



McNeil Consumer Healthcare
McNeil Consumer Healthcare
rt Washington, PA 19034-2299

Approved by FDA on 11/15/93
Mfr report #
UP/Dist report #
FDA use only

Page ___ of ___

A Patient information

1. Patient identifier
2. Age at time of event: 52 yrs
or Date of birth:
3. Sex (X)female ()male
4. Weight unk lbs or kgs

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 TYLENOL Analgesic Unknown
#2
2. Dose, frequency & route used
#1 2-4 pills, od, po
#2
3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 past 10 years
#2
4. Diagnosis for use (indication)
#1 arthritis
#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

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 8/99 (mo/day/yr)
4. Date of this report 09/27/99 (mo/day/yr)

5. Describe event or problem
Consumer alleges that the use of one of our TYLENOL® acetaminophen products was associated with LIVER FUNCTION TESTS ABNORMAL (increased liver enzymes). According to consumer, routine lab tests in 8/99 revealed an unspecified elevation in liver enzymes. Consumer reports being on multiple medications but refused to specify.

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
() other:
4. Date received by manufacturer (mo/day/yr)
09/27/99
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
1243710A

6. Relevant tests/laboratory data, including dates
8/99: unspecified increase in liver enzymes

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
none

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



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

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