RECEIVED AT DRUG SAFETY SURVEILLANCE

15-JAN-1998-0608

VOLUNTARY

lth professionals

ts and product pr

Individual Safety Report

3018843-8-00

Page of

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
In confidence	43 or ____ Date of birth: [redacted]	☐ female ☒ male	137 lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death
   - ☒ life-threatening
   - ☒ hospitalization - initial or prolonged
   - ☒ disability
   - ☐ congenital anomaly
   - ☒ required intervention to prevent permanent impairment/damage
   - ☐ other

3. Date of event: 4/10/97

4. Date of this report: 1/6/98

5. Describe event or problem: I came down with the flu, it lasted 10 days, then a cold that turned into pneumonia followed. I could not eat, because when I did it would cause severe abdomial bloating, pain. My feet and ankles swelled to twice there normal size, and then the swelling started up my legs, this is when I sought medical help. I was drinking about a 6pac of beer a day when this was happening and taking OTC pain + fever drugs as directed. I have severe liver damage from this, and believe acetaminophen is the cause. This almost killed me, please warn the public.

6. Relevant tests/laboratory data, including dates: Radiological Tests 5/9/97 to 5/12/97; Liver profile Tests; Chemistry + Hyperal Profile tests; Blood Bank Testing + HIV Test; Upper G.I. and small bowel follow through. and many more.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.): Bronchitis, 6pac of Beer a day, 2 pack cigarettes, white, + 1/8 cherokee Indian

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 Tylenol
   - #2 Extra strength Tylenol

2. Dose, frequency & route used
   - #1 as directed
   - #2

3. Therapy dates (if unknown, give duration)
   - #1 20 days off and on
   - #2

4. Diagnosis for use (indication)
   - #1 Fever + pain
   - #2

5. Event abated after use stopped or dose reduced
   - #1 ☒ yes ☐ no ☐ doesn't apply
   - #2 ☒ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
   - #1
   - #2

7. Exp. date (if known)
   - #1
   - #2

8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☐ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device: 75942

3. Manufacturer name & address

4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other

5. Expiration date

6. model #
   catalog #
   serial #
   lot #
   other #

7. If implanted, give date

8. If explanted, give date

9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted]

2. Health professional? ☐ yes ☒ no

3. Occupation: carpenter

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

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.