALSO, I AM  PREGNANT & VERY CONCERNED IF THESE  PRODUCTS COULD HAVE ADVERSE EFFECT ON	_	ted to adverse e	event			
Date of event 09/01/ Date of report 1/10/2002  Describe event or problem  MY DAUGHTER,AGE 5 1/2 YRS, ATTENDS  KINDERGARTEN.WE HAVE BEEN SUFFERING  THRU REPEATED OUTBREAKS OF HEAD LICE SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT  COMES BACK(2 OTHER CHILDREN IN THE CLASS  HAVE ALSO BEEN AFFECTED).I AM VERY  DESPARATE.   PROBUCTS AGGRAVATE IT.ALSO,I AM  PREGNANT & VERY CONCERNED IF THESE  PRODUCTS COULD HAVE ADVERSE EFFECT ON	death	disability				
Date of event 09/01/ Date of report 1/10/2002  Describe event or problem MY DAUGHTER, AGE 5 1/2 YRS, ATTENDS KINDERGARTEN.WE HAVE BEEN SUFFERING THRU REPEATED OUTBREAKS OF HEAD LICE SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT COMES BACK(2 OTHER CHILDREN IN THE CLASS HAVE ALSO BEEN AFFECTED). I AM VERY DESPARATE.  Relevant tests/laboratory data  Other relevant history, including preexisting condition MY DAUGHTER & I BOTH HAVE ASTHMA - THE PRODUCTS AGGRAVATE IT.ALSO, I AM PREGNANT & VERY CONCERNED IF THESE PRODUCTS COULD HAVE ADVERSE EFFECT ON	☐ life-threatening	□ congenital	anomaly			
Date of event 09/01/ Date of report 1/10/2002  Describe event or problem  MY DAUGHTER,AGE 5 1/2 YRS, ATTENDS  KINDERGARTEN.WE HAVE BEEN SUFFERING  THRU REPEATED OUTBREAKS OF HEAD LICE SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT  COMES BACK(2 OTHER CHILDREN IN THE CLASS  HAVE ALSO BEEN AFFECTED).I AM VERY  DESPARATE.  Relevant tests/laboratory data  Other relevant history, including preexisting condition  MY DAUGHTER & I BOTH HAVE ASTHMA - THE  PRODUCTS AGGRAVATE IT.ALSO,I AM  PREGNANT & VERY CONCERNED IF THESE  PRODUCTS COULD HAVE ADVERSE EFFECT ON	$\square_{ m hospit}$ alization	required in	tervention			
Describe event or problem MY DAUGHTER,AGE 5 1/2 YRS, ATTENDS KINDERGARTEN.WE HAVE BEEN SUFFERING THRU REPEATED OUTBREAKS OF HEAD LICE SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT COMES BACK(2 OTHER CHILDREN IN THE CLASS HAVE ALSO BEEN AFFECTED).I AM VERY DESPARATE.  Relevant tests/laboratory data  Other relevant history, including preexisting condition MY DAUGHTER & I BOTH HAVE ASTHMA - THE PRODUCTS AGGRAVATE IT.ALSO,I AM PREGNANT & VERY CONCERNED IF THESE PRODUCTS COULD HAVE ADVERSE EFFECT ON	other:					
MY DAUGHTER, AGE 5 1/2 YRS, ATTENDS KINDERGARTEN. WE HAVE BEEN SUFFERING THRU REPEATED OUTBREAKS OF HEAD LICE SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT COMES BACK(2 OTHER CHILDREN IN THE CLASS HAVE ALSO BEEN AFFECTED). I AM VERY DESPARATE.  Relevant tests/laboratory data  Other relevant history, including preexisting condition MY DAUGHTER & I BOTH HAVE ASTHMA - THE PRODUCTS AGGRAVATE IT.ALSO, I AM PREGNANT & VERY CONCERNED IF THESE PRODUCTS COULD HAVE ADVERSE EFFECT ON	Date of event 09/0	)1/ <b>Date</b>	of report	1/10/2002		
Other relevant history, including preexisting condition MY DAUGHTER & I BOTH HAVE ASTHMA - THE PRODUCTS AGGRAVATE IT.ALSO,I AM PREGNANT & VERY CONCERNED IF THESE PRODUCTS COULD HAVE ADVERSE EFFECT ON	MY DAUGHTER,AGE 5 1/2 YRS, ATTENDS KINDERGARTEN.WE HAVE BEEN SUFFERING THRU REPEATED OUTBREAKS OF HEAD LICE SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT COMES BACK(2 OTHER CHILDREN IN THE CLASS HAVE ALSO BEEN AFFECTED).I AM VERY					
	Other relevant his MY DAUGHTER & PRODUCTS AGG PREGNANT & VE PRODUCTS COUI	story, including & I BOTH HAV RAVATE IT.A RY CONCERN LD HAVE ADV	VE ASTHN LSO,I AM IED IF TH	MA - THE ESE		

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Nix					
RID/OV	IDE				
Dose, frequency,	route use	The	rapy d	ates	
EVERY 10 DAYS	5	09/0	)1	to	
				to 01/02	
Diagnosis for us	e		Event	abated after use	
HEAD LICE			stoppe	d or dose reduced	
			doesn'	t apply	
Lot#	Exp. date		Event	reappeared after	
				duction	
			*****		
NDC# -	-		yes		
Concomitant me	dical produ	cts			
D. Suspect med	lical device				
Brand name					
Type of device					
Manufacturer na	me and add	Ires	Oner	ator of device	
ivianulucturer ne	inic and add	ii Col	ı Â		
				ealth professional	
			user facility distributor		
			Expii	ration date	
model #			- If im	planted, give date	
catalog #			-   111 11111	pianteu, give date	
serial # lot #			TC	.14.1	
lot # other #			- In exp	planted, give date	
	C14				
Device available $\square_{ m yes} \ \square_{ m no}$	_			urer / /	
Concomitant me	dical produ	cts	ianuraci	urer//	
	arem produ				
<b>-</b>					
E. Reporter				(504) 440, 6405	
Name and addre		Ĺ	hone #	(781)449-6487	
The National Pe	diculosis A	sso	ciation		
P.O. Box 610189	, Newton, M	ΙΑ. (	02461		
Health professio	nal Occuj	oatio	n	Also reported to	
$ \mathbf{V}_{\text{yes}}  \square_{\text{no}} $	)			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma			an 🔲	□distributor	

		_							
A. Patient	Inform	ation							
Patient Ide	entifier	Date of birth	Sex	Weight					
	786	02/07/96	female	38	lbs				
B. Advers	e event	or product p	roblem						
		Product Prol	olem						
Outcomes	attribut	ted to adverse	event						
death		disability							
	life-threatening Congenital anomaly								
	_								
□hospita	lization	required i	ntervention		_				
other:									
Date of eve	ent 01/0	09/02 <b>Dat</b>	e of report	1/9/20	002				
Describe e	vent or	problem							
		en sent home 5							
		reated her with							
		tion medication	. We have	followed al	11				
of your sug	gested to	reatments							
Relevant te	ests/labo	oratory data							
Other rele	vant his	story, includin	g preexisti	ng conditi	ion				
none									

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name: Clear						
RID, NIX, Quell						
Dose, frequency,	ates					
every 10 days for	2 months	111	001			
, ,				to 010602		
Diagnosis for us	<u>e</u>		Event	abated after use		
Lice or nits seen b				d or dose reduced		
Lice of files seen t	y school hui	sc.				
T 4 11	B 14			t apply		
Lot #	Exp. date			reappeared after		
			reintro	duction		
NDC# -	_		yes			
Concomitant me	dical produ	ets				
Concomitant inc	uicai produ	cis				
D. Suspect med	lical device					
Brand name						
Type of device						
	me and add	lress	Oper	ator of device		
Manufacturer name and address Operator of device health professional						
user facility						
distributor						
		Expi	ation date			
model #						
catalog #			If im	planted, give date		
serial #			-			
lot #			_ If exp	olanted, give date		
other #						
<b>Device available</b> $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$				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 $\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $						
C 114						
If you do NOT was disclosed to the ma	•	•	an 🔲	distributor		
disclused to the ma	muraciurer, p	race	an 🔳	distributor		

A. Patient	Inform	ation							
		Date of birth	0	Waight					
Patient fue	785	03/04/52	Sex female	Weight 135	lbs				
B Advers		or product p		133	103				
D. Advers	o o voin	Adverse Ev							
Outcomes :	attribut	ted to adverse	event						
death	Outcomes attributed to adverse event  Outcomes attributed to adverse event  Outcomes attributed to adverse event  Outcomes attributed to adverse event								
	☐ life-threatening ☐ congenital anomaly								
$\square_{\text{hospital}}$	_		ntervention						
	nervousr								
Date of eve	ent 12-0	01 <b>Date</b>	e of report	1/7/2	2002				
Describe ev	vent or	i							
		extreme itching	and nervous	snee.					
D.1	-4-/I-1-								
Relevant te	ests/labo	oratory data							
			• .•						
Other relev	vant his	story, including	g preexisti	ng condi	tion				
l									

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name:					
lindane					
Dose, frequency	route use	The	rapy d	ates	
1%					
			to		
Diagnosis for us	P		Event	abated after use	
head lice			stopped or dose reduced		
nead nce					
			no		
Lot#	Exp. date		Event	reappeared after	
			reintro	duction	
NIDC #			doesn'	t apply	
NDC# -	-				
Concomitant me	dical produ	cts			
D. Suspect med	dical device	<del>)</del>			
Brand name					
Type of device			1_		
Manufacturer na	ime and add	lress	_	ator of device	
				ealth professional	
			user facility		
			Шd	istributor	
			Expi	ration date	
model #					
catalog #			-  If im	planted, give date	
serial #					
lot # other #			- If exp	olanted, give date	
Device available $\square_{ m yes} \ \square_{ m no}$				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, MA. 02461					
Health professio	nal Occup	oatio	n	Also reported to	
	)			manufacturer	
If you do NOT wa	nt your identi	ty		user facility	
disclosed to the ma			an 🔲	□distributor	

A. Patient Inform	ation								
Patient Identifier	Date of birth	Sex	Weight						
779	1925/09/23	female	120	lbs					
B. Adverse event	or product p	roblem							
	Product Problem								
Outcomes attribut	ed to adverse o	event							
$\Box_{\text{death}}$	□ death □ disability								
☐ life-threatening	□ congenital	anomaly							
□ hospitalization	required in	ntervention							
other:									
Date of event 200	1/10/15 <b>Date</b>	e of report	12/22/2	2001					
Describe event or	problem								
My mother, who is	-	_		-					
case of head lice, ev									
how she gets them a able to get rid of the				•					
able to get ha of the	ani. It nas occii	about 2 1/2	months.						
Relevant tests/labo	oratory data								
	<b>,</b>								
Other relevant his	tory, including	g preexisti	ng condi	tion					
None of the over the									
her at all.									

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Kwell					
Nix					
Dose, frequency,	route use	Thera	py d	ates	
used about 15 time	es in the	10/15/	2001	4-	
last 2 1/2 months				to 21/12/2001	
Diagnosis for us	<u> </u>	Ev	vent :	abated after use	
				d or dose reduced	
shower, put on cre shower off	am mise,				
		n	0		
Lot#	Exp. date			reappeared after	
		re	intro	duction	
NID C II		v	es		
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	
			_	ealth professional	
user facility					
				istributor	
"		]	схри	ration date	
model #		h	If im	planted, give date	
catalog # serial #		[*		pianicu, give unic	
seriai # lot #			re arre	lanted size data	
other #			пехр	planted, give date	
	C 1 4				
Device available $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$			faat	, , , , , , , , , , , , , , , , , , ,	
Concomitant me	dical produ	rte	iuraci	urer//	
concomitant me	aicai produ	cus			
E. Reporter					
Name and addre	SS	pho	ne#	(781)449-6487	
The National Pe	diculosis A	ssocia	ition		
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
	-			manufacturer	
If you do NOT want your identity user facility					
n you do non war	nt vour identi	tv		user facility	

A. Patient Inform	ation							
Patient Identifier	Date of birth	Sex	Weight					
776	12/29/88	female	48	lbs				
B. Adverse event	t or product p	roblem						
	Adverse Ev	ent						
Outcomes attribut	ted to adverse o	event						
death	disability							
☑ life-threatening	☑ life-threatening □ congenital anomaly							
hospitalization	required in	ntervention						
other: cancer -	medulloblastom	a						
Date of event 6/13	3/98 <b>Date</b>	e of report	12/19/2	2001				
Describe event or	=							
Diagnosed withtum								
with repeated head I would like to know								
between use of linds				ıc				
Relevant tests/labo	oratory data							
Other relevant his	story, including	g preexisti	ng condi	tion				
none								

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Kwell	· · ·				
rid and to	ea tree oil				
Dose, frequency	, route use	The	rapy d	ates	
fairly regularly ov		199			
years				to 1998	
Diagnosis for us	e		Event abated after use		
recurrent head lice	e		stoppe	d or dose reduced	
			doesn'	t apply	
Lot #	Exp. date			reappeared after oduction	
NDC# -	_		doesn'	t apply	
Concomitant me	dical produ	ote			
D. Suspect mee	dical device				
D. Suspect med Brand name	alcai device	<del>)</del>			
Type of device					
Manufacturer na	ame and add	lress	$\square_{\mathrm{h}}$	ator of device ealth professional ser facility istributor	
			Expi	ration date	
model #			If im	planted, give date	
catalog # serial #			-	planted, give date	
lot #			If ext	planted, give date	
other #				, g., e uute	
Device available for evaluation?  yes no returned to manufacturer / /  Concomitant medical products					
E. Reporter					
Name and addre	ss	p	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	ciation		
P.O. Box 610189, Newton, MA. 02461					
Health professio  ✓ yes □ no	_	patio	n	Also reported to manufacturer	
If you do NOT wa				user facility	
disclosed to the ma	anufacturer, p	lace	an 🔳	□distributor	

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
768	01/28/92	female	72 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Prod	luct Proble	em
Outcomes attribut	ted to adverse e	event	
$\Box_{\text{death}}$	disability		
☐life-threatening	Congenital	anomaly	
□ <sub>hospitalization</sub>			
other:	<u> </u>		
Date of event 11/2	20/01 <b>Date</b>	of report	12/12/2001
Describe event or	problem		
Head lice infestation	_		
Relevant tests/labo	ratory data		
	ratory amon		
Other relevant his	story including	nreevisti	ng condition
Scabbies Head sore		, precaisti	ng condition

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name: lindane						
Dose, frequency,	route use	The	rapy d	ates		
10 min rinse apply			22/01			
two weeks 1%				to 12/12/01		
Diagnosis for us	e		Event	abated after use		
Examined found s			stopped or dose reduced			
infestation	vere nead nec			t apply		
Lot #	F J-4-					
Lot #	Exp. date			reappeared after		
			reintro	duction		
NDC# -	_		doesn'	t apply		
Concomitant me	dical produ	cts				
Internal antibiotics	=					
	s seasones en	Juii				
D. Suspect med	dical device					
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
			$\square_{\mathrm{h}}$	ealth professional		
user facility						
distributor						
Expiration date			ation date			
model #			_			
catalog # If implanted, give			planted, give date			
serial #			-			
lot #			_ If exp	olanted, give date		
other #						
Device available $\square_{ m yes} \ \square_{ m no}$				urer//		
Concomitant me	dical produ	cts				
E. Reporter						
Name and address phone # (781)449-6487						
The National Pediculosis Association						
P.O. Box 610189	, Newton, M	<b>ΙΑ</b> . (	02461			
Health professio	_	oatio	n	Also reported to		
✓ yes □ no □ manufacturer						
If you do NOT was	•	-		user facility		
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor		

A. Patient Inform Patient Identifier		G	777 - 1 - 1 - 4	
			Weight	1120
761	12-24-90	male	75	lbs
B. Adverse event	Adverse Ev			
Outcomes attribut				
Utcomes attribut	disability			
life-threatening	_			
hospitalization	_ ~	_		
other:	— required r	IIICI VCIIII		
	Dod Dod	· C	10/5//	2001
Date of event 19/9		te of repo	rt 12/5/2	2001
Describe event or Used prescribed line Subsequently experdamage, adhd.  Relevant tests/labo	dane for scabies ienced seizures			
Reievällt tests/lab	Pawiy uata			
Other relevant his		g preexis	sting condi	tion
no pre existing med	ical conditions			

Triage Unit Sequence #	

C. Suspect r	medication(s)			
Name: Kwe	11			
Dose, freque	ncy, route use	The	rapy d	ates
applied and le	ft on overnight	1993	3	
	_			to 1994
Diagnosis for	r use	]	Event :	abated after use
scabies				d or dose reduced
5040105			no	
Lot #	Exp. date			
LOI π	Exp. date			reappeared after
			reintro	oduction
NDC#	<del></del>		yes	
	medical produ	ıcts		
Concomitant	medicai prodi	ucts		
D. Suspect r	nedical devic	:e		
Brand name				
Type of devic	e			
	r name and ad	ldress	Oper	ator of device
			_	ealth professional
				ser facility
				istributor
				ration date
model #			Expii	ation date
catalog #			If im	planted, give date
serial #				, ,
lot #			If exp	olanted, give date
other #			1	, , ,
Device availa	ble for evalua	tion?		
	no 🔲 returned			urer/_/
Concomitant	medical produ	ucts		
E. Reporter				
Name and ad	dress	pl	none #	(781)449-6487
The National	l Pediculosis A			,
P.O. Box 610	189, Newton, 1	MA. 0	2461	
nealm brotes		patio	n	Also reported to
w <sub>yes</sub> [		patio	n	Also reported to manufacturer
<b>✓</b> yes	ssional Occu		n	

A Dations	l	-1:		
A. Patient			a	
Patient Ide		Date of birth	Sex	Weight
	758	24/02/81	male	147 lbs
B. Advers	e event	or product p		
		Adverse Eve		
_	attribut	ted to adverse o	event	
death		Udisability		
□ life-thre	eatening	□ congenital	anomaly	
$\square_{\text{hospita}}$	lization	required ir	ntervention	
other:				
Date of eve	ent 07/1	19/97 <b>Date</b>	e of report	12/3/2001
Describe e	vent or			
		. I had been trea	ted twice w	vith lindane
		itching very bac		
		applied more of	•	
on I'm still s	suffering	g. It's ruining my	life. What	can I do
about it?				
Relevant te	ests/labo	oratory data		
Other rela	vant hi	story, including	n nroovisti	ng condition
Asthma	vant IIIS	otory, menuali	g pi cexisti	ng conunuon
Astillia				

C. Suspect med	dication(s)			
Name: lindane				
Dose, frequency	, route use	The	rapy d	ates
I applyed to that :	area 2-3	07/1	997	
times in one week				to 11/1997
Diagnosis for us	Δ	1	Event	abated after use
Scabies	·			d or dose reduced
Scables				
"	l • ·	_	doesn	t apply
Lot#	Exp. date			reappeared after
			reintro	duction
NDC# -			doesn'	t apply
	-			
Concomitant me	dical produ	cts		
none				
D. Suspect med	dical device	•		
Brand name				
Type of device			T <sub>0</sub>	4 63 .
Manufacturer na	ame and add	iress		ator of device
			l III	ealth professional
				ser facility
				istributor
			Expi	ration date
model #			- TC :	-lautad atus data
catalog #			· III IM	planted, give date
serial # lot #			T.C.	1 4 1 1 1 4
other #			III exp	planted, give date
	£			
<b>Device available</b> □ <sub>yes</sub> □ <sub>no</sub>			anufact	uror / /
Concomitant me				<u></u>
	ureur produ			
E. Reporter				
Name and addre	SS	p]	hone #	(781)449-6487
The National Pe	diculosis A	ssoc	ciation	
P.O. Box 610189	, Newton, M	1A. (	02461	
Health professio	nal Occup	patio	n	Also reported to
$\mathbf{v}_{\mathrm{yes}}$	_			manufacturer
If you do NOT wa	nt your identi	ity		user facility
disclosed to the ma			an 🔲	□distributor

A. Patient Identifier   Date of birth   Sex   Weight   756   03/31/91   female   93   1bs    B. Adverse event or product problem   Product Problem      Product Problem   Outcomes attributed to adverse event   death   disability   life-threatening   congenital anomaly   hospitalization   required intervention other:     Date of event   10/01/   Date of report   12/1/2001     Describe event or problem   None of the products I have been using for my children seem to be working prescription or not.						
B. Adverse event or product problem    Product Problem	A. Patient	Inform	ation			
Product Problem  Outcomes attributed to adverse event   death	Patient Ide	entifier	Date of birth	Sex	Weight	
Outcomes attributed to adverse event   death		756	03/31/91	female	93	lbs
Outcomes attributed to adverse event   death	B. Advers	e event	or product p	roblem		
death disability congenital anomaly hospitalization required intervention other:  Date of event 10/01/ Date of report 12/1/2001  Describe event or problem  None of the products I have been using for my children seem to be working prescription or not.			Product Pro	olem		
life-threatening congenital anomaly hospitalization required intervention other:  Date of event 10/01/ Date of report 12/1/2001  Describe event or problem  None of the products I have been using for my children seem to be working prescription or not.	Outcomes	attribut	ted to adverse	event		
life-threatening congenital anomaly hospitalization required intervention other:  Date of event 10/01/ Date of report 12/1/2001  Describe event or problem  None of the products I have been using for my children seem to be working prescription or not.	death		disability			
hospitalization required intervention other:  Date of event 10/01/ Date of report 12/1/2001  Describe event or problem  None of the products I have been using for my children seem to be working prescription or not.  Relevant tests/laboratory data		eatening		anomaly		
Date of event 10/01/ Date of report 12/1/2001  Describe event or problem  None of the products I have been using for my children seem to be working prescription or not.  Relevant tests/laboratory data		_				
Date of event 10/01/ Date of report 12/1/2001  Describe event or problem  None of the products I have been using for my children seem to be working prescription or not.  Relevant tests/laboratory data		iizatioii	— required i	inci vention		
Describe event or problem  None of the products I have been using for my children seem to be working prescription or not.  Relevant tests/laboratory data	L	4 10//	)1/   <b>D</b> /		10/1/0	1001
None of the products I have been using for my children seem to be working prescription or not.  Relevant tests/laboratory data			l	e of report	12/1/2	2001
seem to be working prescription or not.  Relevant tests/laboratory data			=		1 '1 1	
Relevant tests/laboratory data					children	
	seem to be	working	g prescription o	r not.		
Other relevant history, including preexisting condition	Relevant te	ests/labo	oratory data			
Other relevant history, including preexisting condition						
Other relevant history, including preexisting condition						
Other relevant history, including preexisting condition						
Other relevant history, including preexisting condition						
Other relevant history, including preexisting condition						
	Other rele	vant his	story, includin	g preexisti	ng condi	tion
			- '		_	

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix					
Lindane	1% shampoo				
Dose, frequency	, route use	The	rapy d	ates	
Nix-applied libera	ılly all	10/0	)1	to	
overhead1xevery′	7-14days			to 12/01	
Diagnosis for us	e		Event	abated after use	
Lice			stopped or dose reduced		
			no		
Lot#	Exp. date		Event	reappeared after	
	1			duction	
NDC# -	-		yes		
Concomitant me	dical produ	cts			
Lindane 1% sham	poo 11/17/01	l			
D. Suspect med	dical device	<del>)</del>			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
				ealth professional	
user facility					
distributor					
			Expi	ration date	
model #					
catalog #			. If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
Device available $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$			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					
▼yes □no □manufacturer					
If you do NOT wa	•	•		user facility distributor	
disclosed to the ma	anutacturer, p	lace	an 🔳		

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
753	12/11/93	female	70 1	lbs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse e	event		
$\Box_{\text{death}}$	$\Box_{\text{disability}}$			
☐ life-threatening	□ congenital	anomaly		
$\square_{ m hospitalization}$	required in	ntervention		
other:				
Date of event 11/1	13/01 <b>Date</b>	of report	11/22/20	01
Describe event or	problem			
Two treatments with	h lice shampoo,	one treatm	ent with lic	e
cream rinse and one				
lindane were all uns combing, I was still				le.
as 5 days later.	punning out nive,	, crawning a	dants as inti	ic
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng conditio	on
none				

C. Suspect me	dication(s)			
Name: generic l	ice shampoo			
generic l	ice cream rins	se & 1	lindane	
Dose, frequency	, route use	The	rapy d	ates
2lice shampoo		11/1	3/01	
1 lice cream rinse				to 11/22/01
1 lindone Diagnosis for us	se	]	Event	abated after use
none		5	stoppe	d or dose reduced
			no	
Lot#	Exp. date	_	Event	mannanad aftan
	Zapr unit			reappeared after oduction
		ľ	CIIICI	duction
NDC# -	-		yes	
Concomitant me	edical produ	cts		
none				
D. Suspect me	dical device	•		
Brand name				
Type of device			1	
Manufacturer n	ame and add	lress	1 —	ator of device
				ealth professional
				ser facility
			_	istributor
			Expi	ration date
model #			If im	planted, give date
catalog # serial #				piuricu, gree uuce
lot #			If exi	planted, give date
other #			'	, 8
Device available				
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to ma	anufact	turer/_/
Concomitant me	edical produ	cts		
E. Reporter				
Name and addre	ess	pl	none #	(781)449-6487
The National Pe	ediculosis A	ssoc	iation	
P.O. Box 610189	, Newton, N	<b>1</b> A. 0	2461	
Health professio	nal Occuj	oatio	n	Also reported to
$ \mathbf{V}_{\text{yes}} $				manufacturer
If you do NOT wa	nt your identi	ity		user facility
disclosed to the m	anufacturer, p	lace a	an 🔲	□distributor

A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
752	11-23-76	female	300	lbs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse o	event		
$\Box_{\text{death}}$	disability			
☐ life-threatening	Congenital	anomaly		
hospitalization				
other:	1			
Date of event 11-	19 Date	of report	11/20/20	001
Describe event or		or report	11/20/2	001
I used the NIX prod	=	m used the	comb	
provided and when	-			11
alive. I though that i	-			
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condit	ion
		- <b>-</b>	Ü	

Triage Unit Sequence #	

C. Suspect me	edication(s)			
Name: Nix				
Dose, frequenc	y, route use	The	erapy d	ates
used once		11-	19	
				to 11-20
Diagnosis for u	ise		Event	abated after use
still got them				d or dose reduced
still got them			no	
Lot #	Erm dota			
Lot#	Exp. date			reappeared after
			reintro	oduction
NDC# -			doesn	t apply
Concomitant m	adical produ	ete		
	=			1.11
soaked my head	ın vınegar stıl	l did	not wo	rk!!
D. Suspect me	edical devic	е		
Brand name				
Type of device			1.	
Manufacturer 1	name and add	dres		ator of device
			I⊟h	ealth professional
				ser facility
			$\Box_{d}$	istributor
			Expi	ration date
model #			_	
catalog #			_  If im	planted, give date
serial #			-	
lot #			_ If exp	planted, give date
other #				
Device availabl				
$\square_{\text{yes}} \square_{\text{no}}$				urer/_/
Concomitant m	edicai produ	cts		
E. Reporter				
Name and addi	ess	p	hone #	(781)449-6487
		ᆫ		(781)449-6487
Name and addi The National F P.O. Box 61018	Pediculosis A	SSO	ciation	(781)449-6487
The National F P.O. Box 61018	Pediculosis A	ASSO AA.	ciation 02461	
The National F P.O. Box 61018  Health professi	Pediculosis A	ASSO AA.	ciation 02461	(781)449-6487  Also reported to manufacturer
The National F P.O. Box 61018 <b>Health profess</b> i	Pediculosis A 89, Newton, N onal Occu	ASSO AA. ( patio	ciation 02461	Also reported to

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
750	06/02/2000	female	30	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Prod	luct Proble	em	
Outcomes attribut	ed to adverse	event		
$\Box_{\text{death}}$	disability			
☐ life-threatening	□ congenital	anomaly		
$\square_{ m hospitalization}$	required in	ntervention		
other: deep cou	gh			
Date of event 11-	18-2001 <b>Date</b>	e of report	11/19/2	2001
Describe event or	problem			
A few hours after tr		d very deep	cough-fr	om
chest-like croupab	_			
within days I had to				
case of croup. I also bed	used sprayan	iurniture, ii	ncluding r	ier
Relevant tests/labo	ratory data			
recevant tests/labe	ratory data			
Other relevant his	story, including	p preexisti	ng condi	tion
	, cory, meradin	5 Preemen	ng condi	

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix					
Dose, frequency	, route use	Ther	apy d	ates	
used enough to sa	iturate	11-18	3		
hairabout 1oz				to 11-19	
Diagnosis for us	se.	F	Event :	abated after use	
Lice				d or dose reduced	
Lice					
<del>-</del>	<b>I</b>		no		
Lot#	Exp. date			reappeared after	
0j1708		r	reintroduction		
NDC# -	<u>-</u>	<del></del>	yes		
Concomitant me	dical produ	ete			
Concomitant me	cuicai produ	CIS			
D. Suspect med	dical device	•			
Brand name					
Type of device					
Manufacturer n	ame 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 #			If exp	olanted, give date	
other #			'	, 5	
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}}  \square_{\mathrm{no}}$			nufact	urer/_/	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	ess	ph	one#	(781)449-6487	
The National Pe		<u> </u>		(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
	ediculosis A	SOUCI			
			2461		
P.O. Box 610189	, Newton, N	IA. 02		Also reported to	
P.O. Box 610189 <b>Health professi</b> o	Newton, Monal Occup	IA. 02		Also reported to	
P.O. Box 610189	O, Newton, Monal Occup	IA. 02 pation		Also reported to manufacturer user facility	

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
749	06-27-95	female	42 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Prod	luct Proble	em
Outcomes attribut	ted to adverse o	event	
$\Box_{\text{death}}$	disability		
☐ life-threatening	Congenital	anomaly	
hospitalization	☐required in	-	
other:			
Date of event 11-	16-01 <b>Date</b>	of report	11/19/2001
Describe event or		or report	11/17/2001
My daughter reacte	=	elts swellin	of the
wrists, prickly pimp			-
areas.		C	
Relevant tests/labo	oratory data		
Other relevant his	story, including	g preexisti	ng condition

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Nix					
Dose, frequency,	route use	The	rapy d	ates	
first application a		11-1			
dosage				to 11-19	
Diagnosis for us	e		Event :	abated after use	
single application for head lice stopped or dose redu					
and nits	ioi nead nec				
	<b>.</b>		yes		
Lot #	Exp. date			reappeared after	
			reintro	duction	
NDC# -	_		yes		
Concomitant me	dical produ	rts			
Used vinegar, may					
Osed vinegar, may manual removal	omiaise, and	ı			
manaar removar					
D. Suspect med	lical device				
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			I —	ealth professional	
user facility					
				istributor	
Expiration date					
model #					
catalog #			If im	planted, give date	
serial #					
lot #			_ If exp	olanted, give date	
other #					
<b>Device available</b> □ yes □ no				urer / /	
Concomitant me					
•					
E. Reporter					
Name and addre	ss	p	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	ciation		
P.O. Box 610189	, Newton, M	IA. (	02461		
Health professio	-	oatio	n	Also reported to	
<b>✓</b> yes □no				manufacturer	
If you do NOT was	•	•		user facility distributor	
disclosed to the ma	ınufacturer, p	lace	an 🔳	-uisuidutor	

A. Patient Inform								
Patient Identifier	Date of birth	Sex	Weight					
745	2-12-95	female	40 lbs					
B. Adverse event	or product p	roblem						
Advers	Adverse Event & Product Problem							
Outcomes attribut	ted to adverse e	event						
$\Box_{\text{death}}$	disability							
☐ life-threatening ☐ congenital anomaly								
hospitalization	□required in							
other:								
Date of event 11-	n1 Dots	of woment	11/14/2001					
		of report	11/14/2001					
<b>Describe event or</b> Live lice were foun	_	t First soon	diad DID					
then the following of								
small imature lice.			-					
complained of stom								
Relevant tests/labo	ratory data							
	orunory units							
04 1 41:		• ,•	7***					
Other relevant his			ng condition					
Have had lice withi	ii the past 5 moi	nuis prior						

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Rid					
NIX, lice	e free				
Dose, frequency,	, route use	The	rapy d	ates	
followed direction			9-01		
		to 11-14-01			
Diagnosis for us	Δ		Event	abated after use	
fou	C			d or dose reduced	
10u			Stopped of dose reduced		
<b>-</b>	n 1.		yes		
Lot#	Exp. date			reappeared after	
			reintroduction		
NDC# -			doesn'	t apply	
	dical prod	otc			
Concomitant me	aicai produ	cis			
D. Suspect med	lical dovice				
	ilcai device	7			
Brand name Type of device					
Manufacturer na	me and add	lrese	Oner	ator of device	
iviandiaciarei in	inic una uac	11 05	ΙÂ	ealth professional	
				ser facility	
				istributor	
			_	ration date	
			Expii	auon uate	
model # catalog #			- If im	planted, give date	
serial #			-   '	, , ,	
lot #			If ext	planted, give date	
other #				, , ,	
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to m	anufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	n	hone #	(781)449-6487	
The National Pe		ᆮ		( - ) =	
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occuj	oatio	n	Also reported to	
	_			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma	-	-	an 🔲	□distributor	

A. Patien	t Inform	ation		
		Date of birth	Sex	Weight
	744	6/17/52	female	180 lbs
B. Adver	se even	or product p	roblem	
	Advers	e Event & Proc	luct Proble	em
Outcomes	s attribut	ted to adverse	event	
$\Box_{\text{death}}$		$\Box_{disability}$		
□ <sub>life-thi</sub>	reatening	□ congenital	anomaly	
$\square_{\mathrm{hospit}}$	alization	required in	ntervention	
other:	Chemica	ıl sensitivity wo	rse	
Date of ev	vent 1/9'	7 Date	e of report	11/11/2001
Describe	event or			
		on two occasion		
	_	id I developed a		-
		head. Pharmacis OT killing the lic		
are resista		of killing the in	e. Filalilla	ast said they
Relevant 1	tests/laha	oratory data		
reie vant	icsis/ius	Juiory dutu		
Other rel	evant his	story, includin	a nreevisti	ng condition
Fibromyal		story, including	g preexisti	ng condition
Sjogrens	514			

C. Suspect medication(s)						
Name: Rid						
Dose, frequency,	route use	The	erapy d	ates		
1		1/97	7			
			to 3/97			
Diagnosis for us	e		Event	abated after use		
lice			stopped or dose reduced			
			no			
Lot #	Exp. date		Event	roannoard after		
	1			reappeared after oduction		
			Cinti	duction		
NDC# -	-		yes			
Concomitant me	dical produ	cts				
My weight is my	business. No	t to	be repo	orted on the		
internet. Sorry.			20 10pc			
,						
D. Suspect med	lical device					
Brand name						
Type of device						
Manufacturer na	me and add	lres	Oper	ator of device		
				ealth professional		
			user facility			
			distributor			
				ration date		
			Expi	auon uate		
model # catalog #		-	- If implanted, give date			
serial #			-   '	, 8		
lot #			If ext	planted, give date		
other #				Junica, gree aute		
Device available	for evaluati	on?	<u> </u>			
$\square_{\mathrm{yes}}  \square_{\mathrm{no}}$	returned	to m	nanufact	urer/_/		
Concomitant me						
E. Reporter						
Name and addre	ss	p	hone #	(781)449-6487		
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
			Also reported to			
✓ yes □no □manufactur				manufacturer		
f you do NOT want your identity user facility						
lisclosed to the manufacturer, place an distributor						

A. Patient Infor					
Patient Identifi	er Date	of birth	Sex	Weight	
743	8/20	/93	female	62	lbs
B. Adverse eve	nt or p	roduct p	roblem		
Adve	rse Eve	nt & Prod	luct Proble	m	
Outcomes attrib	uted to	adverse o	event		
$\Box_{\text{death}}$		disability			
□ life-threatening		congenital	anomaly		
hospitalizatio	_		ntervention		
other: scalp b		required ii	iter vention		
		15.		11/0/0	2001
	1/5/2001		e of report	11/8/2	2001
Describe event o	_			,	
My daughter was treated with RID.					of
her head/neckline		ed to buil	i nei scaip a	at the base	3 01
We also tried Mir	neral Oil	& vinega	.It Failed a	lso.	
Relevant tests/la	borator	v data			
		•			
Other relevant	history	includia	n npovisti	na aondi	tion
Other relevant	mstory,	menani	g preexisti	ng conun	uon

Triage Unit Sequence #	

<del></del>				-
C. Suspect m	edication(s)			
Name: Rid				
minera	ıl oil & vinegar			
Dose, frequen	cv, route use	The	rapy d	ates
The whole bottl	-		05/200	
used Once.	01 142,	110/	00,200	to 11/09/2001
Diagnosis for	1150	l Iı	Event	abated after use
Lice	usc			d or dose reduced
Lice				
<b>T</b> . !!	<b>I</b> D 1.		no	
Lot#	Exp. date			reappeared after
		]	reintro	oduction
NDC# -			yes	
Concomitant n	nadical produ	ete		
	-		al manta	
11/8/2001 Min	erai on/ vinegai	equa	ai parts	•
D. Suspect m	edical device	;		
Brand name				
Type of device				
Manufacturer	name and add	lress	Oper	ator of device
			$\Box_{\rm h}$	ealth professional
			$\square_{\mathrm{u}}$	ser facility
			$\square_{\mathrm{d}}$	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device availab $\square_{ m yes} \ \square_{ m nc}$	le for evaluati		c .	
Concomitant r			anuraci	turer/_/
Concomitant i	nculcal produ	CLS		
E. Reporter		4		(504) 440 5405
Name and add		_		(781)449-6487
The National				
P.O. Box 6101	89, Newton, N	<b>1A</b> . 0	2461	
Health profess	sional Occup	oatio	n	Also reported to
,	no			manufacturer
If you do NOT v	•	•		user facility
disclosed to the	manufacturer, p	lace a	an 🔲	□distributor

A. Patient I								
Patient Ider				Sex	Weight			
	742	10/05/96		female	42	lbs		
B. Adverse								
I	Advers	e Event &	Prod	luct Proble	em			
Outcomes a	ttribut	ted to adv	erse e	event				
death		disal	bility					
☐ life-threatening ☐ congenital anomaly								
$\square_{ m hospitali}$	zation	$\square_{\text{requ}}$	ired ir	ntervention				
other: SI	EVERI	E IRRITA	TION	TO SCAL	P & REIN	NFE		
Date of ever	nt 10/1	13/01	Date	of report	11/8/2	2001		
Describe ev	ent or	problem	L					
FOUND LIC		_	O, MD	SAID NE	X-2			
TREATMEN						ED.		
BOUGHT T						N.C.		
TONIGHT. S 2X & FOUN								
MY CHILD'						011		
FINALLY.								
Dolovent too	ta/laha	matany di	nto.					
Relevant tests/laboratory data								
04 1		,		• .•		4.		
Other releva			-		_	tion		
TOO BAD T WEREN'T B						F		
WEKENTD	ьтть.	K EDUCE	TLD	ON THIS	WEDSII	Ľ.		

Triage Unit Sequence #	

C. Suspect me	dication(s)			
Name: Kwell				
NIX				
Dose, frequency	, route use	The	rapy d	ates
30-60ML EVERY	7DAYS	10/1	3/01	
IF NEEDED			to 11/07/01	
Diagnosis for us		<u> </u>	Event	abated after use
_			stopped or dose reduced	
EVERY 7 DAYS	IF NEEDED			a or aose readeed
			no	
Lot#	Exp. date	l	Event	reappeared after
RX			reintro	oduction
#670585299/N			yes	
NDC# -	-		yes	
Concomitant me	edical produ	cts		
NIX-2X, NOW T	HE KWELL	-TH	IS IS S	TILL AN
ONGOING CHA				
LICE MEISTER	FOR 2HRS	STR	AIGHT	ON BOTH
D. Suspect me	dical device	)		
Brand name				
Type of device				
Manufacturer n	ame and add	lress	□ <sub>h</sub>	ator of device ealth professional ser facility istributor
				ration date
model #			Z.ipii	auton dute
catalog #			If im	planted, give date
serial #			·   '	. , ,
lot #			If ext	planted, give date
other #				,, <b>g</b>
Device available  yes no  Concomitant me	returned	to m	anufact	turer <u>/ /</u>
E. Reporter				
Name and addre	ess	p]	hone #	(781)449-6487
The National Pe				·
P.O. Box 610189	, Newton, M	<b>1</b> Α. (	02461	
Health profession	_	patio	n	Also reported to manufacturer
If you do NOT wa	nt your identi	ity		user facility
disclosed to the m	anufacturer, p	lace	an 🔲	□distributor

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
737	6/21/96	female	41	lbs
B. Adverse event	or product p	oroblem		
	Product Pro	blem		
Outcomes attribut	ted to adverse	event		
death	disability			
life-threatening		l anomaly		
□hospitalization	required i	ntervention		
other: it just ne	ver ends			
Date of event 10/3	31/2001 <b>Dat</b>	te of report	11/1/2	2001
Describe event or	problem			
My 5 yr old daughte	_			
without the rest of r				
to occur at least one and prescribed treat		-		
and presented treat	ments aren t w	on inc	a anymor	С.
Relevant tests/labo	retory dete			
Kelevant tests/labe	natory data			
Other relevant his	story includir	a nroovieti	na condi	tion
none	story, menuan	ig preexisti	ng conta	uon
none				

C. Suspect med	lication(s)				
Name: generic li	ice shampoo				
and Nix prescribed					
Dose, frequency, route use The			rapy d	ates	
now i do this at le	ast once a	10/3	1/2002		
month				to 10/31/2001	
Diagnosis for us	<u> </u>		Event :	abated after use	
put in dry hair, let				d or dose reduced	
lather,rinse	stand ten m	111.			
	D 14		yes		
Lot #	Exp. date			reappeared after	
?			reintro	duction	
NDC# -			yes		
	-				
Concomitant me	dical produ	cts			
same					
D. Suspect med	dical device	<del>)</del>			
Brand name					
Type of device		_			
Manufacturer na	ame and add	lress	1 —	ator of device	
				ealth professional	
				ser facility istributor	
			_		
			Expir	ration date	
model #			Te:	nlantad siva data	
catalog #			.   111 11111	planted, give date	
serial # lot #			T.C	lantad atmodata	
other #			III exp	planted, give date	
Device available	for ovelve	ion?			
yes $\square_{\text{no}}$			anufact	urer / /	
Concomitant me				· · · · · · · · · · · · · · · · · · ·	
F					
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe					
P.O. Box 610189, Newton, MA. 02461					
Health professio  ✓ yes □no	_	oatio	n	Also reported to manufacturer	
-		4		user facility	
If you do NOT was disclosed to the ma			an 🔳	distributor	
arserosea to the III8	muraciurer, p	iact	an 🔳	31511104101	

A. Dationt	l	-1:		
A. Patient			a	
Patient Ide		Date of birth	Sex	Weight
	729	8/9/68	female	185 lbs
B. Advers	e even	or product p		
		Product Prob		
_	attribut	ted to adverse o	event	
death		□disability		
☐ life-thre	eatening	Congenital	anomaly	
hospita	lization	☐ required in	ntervention	
other:				
Date of eve	ent 4/00	0-10-01 <b>Date</b>	e of report	10/25/2001
Describe e	vent or	problem		
I HAVE HA	AD HEA	AD LICE FOR A	ALMOST 2	YEARS I
HAVE TRI	ED EVI	ERYTHING PL	EASE HEI	LP ME
Relevant te	ete/laho	oratory data		
Keievani u	.sts/1abt	natory data		
04 :			• .•	70.0
		story, including	g preexisti	ng condition
I ALSO HA	AVEMS	<b>S</b>		

C. Suspect med	lication(s)				
Name: Rid	ilcation(s)				
LINDANE					
Dose, frequency, route use The			rapy da	ates	
EVERY FEW WE	EEKS	4-21		to	
				5-21	
Diagnosis for use			Event abated after use		
HEAD LICE			stopped or dose reduced		
			no		
Lot #	Exp. date			1 6	
Lot "	Zapi date			reappeared after duction	
			i emu o	duction	
NDC# -	_		yes		
Concomitant me	dical produc	rts			
LICE ARREST M	=		IE NIV	CUT 10	
INCHES OF MY					
COUNTLESS TIMES I AM ON THE VERGE OF USING  D. Suspect medical device					
Brand name	iloai acvice				
Type of device					
<u>1 ype of device</u> Manufacturer na	me and add	Irocc	Oper	ator of device	
Manufacturer na	illic allu aud	11 633	l Â		
				ealth professional ser facility	
				istributor	
			-		
			Expir	ation date	
model #			If im	planted, give date	
catalog			.	plantea, give aute	
lot #			If evr	planted, give date	
other #			III CAP	nunceu, give unce	
Device available	for evaluati	on?			
$\square_{\text{yes}} \square_{\text{no}}$			anufact	urer//	
Concomitant me					
E. Reporter					
Name and addre	99	- n	homo #	(791)///0 6/197	
The National Pe		ഥ	hone #	(781)449-6487	
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
$\mathbf{v}_{\mathrm{yes}}  \square_{\mathrm{no}}$	_			manufacturer	
If you do NOT was	nt your identi	ty		user facility	
disclosed to the manufacturer, place an distributor				distributor	

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
726	4/9/51	male	220 lbs
B. Adverse event	t or product p	roblem	
Advers	e Event & Prod	luct Proble	em
Outcomes attribut	ted to adverse e	event	
death	disability		
life-threatening	Congenital	anomaly	
□hospitalization	required in	ntervention	
other:			
Date of event 9/10	0-01 <b>Date</b>	of report	10/22/2001
Describe event or	problem		
ACCORDING TO	_	MY TEST	OSTERONE
WENT UP 500 TO			
SHOWED MY TH LOWERED.	ROID MAY, M	AY HAVI	E BEEN
LOWERED.			
Relevant tests/labo	oratory data		
Other relevant his	story including	nreevisti	ng condition
HAVE A VERY LO			
LIVER ENZYMES			
GLAND OUTPUT	Γ.		

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: lindane					
Dose, frequency, route use Therapy dates					
		1/01			
,		,,01	to 10/4/01		
Diagnosis for use			E4		
J		Event abated after use stopped or dose reduced			
SCABIES			stopped of dose reduced		
			no		
Lot#	Exp. date		Event	reappeared after	
			reintroduction		
			doesn'	t apply	
NDC# -	-		doesii	t apply	
Concomitant me	dical produ	cts			
D. Suspect med	dical device	)			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			1 —	ealth professional	
				ser facility	
				istributor	
			Expir	ration date	
model #			*		
model # catalog #			If implanted, give date		
serial #					
lot #			If exp	olanted, give date	
other #				. , ,	
<b>Device available</b> □ yes □ no				uror / /	
Concomitant medical products					
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	diculosis A	ssoc	ciation		
P.O. Box 610189	P.O. Box 610189, Newton, MA. 02461				
Health professio  ✓ yes □no	- 1 -	patio	n	Also reported to manufacturer	
			user facility		
If you do NOT was	•	•		distributor	
disclosed to the ma	ınuracturer, p	тасе	an 🔳	— 0130100001	

A. Patient	Jeform	ation					
			1~				
Patient 1d		Date of birth	Sex	Weight			
	724	04/17/99	male	27	lbs		
B. Advers	e event	or product p					
		Product Prol	olem				
_	attribut	ted to adverse	event				
death	death disability						
∐life-thr	☐ life-threatening ☐ congenital anomaly						
$\square_{ m hospita}$	alization	□ <sub>required</sub> i	ntervention				
other:							
Date of ev	<b>ent</b> 10/1	13/2001 <b>Dat</b>	e of report	10/21/2	2001		
Describe e	vent or		<u> </u>				
treated for							
Relevant t	ests/labo	oratory data					
		·					
Other rele	vant his	story, includin	g preexisti	ng condi	tion		

Triage Unit Sequence #	

C. Cuanast mas	lication(a)			
C. Suspect med	ilcation(s)			
Name: Nix				
kwell				
Dose, frequency, route use The		The	rapy d	ates
3 times 10/1		10/1	3/01	
				to 10/21/01
Diagnosis for us	<u></u>	-	Event	abated after use
_	•			d or dose reduced
nead nce	nead lice			
			no	
Lot #	Exp. date	]	Event	reappeared after
		]	reintro	duction
NID C II		_	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
			_	ealth professional
				ser facility
				istributor
				ration date
model #			L.Api.	auton dute
catalog #			If im	planted, give date
serial #			·	, ,
lot #			If ext	planted, give date
other #				, <b>g</b>
Device available	for evaluati	ion?		
$\square_{\text{yes}} \square_{\text{no}}$			anufact	urer / /
Concomitant me	dical produ	cts		
	-			
E. Reporter				
Name and addre	SS	pl	hone #	(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	<b>1</b> A. 0	)2461	
Health professio	nal Occup	oatio	n	Also reported to
$\mathbf{\nabla}_{\mathrm{yes}}$ $\mathbf{\square}_{\mathrm{no}}$	_			manufacturer
If you do NOT was	nt vona idoati			user facility
	nt your menn	ltv		

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
723	9/14/1993	female	100 lbs
B. Adverse even	t or product p	roblem	
Advers	se Event & Proc	luct Proble	em
Outcomes attribu	ted to adverse	event	
$\Box_{\text{death}}$	disability		
□ life-threatening	g  ongenital	anomaly	
hospitalization	_		
other: vomiting			
Date of event 8/1	T	of monomt	10/20/2001
		e of report	10/20/2001
Describe event or my daughter was p	=	E Ithad -	•
my daughter was plunbelievably strong			
threw up from the			
experience for the b	_		
problem since July		Č	U
Delevent tests/leb	anatany data		
Relevant tests/lab	oratory data		
Other relevant hi	story, includin	g preexisti	ng condition

Triage Unit Sequence #	

C. Suspect medication(s)						
Name: Ovide						
Dose, frequency,	route use	The	rapy d	ates		
once		8/15	/2001	to		
				8/15/2001		
Diagnosis for use	2		Event a	abated after use		
LICE			stoppe	d or dose reduced		
			yes			
Lot#	Exp. date			1 - 64		
Lot "	Zapi dute			reappeared after oduction		
			CIIILI	duction		
NDC# -	-		no			
Concomitant med	dical produ	cts				
Have used NIX ov	er and over	again	but sti	ll have lice and		
nits.		Ü				
D. Suspect med	ical device	•				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
				ealth professional		
				ser facility		
			-	istributor		
			Expir	ration date		
model #			If im	planted, give date		
catalog # serial #			11 1111	pianicu, give uaic		
lot #			If evr	olanted, give date		
other #			III CAL	Junicu, give unic		
Device available	for evaluat	ion?	1			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			anufact	urer//		
Concomitant med	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						
$\mathbf{v}_{\mathrm{yes}}$ $\square_{\mathrm{no}}$				manufacturer		
If you do NOT war	nt your ident	ity		user facility		
disclosed to the ma	nufacturer, p	lace	an 🔲	distributor		

A D. (1)	1				
A. Patient					
Patient Ide	entifier	Date of birth	Sex	Weight	
	722	11/3/94	female	45	lbs
B. Advers	e event	or product p	roblem		
		Product Prob	lem		
Outcomes	attribut	ted to adverse o	event		
$\Box_{\text{death}}$		disability			
□ <sub>life-thre</sub>	eatening	Congenital	anomaly		
	lization		ntervention		
other:		1			
Date of eve	ent 10/1	17/01 <b>Date</b>	of report	10/17/20	01
Describe e	vent or		•		
		on since aug.trie	ed 4 differe	nt	
		hampoo from dr			
permanentl	ly.				
Relevant to	ests/labo	oratory data			
Other rele	vant his	story, including	p preexisti	ng conditia	on
other refe	vant m	, tory, merading	5 precasu	ng conditio	<b>711</b>

Triage Unit Sequence #	

C. Suspect	medication(	(s)			
Name: mala	thion				
Dose, freque	ncy, route u	se T	her	apy d	ates
1.5ml		8	8/8/0	1	
					to 10/17/01
Diagnosis for	r iise		Ī	Event :	abated after use
headlice reocc					d or dose reduced
neadnee reoce	urring				
<b>T</b> 4 !!	ID 1.4		-	no	
Lot#	Exp. dat	e			reappeared after
			r	eintro	oduction
NDC #				yes	
		1			
Concomitant	=				
used pronto,n	ix,rid then rx	aug -	oct	t.every	10 days
D. Suspect	nedical dev	/ice			
Brand name					
Type of device					
Manufacture	r name and	addr	ess	Oper	ator of device
					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 availa					
$\square_{\mathrm{yes}} \square_{\mathrm{1}}$					urer//
Concomitant	medical pro	duct	S		
E. Reporter					
Name and ad			T	one #	
, and and au	dress		ph	ione #	(781)449-6487
		s As			(781)449-6487
The Nationa P.O. Box 610	l Pediculosi		soci	iation	(781)449-6487
The Nationa P.O. Box 610	l Pediculosi 189, Newtor	n, Ma	soci	iation 2461	
The Nationa	l Pediculosi 189, Newtor		soci	iation 2461	Also reported to manufacturer
The Nationa P.O. Box 610  Health profe	l Pediculosi 189, Newtor ssional Oc	n, Ma	soci A. 0	iation 2461	Also reported to

A. Patient Inform	nation				
Patient Identifie	r Date of l	birth	Sex	Weight	
716	06-13-9	4	female	74	lbs
B. Adverse ever	nt or prod	luct pi	oblem		
	Produc				
Outcomes attrib			event		
death	∐disa	bility			
☐ life-threatenin	g ∐con≀	genital	anomaly		
□hospitalizatio	n □requ	iired in	tervention		
other:					
Date of event 10	0-01-01	Date	of report	10/15/2	2001
Describe event o	r problem				
Daughters have be					the
counter medication	is twice. S	till find	ling live lic	e	
Relevant tests/lal	oratory d	lata			
			•		
Other relevant h	istory, inc	cluding	g preexisti	ng condi	tion

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: Kwell				
Dose, frequency	, route use	The	rapy d	ates
3%		10-0	01-01	
				to 10-10-01
Diagnosis for us	e		Event :	abated after use
Head Lice				d or dose reduced
21000			doesn'	t apply
Lot#	Exp. date		Event	reappeared after
				duction
			*****	
NDC# -	-		yes	
Concomitant me	dical produ	cts		
Nix Creme				
D. Suspect med	dical device	9		
Brand name				
Type of device				
Manufacturer na	ame and add	dress	Oper	ator of device
			$\square_{\mathrm{h}}$	ealth professional
				ser facility
			$\square_{\mathrm{d}}$	istributor
			Expi	ation date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	olanted, give date
other #				
Device available				
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				urer//
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	ess	p]	hone #	(781)449-6487
				· /
The National Pe	ediculosis A	SSOC		
The National Pe P.O. Box 610189			02461	
P.O. Box 610189	, Newton, M	ΙΑ. (		Also reported to
	, Newton, Monal Occup	ΙΑ. (		Also reported to manufacturer
P.O. Box 610189 <b>Health professio</b>	O, Newton, Monal Occup	IA. ( patio		

A. Patient Info	orm	ation				
Patient Identif	ier	Date of b	irth	Sex	Weight	
712	2	2-11-91		female	80	lbs
B. Adverse ev	ent	or prod	uct pı	oblem		
		Product	Prob	lem		
Outcomes attri	ibut	ed to adv	erse e	event		
death		∐disa	bility			
☐ life-threaten	ning	□cong	genital	anomaly		
hospitalizat	ion	□requ	ired in	tervention		
other:						
Date of event	10/1	2/01	Date	of report	10/12/2	2001
Describe event	or	problem				
head lice appear						
and now we are daily	usin	g the oliv	e oil tı	reatment, ha	air washin	g
dany						
Relevant tests/	labo	ratory d	ata			
Othon molorom	. hia	tour inc	ludin.	v nuosvisti	na sandi	·i.am
Other relevant	l HIS	tory, inc	ıuaınş	g preexisti	ng conan	lion

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: lindane				
olive oil,	nix			
Dose, frequency	, route use	The	rapy d	ates
10 days		7/15		
				to 9/30/01
Diagnosis for us	Δ		Event	abated after use
?	·			d or dose reduced
•				
T . !!	E 14			t apply
Lot#	Exp. date			reappeared after
			reintro	oduction
NDC# -	_		doesn	t apply
Concomitant me	dical produ	otc		
Concomitant me	uicai prouu	CIS		
D. Suspect med	lical dovice			
	ilcai device	•		
Brand name Type of device				
Manufacturer na	ama and add	Irace	Oper	ator of device
ivianuiaciurei na	anic and add	II CSS		
				ealth professional ser facility
				istributor
			Expi	ration date
model #			If im	planted, give date
catalog # serial #			-	planted, give date
lot #			If evi	olanted, give date
other #				nanteu, give date
Device available	for evaluati	ion?		
$\square_{\text{yes}} \square_{\text{no}}$				curer / /
Concomitant me				
E. Reporter				
Name and addre			h #	(701)440 6407
		ᆮ		(781)449-6487
The National Pe				
P.O. Box 610189		1A. (	)2461	
Health professio	_	patio	n	Also reported to
$ \mathbf{V}_{\text{yes}}  \mathbf{\square}_{\text{no}} $	)			manufacturer
If you do NOT wa				user facility
disclosed to the ma	anufacturer, p	lace	an 🔲	□distributor