MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
709	9-13-90	female	80 lbs

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: diarhea/headache

Date of event 10-9-2001 **Date of report** 10/10/2001

Describe event or problem

diarhea, headache, dizzyness,nausea

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
full box-3 treatments, seven days apart

Therapy dates
9-20-2001 to 10-01-2001

Diagnosis for use
headlice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
703	10-22-91	female	78 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 10-06-01 **Date of report** 10/6/2001

Describe event or problem

nothing is killing them not rid or nix not even lindane1%. What do I do now. I have even tryed oil over-nite.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
rid and nix

Dose, frequency, route use
reg dose 7-10 days

Therapy dates
09-01-01 to 10-06-01

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
702	05/12/95	female	35 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 06/20/01 **Date of report** 10/5/2001

Describe event or problem

THEY JUST DON'T DIE!!!!!!!!!!!!!
WE CAN NOT GET RID OF THESE HORRIBLE THINGS.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Kwell also

Dose, frequency, route use
every seven days if live lice are found

Therapy dates
6/2001 to 10/2001

Diagnosis for use
live brownish lice found as well as nits.

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
pronto, nix , and kwell used. also tea tree treatments.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
699	10/8/83	female	130 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: extreme pain

Date of event 9/27/01 **Date of report** 9/30/2001

Describe event or problem

I had pubic lice and the doctor gave me lindane shampoo to kill them. It killed the lice but now I have sores near my urethra which make it extremely painful to urinate and even walk normally.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Hypothryoidism

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
One time for 4 minutes.

Therapy dates
9/27/01 to 9/27/01

Diagnosis for use
crabs

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
697	2/12/99	female	26 lbs

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:

Date of event 9/20/01 **Date of report** 9/28/2001

Describe event or problem

I tried nix twice, washed all bed linens, used lice spray for matresses & couches, still pulling out live lice. Use the Nix comb after every bath, lice are still kicking. I now notice a rash on the back of her neck/upper back. even used olive oil!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
olive oil

Dose, frequency, route use
twice with nix within 4 days, then olive oil

Therapy dates
9/20/01 to 9/29/01

Diagnosis for use
treat lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #
9J1989

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
696	10/10/1996	male	35 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 08/08/2001 **Date of report** 9/27/2001

Describe event or problem

my daughter got head lice every treatment we used has failed my doctor has prescribed everything from lindane to acticin

Relevant tests/laboratory data

Other relevant history, including preexisting condition

asthma

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use

every 8 days

Therapy dates

08/08/2001 to 09/27/2001

Diagnosis for use

reaply after 10 days

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

this is a constant battle i have used probably every lice product out there

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
694	5-2-95	female	40 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 7-2-01 **Date of report** 9/24/2001

Describe event or problem

First occured July 2, on family vacation. MANY treatements including prescrioption products from physician have failed.Followed instructions meticulously, scoured house. Now showing up on our son and my wife.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid
NIX, Prescription of Lindane

Dose, frequency, route use
Every week since July 2, 2001

Therapy dates
7-2-01 to 9-24-01

Diagnosis for use
Failed

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
689	7/27/94	male	55 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 6/2001 **Date of report** 9/13/2001

Describe event or problem

WE SEEM TO GET RID OF THEM AND THEM 7-10 DAYS LATER THEY COME BACK. HAVE WASHED EVERYTHING IN HOT WATER INCLUDING BEDDING MATTRESSES AND FURNITURE AND THE CARPET FLOORS.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
LICE AWAY, VEGETABLE OIL, AND LINDAN

Dose, frequency, route use
EACH TIME SHE GETS THEM ABOUT EVERY TWO WEEKS

Therapy dates
6/2001 to 9/2001

Diagnosis for use
ONCE EVERY 7-10 DAYS.

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
678	10/24/62	female	115 lbs

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: Antibotic Therapy for Infection

Date of event 02/20/00 **Date of report** 9/3/2001

Describe event or problem

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

Relevant tests/laboratory data

Other relevant history, including preexisting condition

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

C. Suspect medication(s)

Name: lindane
Kwell Shampoo

Dose, frequency, route use
Apply, let dry rinse off.

Therapy dates
03/01 to 09/01

Diagnosis for use
Scabicide, body lice , pest removal.

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

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

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
676	03-08-91	female	055 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 8-14/9-1 **Date of report** 9/2/2001

Describe event or problem

we can not get rid of lice. i'v e tried three different treatments. we've
washed her bed linens and pillow each time. vacumed her room and the house too. i am checking her head daily for an hour at a time manually removing any nits found.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

my daughter has asthma. she is allergic to cats, dust mites and sulfa based drugs.

C. Suspect medication(s)

Name: Rid
lindane and nix

Dose, frequency, route use
1st Rid. 2nd lindane. 3rd nix. last rid

Therapy dates
8-14-01 to 9-1-01

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #
rid 01050015

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

lidane used on 8-20 no numbers available. purchased at walgreens
2001 custer road in plano tx 75075. next was the nix used

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
672	10/31/55	female	127 lbs

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: has seen doctors

Date of event 10/31/00 **Date of report** 8/28/2001

Describe event or problem

Hair falling out 4inches worth
teeth are loose
finger nails stopped growing
headaches, chest pains, son (sorethroat), unexplained vomiting, dark under eyes, asthma - both very tired

Relevant tests/laboratory data

Other relevant history, including preexisting condition

n/a

C. Suspect medication(s)

Name: Nix
lindane shampoo 1%

Dose, frequency, route use
Qty. 60 nurse said one time left on for 8-10min

Therapy dates
10/31/00 to 10/31/00

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #
rx6137375

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Rid, Equate, Nix

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
667	5/9/93	female	85 lbs

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: loss school,parent threatened

Date of event 3/10/00 **Date of report** 8/22/2001

Describe event or problem

lice from school other parents tried nix ridover counter products

Relevant tests/laboratory data

Other relevant history, including preexisting condition

na

C. Suspect medication(s)

Name: LiceGuard rid

Dose, frequency, route use

requiered

Therapy dates

0000 to 0000

Diagnosis for use

0na

Event abated after use stopped or dose reduced

doesn't apply

Lot #

na

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

tree oil works please spread the word located in the health food store please call me ifyou need input.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
656	05-03-94	female	60 lbs

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:

Date of event 07-28-01 **Date of report** 8/8/2001

Describe event or problem

Exposed on a Sunday, used Rid equivalent on Sunday night. Retreated 1 week later. 1 week after that found live lice - adult, nymphal stage and nits. Retreated again. Found viable lice next day.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use
3 times

Therapy dates
7-28-01 to 8-6-01

Diagnosis for use
for treatment against lice and nits

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

Soaked head in oil, washed out, used blow dryer on hair, picked through hair for 2 hours.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
651	08-22-90	female	105 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 7-03-01 **Date of report** 8/3/2001

Describe event or problem

head lice and i can get them stopped

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

over the counter,a pill,spray,etc.

Dose, frequency, route use

folowed directions and repeated assaid

Therapy dates

07-03-01 to 08-03-01

Diagnosis for use

lice still there

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
650	09/09/92	female	50 lbs

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: hairloss

Date of event 06/10/00	Date of report 8/3/2001

Describe event or problem

Hairloss

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use	Therapy dates
As recommended by physician	060100 to 073100

Diagnosis for use	Event abated after use stopped or dose reduced
Headlice	yes

Lot #	Exp. date	Event reappeared after reintroduction
		yes

NDC # - -

Concomitant medical products

Lindane and Malathion

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address	Operator of device
	☐ health professional ☐ user facility ☐ distributor

	Expiration date
model # _____ catalog # _____ serial # _____ lot # _____ other # _____	If implanted, give date
	If explanted, 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	

Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
644	5/13/92	female	50 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 6/11/01 **Date of report** 7/30/2001

Describe event or problem

constant reinfestation from using the perscription Lindane.I first tried RID. Did not work.Then my doctor prescribed Lindane, I have treated her several times with this product. What are the adverse side effects.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
shampooinhair . then reapply 1 week later.

Therapy dates
6/11/01 to 6/30/01

Diagnosis for use
haed lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
642	06/24/92	female	70 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 07/14/01 **Date of report** 7/28/2001

Describe event or problem

We have used a whole bottle of Rid in the past 2 weeks and she still has active lice. I will not use lindane I called pediatrician and thats what they wanted to give her so I said NO

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid
Vaseline,OLIVE oil

Dose, frequency, route use
every 7 days

Therapy dates
7/14/01 to 7/28/01

Diagnosis for use
active lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
641	21/05/91	female	70 lbs

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:

Date of event 10/01/1993 **Date of report** 7/28/2001

Describe event or problem

after treat.for scabies with Kwalada my daughters kidneys shutdownShe ws in hosp.for a week, put on Prednisone for a year

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
at least 4 treaments one week apart

Therapy dates
06/92 to 09/92

Diagnosis for use
scabies

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
640	7-11-76	male	170 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event	7/2001	Date of report	7/27/2001

Describe event or problem

Husband treated 3 times in one week with Lindane in Ventura County Jail. Finally had to shave his head. Was given NO instructions or warnings on how to use Lindane.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use	Therapy dates
three times in one week	7-15-2001 to 7-22-2001

Diagnosis for use	Event abated after use stopped or dose reduced
head lice	doesn't apply

Lot #	Exp. date	Event reappeared after reintroduction
		doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
636	05/09/1990	female	85 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 07/10/2001 **Date of report** 7/25/2001

Describe event or problem

for the last 3 -4 yrs this problem with head lice has reoccurred every 4-6 wks ,with out fail.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

n/a

C. Suspect medication(s)

Name: Kwell

A-200 , rid , lice awaylice combs,etc,every thing

Dose, frequency, route use

every 4-6 wks

Therapy dates

09/1996 to 07/2001

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

n/a

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

all of the above

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
631	09/07/94	female	70 lbs

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: severe itching

Date of event 07/9/01 **Date of report** 7/21/2001

Describe event or problem

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

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Mother has had allergies all her life. Daughter is allergic to pencillin, but usually okay with most products.

C. Suspect medication(s)

Name: lindane
Nix (twice)

Dose, frequency, route use
4 minute shampoo with lindane - used once

Therapy dates
07/09/01 to 07/09/01

Diagnosis for use
Head lice reinfestation

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
Nix 05/25/01 and 06/01/01

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

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MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
628	12/20/93	female	75 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 11/15/98 | **Date of report** 7/19/2001

Describe event or problem

I treated our 4 year old daughter for head lice in 1998.
Less than one week later she was vomiting about a week later
she turned jaundice. Her liver was not working properyly.
Liver Biopsy showed Stage 4 Inflammation.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Very healthy until this incident.
We are still treating her.

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
Used once. 10 minutes.

Therapy dates
11/15/98 to 11/15/98

Diagnosis for use
Head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
627	12-27-96	female	46 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 20/00/ **Date of report** 7/19/2001

Describe event or problem

C

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C

C. Suspect medication(s)

Name: generic lice shampoo

Dose, frequency, route use

1 BODLE

Therapy dates

2000 to 2001

Diagnosis for use

RF

Event abated after use stopped or dose reduced

no

Lot #

D

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

ALL

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
622	6/30/92	female	85 lbs

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: hives

Date of event	Date of report
7/13/01	7/13/2001

Describe event or problem

My daughter and I both began to break out in hives. Daughter complained of burning sensation to her scalp and intense itching.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

N/A

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use	Therapy dates
approx 1 oz of shampoo for 10 minutes	7/13/01 to 7/13/01

Diagnosis for use

Lice treatment

Event abated after use stopped or dose reduced

doesn't apply

Lot #	Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

N/A

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
619	02-18-82	female	175 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: dizziness

Date of event 05-21-01 **Date of report** 7/10/2001

Describe event or problem

After applying Lindane at night, I woke up the following morning extremely dizzy and nauseous. The symptoms continued severley for 24 hours and 2 months later I still suffer from dizzy spells and light-headedness

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
Applied from neck down for one night.

Therapy dates
05-20 to 05-21

Diagnosis for use
Scabies

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
616	3-16-1995	female	49 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 6-25-2001 **Date of report** 7/4/2001

Describe event or problem

Used NIX on hair as directed (twice) seven days apart. Each time reinvestation occured. The dr. perscribed Kwell but the generic we got was Lindane.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
also Lindane

Dose, frequency, route use
Nix (2nd dose seven days after inital dose.

Therapy dates
6-25-2001 to 7-3-2001

Diagnosis for use
Treatment of lice.

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association
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phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
610	5/1967	female	236 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 6/2001 **Date of report** 6/27/2001

Describe event or problem

been fighting head lice for a month.used two generic brands of rid,lice free,lindane,olive oil, vinegar,mineral oil,5% pyrethin, &vaseline. They all help some, but within hours of washing them out, i'm getting bitten again.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

Acticin- 5%

Dose, frequency, route use

leave on 8hrs w/ shower cap each night for 3 days.

Therapy dates

6/01/2001 to 6/30/2001

Diagnosis for use

persistent head lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction

doesn't apply

Concomitant medical products

walmart & kmart generic brands of rid, lice free,olive oil,mineral oil,vinegar, vaseline,lindane. treatments used during month of june 2001. All helped, but within hours of

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
609	6/4/73	female	100 lbs

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: see below

Date of event	Date of report
7/15/00	6/26/2001

Describe event or problem

continually re-occurent urticaria, headaches, sore eyes, occassional random memory loss, fatigue, depression.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use	Therapy dates
60 grams & used 2-3 times per week for 3 months.	7/00 to 10/15/00

Diagnosis for use
scabies

Event abated after use stopped or dose reduced
doesn't apply

Lot #	Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
607	6-11-78	female	152 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 06/22/01 **Date of report** 6/26/2001

Describe event or problem

After contracting lice from a child who is known to have had it for over a year, My familyhas tried every possible treatment imaginable including prescription with daily cleanings. This has been going on for a month

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
1% once

Therapy dates
6-5-01 to 06/26/01

Diagnosis for use
none

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
generic shampoo, RID, NIX, Lice Gel plus nit combing

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
605	6-11-95	male	40 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 5-31-01 **Date of report** 6/24/2001

Describe event or problem

Medication prescribed didn't cure problem

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane 1%

Dose, frequency, route use

apply at bedtime repeat in 7 days

Therapy dates

5-31-01 to 6-07-01

Diagnosis for use

scabies

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
602	5/17/94	female	60 lbs

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:

Date of event 6/9/01 | **Date of report** 6/21/2001

Describe event or problem

48 hours after nix treatment I still found live lice. My daugther ran a temperature the next morning after use, may not be related.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
one application

Therapy dates
6/9/01 to 6/9/01

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
600	24/01/1958	female	100 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: menstrual disorder

Date of event 9/5/96 **Date of report** 6/20/2001

Describe event or problem

My menstruation stopped the same day that I had to fumigate my house with gamma hch and tbto and I started having more and more menstrual disorders. Sometimes I don,t have my menstruation in five months when I was regular before.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have tried to find a link between my health problems and the funigation without any luck. I know that maybe this is not the right place for my question, but could you please help me to find an answer to my question? Thanks a lot

C. Suspect medication(s)

Name: pesticidal spray fumigation

Dose, frequency, route use

1 day

Therapy dates

9/5/96 to 9/5/96

Diagnosis for use

termites

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association

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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
598	02/06/1990	female	80 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 05/01/2000 **Date of report** 6/18/2001

Describe event or problem

lindane, ovide, kerosene, rid and nix. did not work. still found live bugs

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
ovide

Dose, frequency, route use
Q 2weeks for a period of approximately 6 months.

Therapy dates
08011999 to 05012000

Diagnosis for use
headlice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
dessert essence tea tree oil shampoo. 05012000 removed lice

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
593	03/05/65	female	135 lbs

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:

Date of event 05/09/01 **Date of report** 6/12/2001

Describe event or problem

Head became itchy, found nits, used RID, followed up with RID seven days later, then the whole house was covered with little black dots

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Postive Rheumatoid Factor, High Blood Pressure, Degenerative Disc Disease, Chronic Pain with chronic EBV titers (1200+)

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

Shampooed with Kwell, did the Kwell lotion

Therapy dates

5/10/01 to 06/13/01

Diagnosis for use

Lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
592	9-30-94	female	90 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 05-27-01 **Date of report** 6/12/2001

Describe event or problem

We have been battling this for 1 month.Have used Nix,Rid and Ovide.
Still we are having live lice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Recurrent UTI'S

C. Suspect medication(s)

Name: Ovide
NIX,RID,MAYO,CLEAR,VINEGAR

Dose, frequency, route use
EVERY 5 DAYS

Therapy dates
05-27-01 to 06-11-01

Diagnosis for use
LICE

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
585	4-6-95	female	48 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 3/01 **Date of report** 6/10/2001

Describe event or problem

Since March, I have not been able to keep my child free of lice for more than 3 weeks. My Dr. prescribed Lindane shampoo and we have used it repeatedly. No one told me that it was not safe to do so.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane 10%

Dose, frequency, route use

Left on 5 minutes.

Therapy dates

3/01 to 6/01

Diagnosis for use

to kill lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
581	03/27/97	female	30 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 10/00/ **Date of report** 6/1/2001

Describe event or problem

We've tried all the over the counter products and even baby oil.I spend hours treating her hair and making sure I get all the nits and a week later its back!
.What do I do?I follow the directions and no one else in the house has it.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Lice Be Gone
Nix,Kwell,Generic,Rid

Dose, frequency, route use
every ten days or as directed

Therapy dates
10/00 to 05/01

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
578	03-06-88	female	135 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 05-29-01 **Date of report** 5/29/2001

Describe event or problem

the lindane shampoo did not kill the bugs and i am very worried about the adverse reaction it will have on my child

Relevant tests/laboratory data

Other relevant history, including preexisting condition

head lice is a very big problem that we can't seem to get rid of with this child.

C. Suspect medication(s)

Name: Kwell 1%

Dose, frequency, route use

1 1/2 2oz. bottle

Therapy dates

05-29-01 to 05-29-01

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

no

Lot #

not known

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

over the counter medication

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
576	5-12-82	female	150 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other: presciption of lindane

Date of event 5-25-01 **Date of report** 5/27/2001

Describe event or problem

My daughter has not been able to get rid of her lice. She's been sick/cause lice. Needs to get rid of them

Relevant tests/laboratory data

Other relevant history, including preexisting condition

She is otherwise healthy.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

one time

Therapy dates

5/01- to 5/01

Diagnosis for use

lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
575	19/55/	male	200 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 8/97 **Date of report** 5/27/2001

Describe event or problem

Nix caused me (45-year old male) to stop breathing twice one night while
>sleeping (very scary to wake up not breathing) so I had to get up and
>shampoo, change pillowslip and put on my wife's shower cap. Then no
problem.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Very sensitive to fumes, odors, chemicals, I take atenolol for atrial fibrillation

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
directions on box, used once

Therapy dates
8/97 to 8/97

Diagnosis for use
Found nit in hair

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
no

NDC # - -

Concomitant medical products
atenolol

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
573	1/31/95	female	45 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: nothing now, I've used lindaine and nix 8-10 time

Date of event 1/01 **Date of report** 5/21/2001

Describe event or problem

not informed of products lethalness, and am terrified that my girls may be affected.....do i have them tested for any blood disorders, spleen, etc.....

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Kwell

nix

Dose, frequency, route use

8-10 times in last 5 mos

Therapy dates

01/01 to 5/19/01

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

nix, nix spray

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
572	07/92/	female	56 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: continued infection

Date of event 05/15/01 **Date of report** 5/21/2001

Describe event or problem

Treated scabies outbreak with Lindane cream. Cream failed to kill scabies-continue to produce new areas of infection. Will need to follow up with Dr. for possible retreat. I do not want to use Lindane again as I am discovering it is very dangerous.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Scabies went undiagnosed for 7 weeks even though under physician care. Dr. misdiagnosed as poison ivy and wanted to pursue oral steroid therapy. Mother protested this therapy and pursued care with another physician in the practice. Scabies was then dia

C. Suspect medication(s)

Name: lindane
1% lotion

Dose, frequency, route use
Apply cream from neck to toes.Remove p 8 to 10 hrs

Therapy dates
05/15/01 to 05/20/01

Diagnosis for use
Scabies

Event abated after use stopped or dose reduced
doesn't apply

Lot #
NDC 0472-0570-16

Exp. date

Event reappeared after reintroduction
no

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
569	10/23/53	female	130 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 2/01

Date of report 5/14/2001

Describe event or problem

my son got scabies last august,had 2 tx failures w/lindane and 3 w/
elimite. Now I have it since Feb and had 3 tx failure with elimite

Relevant tests/laboratory data

Other relevant history, including preexisting condition

No preexisting conditions

C. Suspect medication(s)

Name:

elimite

Dose, frequency, route use

apply ,leave on 12 hours then wash off

Therapy dates

9/00 to 5/01

Diagnosis for use

scabies

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
565		female	105 lbs

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: Home and property contamination

Date of event 19/99/2000 **Date of report** 5/8/2001

Describe event or problem

Allercare Spray by SC Johnson 8/99- recall 1/00.Not labelled or registered as pesticide. Act.ingred. same in many scabies treatments: Benzyl Benzoate, causing: respiratory, gastrointestinal, neurotox, immune damage,&infections etc.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

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

C. Suspect medication(s)

Name:

Allercare Dust Mite Spray by SC Johnson-not a m

Dose, frequency, route use

miniscule-much less than on label for usage

Therapy dates

7-8/99 to 1/2000

Diagnosis for use

To rid home of dust mites

Event abated after use stopped or dose reduced

no

Lot #

No EPA registration #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

not related

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
563	10/09/90	female	92 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: reoccurrence

Date of event 04/24/01 **Date of report** 5/7/2001

Describe event or problem

When I bought the metal combs called Licemeister (pediatrician highly recommended a metal comb) there was already something white between the metal teeth.

I wish I took the Licemeisters to the pediatrician to find out what the white things were.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have a dandruff condition. Hemorroids. Generalized Anxiety Disorder.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
1% weekly

Therapy dates
4/24/01 to 5/6/01

Diagnosis for use
headlice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
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phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
559	3-29-62	female	160 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 3-23-01 **Date of report** 4/28/2001

Describe event or problem

head lice problem and wont go away

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

egentric form

Dose, frequency, route use

2 Oz - 7 to 10 days

Therapy dates

3-23-01 to 4-23-01

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

no

Lot #

na

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
556	11-09-55	female	250 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: rash and blisters

Date of event 9/1996 | **Date of report** 4/25/2001

Describe event or problem

Used lice killing shampoo and ended up with a rash and blisters on my scalp. My scalp was itchy and tender . My doctor prescribed Timovate lotion that I had to apply to my scalp twice a day.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

I shampood my hair with this product ONCE!

Therapy dates

9/1996 to 9/1996

Diagnosis for use

Head lice

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
549	05/14/95	female	35 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 03/28/01 **Date of report** 4/11/2001

Describe event or problem

Treated with NIX and lindane and live lice could still be seen. We are currently manually removing when checking on a daily basis. Have tried olive oil overnight.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
NIX

Dose, frequency, route use
lindane 2x left on 10 minutes

Therapy dates
03/28/01 to 04/10/01

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #
unknown

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
NIX 3/28/01 & 3/29/01
lindane 03/30/01 & 03/09/01

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
548	8/28/92	female	45 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☑ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 3-22-01 **Date of report** 4/10/2001

Describe event or problem

My niece, who was perfectly healthy up until three weeks ago,was diagnosed with leukemia(AML). She coincidentally, was treated for headlice with an OTC remedy in the
middle of December. We think it was RID.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Very healthy up until now!

C. Suspect medication(s)

Name: Rid
we THINK it was rid

Dose, frequency, route use
1x

Therapy dates
12/15/00 to 12/15/00

Diagnosis for use
headlice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
545	11/20/98	male	32 lbs

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: secondary rash

Date of event 04/02/00 **Date of report** 4/8/2001

Describe event or problem

Intense itching and raised rash on chest. Looks worse than it was. Itching and discomfort are a lot worse.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

received big bottle for family. 2x within 3 weeks

Therapy dates

03/15/00 to 04/07/00

Diagnosis for use

scabies

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

Doctor has now prescribed hydorocortizone cream mixed with Lac-hydrin 12% cream to be applied twice daily. Stopped use after one day because it irritated rash

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
543	19/97/	female	40 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 01/01/01 **Date of report** 4/7/2001

Describe event or problem

Hundreds of dollars spent and infestation continues....Nix , R&C , and Kwellada-P 1%, alternately as directed , every 7-10 days repeated constantly since January. Household environment treated with R & C spray insecticide.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: R&C
Nix , Kwellada - P

Dose, frequency, route use
as directed , every 7-10 days

Therapy dates
01/01/01 to 07/04/01

Diagnosis for use
headlice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

Nix , R&C , and Kwellada-P 1%, alternately as directed , every 7-10 days repeated since January. Household environment treated with R & C spray insecticide.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
540	06-06-91	female	80 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 1999-2001 **Date of report** 4/4/2001

Describe event or problem

over the counter or perscription meds,shampoos,etc. DO NOT WORK
NIX-RID-A-200--LINDANE

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
several

Dose, frequency, route use
bottle (2oz)and the same 10days later

Therapy dates
1999 to 2001

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
several--the most effective thing I have used is cooking oil and garlic powder with plastic cover tightly on head using the top of thights to hold it on,letting it sit several hours

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
537	05/07/1978	male	200 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: mania

Date of event 8/97 **Date of report** 3/28/2001

Describe event or problem

Within about two months of my last exposure, my behaviour became very reckless, and I experienced a decreased need for sleep, excessive talkativeness, and other symptoms of mania for several weeks. I was later diagnosed as bipolar.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have congenital nystagmus. I also have a history of depression.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
lice shampoo twice and scabies cream once.

Therapy dates
1/97 to 6/97

Diagnosis for use
pubic lice, scabies

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

I was taking st. john's wart. I was also taking various nutritional supplements.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
536	19/59/	female	122 lbs

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:

Date of event 03-14-01 **Date of report** 3/28/2001

Describe event or problem

Despite treatment with RID & Permethrin, and daily sterilization of all bedding, clothing, & household items, we have new bites daily. Have sprayed home, office, car. The pesticides are not working and have made me ill.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

No preexisting medical conditions. All family members are healthy.

C. Suspect medication(s)

Name: Rid
Permethrin Cream 5%

Dose, frequency, route use
RID 5 times/2 wks,
Permethrin twice 14 days

Therapy dates
03/09/01 to 03/28/01

Diagnosis for use
body lice

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
March 7 - March 14, 2001

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
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phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
535	7/28/92	male	93 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 7/16/00 | **Date of report** 3/27/2001

Describe event or problem

Parent told by pediatrician to apply Kwell to whole body. Adam had to be awakened and washed several times as directed by poison control to prevent poisoning. He had temporary respiratory difficulty.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Adam is learning disabled--so this is extra DISGUSTING!!!!!!!!!!!!!!!

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

One whole dermal application left on for 10 hours

Therapy dates

7/16/00 to 7/16/00

Diagnosis for use

Scabies, head lice and crab lice in eyelashes

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

7/2/0 to 7/16/00--Nix and Rid carefully used at pediatrician's direction. NO adverse reactions prior to Kwell

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
534	10/2/90	female	80 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 7/16/00 | **Date of report** 3/27/2001

Describe event or problem

Kwell shampoo was applied to whole body as directed by pediatrician, and left on for 10 hours. Mother had to wash her several times with soap to prevent poisoning, as directed by poison control. She had temporary respiratory difficulty.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

One whole body application left on for 10 hours

Therapy dates

7/16/00 to 7/16/00

Diagnosis for use

Scabies, head lice and crab lice in eyelashes

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

7/2/00 to 7/16/00--Rid and Nix were used before Kwell at physician's direction. There were NO adverse reactions prior to Kwell.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
533	5/28/62	female	154 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 7/16/00 **Date of report** 3/27/2001

Describe event or problem

I was told to apply Kwell shampoo all over myself and my children by a pediatrician. I had to go to the ER because I was having trouble breathing. Two days later I was hospitalized for psychosis.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

No physical problems, but I have received psychotherapy and psychiatric help for anxiety and depression. I have NO history of psychotic illness prior to the use of the Kwell shampoo. I have also consulted with a psychiatrist and a neuropsychologist who

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

One whole dermal application of Kwell shampoo

Therapy dates

7/16/00 to 7/16/00

Diagnosis for use

Scabies, crab and head lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

I had also used Nix and Rid treatments and Pronto and Rid sprays with minimal side effects. We had been lice infested for more than two weeks, from about July 2 to July 16,

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
532	06/26/1996	female	38 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: treatments not working

Date of event 02/20/2001 **Date of report** 3/25/2001

Describe event or problem

we have use over the counter and doctor prescribed meds.I've sprayed every thing. Removed all nits buy cutting out that strand of hair. But two to three days later she has them agian. Also we all have done the treatments. What else can I do?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: lindane
nix/rid

Dose, frequency, route use
as instucted

Therapy dates
02202001 to 03192001

Diagnosis for use
as directed

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
we've been treating once a week since 2/20/01

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
520	01/06/91	female	60 lbs

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:

Date of event 01/16/01 **Date of report** 3/9/2001

Describe event or problem

The day after treating my daughters head flr lice my hands became VERY swollen. Also the next day I found live adults on her head. First infestation accurred in december of 2000.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

Rid, Nix, Lice Free, vinegar

Dose, frequency, route use

first Rid and Lice free 3 weeks later Nix

Therapy dates

12/00 to 03/01

Diagnosis for use

Treatment for headlice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
517	08/16/42	female	140 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 19/98/ **Date of report** 3/8/2001

Describe event or problem

Started receiving prescriptions and subsequently using Kwell lotion every few months starting in the late 70s for scabies treatment. In 1998 started having seizures on a weekly basis.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
every few months

Therapy dates
1975 to 1999

Diagnosis for use
for scabies treatment

Event abated after use stopped or dose reduced
no

Lot #
MDC6043254
7-60

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
513	9-1-90	female	82 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 2-25-01 **Date of report** 2/26/2001

Describe event or problem

My daughter has had 3 episodes of head lice since 1-2001. I have treated her with Rid, Nix, done everything I was told by the health department and she keeps getting re-infested. We need help.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Seizure disorder, mental retardation, autism

C. Suspect medication(s)

Name: Nix
Rid, Lindane

Dose, frequency, route use
every 7-10 days

Therapy dates
1-2001 to 2-25-2001

Diagnosis for use
head lice & nits

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
510	07-24-93	female	56 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 1-16-01 **Date of report** 2/22/2001

Describe event or problem

My daughter had lice 7 times last year and again 2 times this year

Relevant tests/laboratory data

Other relevant history, including preexisting condition

no medical conditions

C. Suspect medication(s)

Name: lindane
Nex

Dose, frequency, route use
lindane 3 times

Therapy dates
01-16-02 to 02-22-01

Diagnosis for use
put on dry hair for 4 min. wash out

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
507	12-12-90	female	70 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: resiliant not dying with the treatment

Date of event 12/23/2000 **Date of report** 2/18/2001

Describe event or problem

Still can't rid of the lice have tried all the over the counter products now going to try the kwell

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Rid

Dose, frequency, route use
Every seven days

Therapy dates
12/23/2000 to 2/17/2001

Diagnosis for use
lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
505	19/55/	male	148 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: chronis symptoms

Date of event 19/74/1980 **Date of report** 2/14/2001

Describe event or problem
please contact me

Relevant tests/laboratory data

Other relevant history, including preexisting condition
none

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
..

Therapy dates
1974 to 1980

Diagnosis for use
Scabies

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
Please contact me (description window won't take all)

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
500	08/25/91	female	66 lbs

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: rash

Date of event 02/06/01 **Date of report** 2/7/2001

Describe event or problem

Head lice, used Clear, Lice B Gone, Rid, Nix, and Ryobi electric comb and nothing seems to kills the lice, or there eggs will not come off folice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Over 2 years ago, our school was almost closed due to the number of head lice cases. I am afraid to say that I beleive as bas as my daughter has it that we could be in the same direction

C. Suspect medication(s)

Name: Clear

Rid, Nix, Clear and Lice B Gone

Dose, frequency, route use

treatment for 4 days

Therapy dates

02/02/01 to 02/07/01

Diagnosis for use

Head Lice

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
499	9-7-1959	female	120 lbs

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: used spray and found it to be irritating to lungs a

Date of event 2/6/2001 **Date of report** 2/6/2001

Describe event or problem

head lice, used nix for 3 weeks now, and still have lice. Last night i left it on for 60 minutes, rinsed, then rinsed with 1/2 cup vinager, 1/2 cup warm water, left hair in towel for 30 min. then applied olive oil and left in hair in towel overnight

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My head had been itching for quite awhile, didnt know what cause was till 3 weeks ago and brushed out a live louse

C. Suspect medication(s)

Name: Nix
vinager, olive oil and rid spray were used,

Dose, frequency, route use
enough to saturate scalp and hair, every six days

Therapy dates
1/13/2001 to 2/5/2001

Diagnosis for use
detected live lice

Event abated after use stopped or dose reduced
no

Lot #
0c1694

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
493	8/9/93	female	50 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 1/19/01 **Date of report** 1/20/2001

Describe event or problem

have treated live infestation with lindane and manually pick out nits and retreated and still have lice and have even tried mayonaise!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

3 times in 2 weeks

Therapy dates

1/8/02 to 1/20/02

Diagnosis for use

treat remove eggs retreat in 10 days

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

no

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
492	06-15-93	female	50 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 01-01-01 **Date of report** 1/15/2001

Describe event or problem

We have had head lice in our home every school year for the last 4 years.We have used every product that the store sales and kwell.We have had as many as 100 alive lice in a little 7 year olds head.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
one application

Therapy dates
01-15-01 to 01-15-01

Diagnosis for use
lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
491	03/29/94	female	52 lbs

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: dunno if reaction or not, but she is breaking out

Date of event 4/98 **Date of report** 1/15/2001

Describe event or problem

got rid of furniture, moved, stuffed animals in storage, nothing working! now she is breaking out with what we thought was ringworm on her head, but doc said psorosis? dunno what it is! red whelps, that itch & bleed, & scab over

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: lindane

pronto, kwell, nix, cooking oil

Dose, frequency, route use

once a week, used the lotion

Therapy dates

04/98 to 01/01

Diagnosis for use

lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

we have used everything under the sun.... nix pronto kwell robo-comb the gold handle comb (that worked, but got broke) rid dog shampoo

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

Expiration date

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
484	09/10/54	female	132 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☑ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 12/01/00 | **Date of report** 1/7/2001

Describe event or problem

Itching, rash, nasal conjestion, tingling in tongue, ringing in ears

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: Kwell
NIX

Dose, frequency, route use
2 Times

Therapy dates
120100 to 121000

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #
Unknown

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
N/A

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
482	6-30-73	female	65 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: nothing is working

Date of event 01-01-01 **Date of report** 1/5/2001

Describe event or problem

I am doing everything exactly right, have had the ongoing problem for over a month and am out of ideas adn money. I have had the problem before and know the proper procedure, but nothings working! All 3 of us have them

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

nix, and rid

Dose, frequency, route use

1 time per week

Therapy dates

10-31-00 to 01-05-01

Diagnosis for use

not workign at all

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

Expiration date

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
478	11/11/90	female	80 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 11/00/ **Date of report** 1/1/2001

Describe event or problem

We have been trying to get rid of lice from my granddaughter for over a year. We have tried every otc medications plus ovide prescribed by doctor. We have combed and tried to remove the eggs and bugs but they keep coming back.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid

olive oil, ovide, pronto,

Dose, frequency, route use

every two weeks about half the bottle.

Therapy dates

090199 to 123100

Diagnosis for use

use once and then wait a week and do it again

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

olive oil. gemeric shampoos, rid mousse, We are ready to shave her head and get her a wig

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
475	04/08/60	female	130 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 07/01/00 **Date of report** 12/28/2000

Describe event or problem

Used lindane two times about a month apart, has severe scalp tingling and pain, has seen three different neurologists

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Using hormone replacement prescription, has since been taken off.

C. Suspect medication(s)

Name: lindane
Nix, Rid

Dose, frequency, route use
Three treatments in approx. 2 weeks of 3 shampoos

Therapy dates
07/01/00 to 12/28/00

Diagnosis for use
Head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

Still seeing neurologists, treated with different meds.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
472	3-18-1965	male	140 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 12-21-00 **Date of report** 12/21/2000

Describe event or problem

three months of trying everything including all the over-the counter products and qwell, following all the directions. I am an RN, may have picked it up from the hospital. We haven't tried the antibiotic or malathion, or the kerosine.

still infested

Relevant tests/laboratory data

Other relevant history, including preexisting condition

my wife and I plan to shave our heads as soon as we get back from xmas vacation - if that doesn't work we may have to cut them off.

C. Suspect medication(s)

Name: Nix
lindane

Dose, frequency, route use
several times

Therapy dates
9/2000 to 12/2000

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
470	02/08/92	female	48 lbs

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: severe asthma

Date of event 18/12/00 | **Date of report** 12/18/2000

Describe event or problem

After treating withmalthion based product child is diagnosed with asthma requiring stronger medication than ever before.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Mild asthma not requiring preventer medication.

C. Suspect medication(s)

Name:

KP24

Dose, frequency, route use	Therapy dates
10ml washed in hair for 5 minutes thenrepeated.	12/00 to 12/00

Diagnosis for use

10

Event abated after use stopped or dose reduced

doesn't apply

Lot #	Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address | **phone #** (781)449-6487

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Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
466	1-2-94	female	50 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 8-00 **Date of report** 12/9/2000

Describe event or problem

After using Nix creme rinse 2 times live kice were still detected.
We have been battling this for months. ANd have used Manual Removal, vacuuming , washing.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
1/2 bottle 2 times

Therapy dates
8/00 to 12/00

Diagnosis for use
live lice and nits

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Pronto, Rid...

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
465	11/30/92	female	48 lbs

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: nausea & headache

Date of event 6/00 **Date of report** 12/6/2000

Describe event or problem

All of the lice shampoos on the market make my child sick and do not work as promised.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell nix, all

Dose, frequency, route use
as prescribed

Therapy dates
6/00 to 9/00

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
463	1-22-1993	female	45 lbs

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: listless,lack of appetite.

Date of event 20/00/ **Date of report** 12/4/2000

Describe event or problem

Can't seem to keep bugs off my daughter no matter what I try. No matter how many ways I've tried nothing kills the lice....nothing.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: Hair Clean 1-2-3

RID,mayonaise,Nix, vaseline, all.

Dose, frequency, route use

As recomended on product lable.

Therapy dates

6/2000 to 12/2000

Diagnosis for use

I don't understand.

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
462	04-14-94	male	49 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: Stomach cramps and vommiting

Date of event 12-02-00 **Date of report** 12/2/2000

Describe event or problem

After treating with Rid and tee tree oil my 6-1/2 year old woke up crying with stomach cramps, vommiting and a temp of 102

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: Rid

tea tree oil

Dose, frequency, route use

Rid Mon Tea tree oil Thurs. Both shampoo

Therapy dates

11-27-00 to 11-30-00

Diagnosis for use

School Nurse Possibly lice. Treat

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

I also used the same treatment on my 2-1/2 year old daughter and myself and so far no symptoms.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
458	03/27/1975	female	120 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: heart problems and I sweat LINDANE

Date of event 11/27/00 | **Date of report** 11/28/2000

Describe event or problem

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

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have allergies.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

cover once and
Repeat after 3 days.

Therapy dates

11/20/00 to 11/24/00

Diagnosis for use

to treat scabies

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Allergra for allergies. To be used indefinately.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
454	12/10/53	female	200 lbs

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 all over body. Chronic - lasting months

Date of event 07/20/00 **Date of report** 11/24/2000

Describe event or problem

After using lindane, I developed urticaria, which, 4 months later I still have. Whenever I scratch my head I develop bumps, and my family still has a problem with the darn lice. They seem invincible.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
RC at other times

Dose, frequency, route use
50 ml - once a week for a month or two.

Therapy dates
05/2000 to 11/2000

Diagnosis for use
nits found on hair

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
452	9/19/1990	female	105 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 2/99-11/00 | **Date of report** 11/21/2000

Describe event or problem

I have been treating my daughter for lice since February, 1999 to the present. Nothing is helping! I launder, bag toys, use bedding spray. I nit-pick and do what is required and recommended.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell
generic lice shampoo

Dose, frequency, route use
Kwell: 1 oz
Generic: as directed

Therapy dates
2/1999 to 11/00

Diagnosis for use
Use for head lice and knit removal

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
451	2-12-93	female	70 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 8/00

Date of report 11/20/2000

Describe event or problem

constant use of lice products resulted in $100's of dollars spent with no relief

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid
Nix, Lindane, Oil, Mayonnaise

Dose, frequency, route use
standard dosage for over the counter every week

Therapy dates
8/00 to 11/00

Diagnosis for use
Lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

oil with mayonnaise with a shower cap overnight and diligent searching one inch at a time through her hair pulling the nits out with my fingernails got rid of them. Those

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
450	12-17-92	female	58 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 08-00 **Date of report** 11/19/2000

Describe event or problem

My daughter has had numerous treatments to head lice, and I regularly and vigorusly pick and comb her hair for nits, and pick the lice, But all our efforts have been for nothing. PLEASE HELP!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
Rid

Dose, frequency, route use
Rid 3x 10 days apart
Lindane 2X 10 days apart

Therapy dates
08-00 to 11-00

Diagnosis for use
Head Lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
447	07/09/91	female	50 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 11/16/00 **Date of report** 11/17/2000

Describe event or problem

After having treated her for the last 3 months with every over the counter product available, nothing helps clear this pest on a more permanent basis. After the last failure, I went to the doctor to get a prescription for head lice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
2 oz. one time, repeat in 7 days if needed.

Therapy dates
9/05/00 to 11/16/00

Diagnosis for use
Nits

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

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

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
444	01-21-96	female	35 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 01-01-99 **Date of report** 11/16/2000

Describe event or problem

Lice are the size of ants. Have tried numerous things since 1/99.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

N/A

C. Suspect medication(s)

Name: lindane

9 out of the list.

Dose, frequency, route use

Since January 1999

Therapy dates

01/99 to 11/00

Diagnosis for use

Head lice - still there, unsuccessful treatments

Event abated after use stopped or dose reduced

no

Lot #

N/A

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

A-200, Clear, Rid, Nix, Lice Free, Mayonnaise, Vinegar, Lindane, Elimite and Pronto have all been used. Lindane and Elimite have only been used once each. The other

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

Expiration date

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
442	08/28/89	female	68 lbs

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:

Date of event 09/13/2000 **Date of report** 11/11/2000

Describe event or problem

She has has head lice since a friend gave it to her staying over. I have tried sooo many treatmeants for her, I'm afraid it's dangerous.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

She is now getting very large lumps in the back of her neck and her head is full of scabbed over blood (this is with washing and coming all
the time).

C. Suspect medication(s)

Name: Rid
mayonnaise

Dose, frequency, route use
approx every two weeks

Therapy dates
06/20/00 to 11/11/2000

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #
not known

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
She's had it consistantly for at leasr one year

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
435	12/26/63	female	130 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☑ required intervention

other: THYROID CANCER

Date of event 07/19/99 **Date of report** 11/2/2000

Describe event or problem

Treated with Lindane/Qwell about 13 yrs. ago, not realizing it had any health precautions with it. Diagnosed with Thyroid Cancer in July, 1999. Through research have realized that my using Qwell may have had something to do with getting Cancer.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
one treatment

Therapy dates
0000 to 0000

Diagnosis for use
scabies

Event abated after use stopped or dose reduced
yes

Lot #
unkown

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
433	04/12/93	female	98 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 09/08/00 **Date of report** 11/1/2000

Describe event or problem

NOne of the over the counter products have worked even prescription Ovide. Now on Bactrim. This is the third outbreak within 3 months.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Ovide
Nix, Rid,Pronto,Generic Lice Shampo

Dose, frequency, route use
followed directions however used every 5 days

Therapy dates
090800 to 110100

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Currently on Bactrim for the next 3 days. Take 4 teaspoons by mouth twice daily.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
429	01/09/74	female	110 lbs

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: very sore scalp

Date of event 28/10/00 **Date of report** 10/28/2000

Describe event or problem

have had nits for about 8months now i have tried every lotion shampoo mouse nit comb and even conditioner and they are still there

Relevant tests/laboratory data

Other relevant history, including preexisting condition

ashma,

C. Suspect medication(s)

Name: tea tree oil

hairclean123,clear,and all the other ones that are

Dose, frequency, route use	Therapy dates
every week	10/02/00 to 28/10/00

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

yes

Lot #	Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

lyclear, clear/fullmarks/hair clean 123/teatree shampoo/teatree conditioner/conditioner and comb electronic nit comb,plastic nit comb metal nit comb i've used

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
427	10/17/55	female	135 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: symptom return

Date of event 06/99/ **Date of report** 10/27/2000

Describe event or problem

out break nine red spots underarm diagnosed scabies. treated with elimite which rid me the problem for year. stored clothing a year. wore infected clothing reinfected same spot. used lindane, elimite. trying to rid using neem & tumeric now.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

elimite 5%

Dose, frequency, route use

30 g once a week

Therapy dates

06/2000 to 10/2000

Diagnosis for use

doctor said to apply then reapply again in 7 days

Event abated after use stopped or dose reduced

no

Lot #

1003152 04-02

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

june 1999 eliomite which worked after 90g in three treatments

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
426	10/28/91	female	80 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: FAMILY INFESTED

Date of event 10/1-10/27 **Date of report** 10/27/2000

Describe event or problem

THE CHILDREN CAME HOME WITH LICE AND WE HAVE BEEN TREATING THEM AND PICKING LICE EVER SINCE.THE LICE SHAMPOOS WE USE ISN'T WORKING.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

IV'E TRIED EVERYTHING

Dose, frequency, route use

ONCE A WEEK

Therapy dates

10/1 to 10/27

Diagnosis for use

LICE AND NITS

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

I HAVE TRIED EVERYTHING AVAILABLE TO ME. I HAVE EVEN RESORTED TO TRYING DOG SHAMPOO BUT IT DON'T WORK EITHER.HELP I'M

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
422	03/05/94	female	58 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: missed school

Date of event 10/17/00 **Date of report** 10/24/2000

Describe event or problem

Several treatments have been used, nothing seems to be working We have used Lindane - not knowing the bad effects of this We keep nit-picking and more seem to appear Help - we are going crazy and she is missing a ton of school!!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: lindane
over the counter lice shampoos and gels

Dose, frequency, route use
lindane - 3 times, generic - 1 time Gels - twice

Therapy dates
10/17/00 to 10/24/00

Diagnosis for use
school nurse and pharmacist

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
417	2/17/90	female	60 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 8/00 **Date of report** 10/18/2000

Describe event or problem

Treated hair once per week for three weeks with RID NIX and prescription Lindane Combed hair with several different styles of combs It is now mid October and we had to treat her hair with the rest of the prescription tonight

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
NIX and RID

Dose, frequency, route use
1 time per week for 3 weeks
Again every 2 weeks

Therapy dates
8/00 to 10/00

Diagnosis for use
Itching first, then found lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

everyone in the house has been treated again and again. everything washed in hot water, vacuumed etc. our house has always been very clean and we all shower every day,

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
408	01/14/2000	male	48 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 08-30-00 **Date of report** 10/10/2000

Describe event or problem

BLISTERING ON FEET AND HANDS

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane 1%

Dose, frequency, route use

RUB ON BODY

Therapy dates

08-27-00 to 09-30-00

Diagnosis for use

SCABBIES

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
406	07-02-94	female	63 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 5/2000 **Date of report** 10/6/2000

Describe event or problem

cna't get rid of infestation of daughter's head lice....

Relevant tests/laboratory data

Other relevant history, including preexisting condition

continued from above ...My son came home with infestation, we jumped on it went to buy nix, a lady recommended mayonaise. We tried mayo & it worked ! At least on our son, a wk later we noticed our daughter had something so we mayo'ed up her & little siste

C. Suspect medication(s)

Name: lindane

nix, clear,mayoniaise,generic lice shampoo & lice

Dose, frequency, route use

10 minutes on head every 2 days

Therapy dates

5/2000 to 10/2000

Diagnosis for use

over the phone,school nurses recommendation

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
399	10/08/1997	female	31 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 09/14/2000 **Date of report** 9/28/2000

Describe event or problem

My daughter was rushed to the emergency room to have her eyes irrigated following the use of a product called "Not Nice to Lice" which was labeled as being non-toxic. She was diagnosed with chemical conjunctivitis.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

History not relevant.

C. Suspect medication(s)

Name: Not Nice to Lice

Dose, frequency, route use

1 8 oz. bottle, one time

Therapy dates

09/14/2000 to 09/14/2000

Diagnosis for use

Don't understand question.

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

An electronic lice comb was used on my daughter's dry hair prior to the use of this "non-toxic" produce.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, 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

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
398	6-29-89	female	87 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 9-1-00 **Date of report** 9/28/2000

Describe event or problem

We have used RID, NIX, Listerine(!), Lindane all unsuccessfully. We carefully followed directions, retreated, still infested

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane 1%

Dose, frequency, route use
shampoo twice 10 days apart

Therapy dates
9/00 to 9/00

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
396	03/27/1991	male	60 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 06/07/2000 **Date of report** 9/27/2000

Describe event or problem

I went to R.I. on in June vacation and my four children ages,9,8,6,3, got head lice.I used over the counter as well as perscreption med.I have returned to Arizona and my children still have lice.I have tried everything and can not get rid of them.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
used six times since June

Therapy dates
6/07/2000 to 09/27/2000

Diagnosis for use
killing lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Rid,A-200

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
395	05/25/94	female	35 lbs

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: difficulty breathing

Date of event 09/25/00 **Date of report** 9/27/2000

Describe event or problem

This was so strong that we almost fainted. had difficulty breathing, felt like vomiting, very dizzy. even worse, the next day; still lice biting into her head. I also got sick: my lungs also hurt, Blisters & hives all over hands/arms, fingers numb.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

we were pretty healthy before putting on the toxic shampoo that should have skull and cross bones on it.

C. Suspect medication(s)

Name: R&C
Pyrethin 0.33%, Piperonyl Butoxide Technical 3.0

Dose, frequency, route use
about 30-40 mL per person

Therapy dates
09/25/00 to 09/25/00

Diagnosis for use
Head lice

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

We are not willing to try any other medications for lice.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, 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

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐