Individual Safety Report

3549453-1-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare

McNeil Consumer Healthcare
ort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	or adult Date of birth:	( )female (X)male	unk lbs or kgs

B Adverse event or product problem

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

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
(x) other: none

3. Date of event (mo/day/yr): unknown

4. Date of this report (mo/day/yr): 01/21/00

5. Describe event or problem

Consumer report received via Internet alleges that the use of an Extra Strength TYLENOL® acetaminophen product was associated with LIVER FUNCTION TESTS ABNORMAL (my liver count is high). Consumer reports taking 3000-4000 mg of Extra Strength TYLENOL "for years now" for an unknown indication. According to consumer, his "liver count is high." Consumer reports his physician stated it "could be TYLENOL that brought it on, or at least is not making it any better." His physician reportedly switched him to Extra Strength EXCEDRIN®. No further information was provided.

6. Relevant tests/laboratory data, including dates

unspecified date: consumer's Internet report indicates "my liver count is high"

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product
#2

2. Dose, frequency & route used

#1 3000-4000 mg/day, po
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown dates; "for years"
#2

4. Diagnosis for use (indication)

#1 unknown
#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 unknown
#2

7. Exp. date (if known)

#1 unknown
#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

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

unknown

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number

215-273-7303

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
(x) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
(x) other: Internet

4. Date received by manufacturer (mo/day/yr)

01/07/00

5.

(A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day ( ) 15-day
( ) 10-day (X) periodic
(X) initial ( ) follow-up #

8. Adverse event term(s)

LIVER FUNC ABNO

9. Mfr. report number

1293361A

E Initial reporter

1. Name, address & phone #

AUG - 9 2000

2. Health professional?

( ) Yes ( ) No

3. Occupation

4. Initial reporter also sent report to FDA

( ) Yes ( ) No ( ) Unk

FDA

Facsimile Form 3500A

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

00 000748