



3203037-3-00-01



McNEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034

Approved by FDA on 11/15/93

Mfr report # _____

UF/Dist report # _____

FDA use only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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| A. Patient information | | | | C. Suspect medication(s) | | | |
| 1. Patient identifier In confidence | 2. Age at time of event: or Date of birth: | 3. Sex () female (X) male | 4. Weight 22 lbs or kgs | 1. Name (give labeled strength & mfr/labeler, if known) #1 Infants' TYLENOL Concentrated Drops #2 | | 2. Dose, frequency & route used #1 500 mg, q4-6h, po #2 | |
| B. Adverse event or product problem | | | | 3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 12/11/98-12/13/98; 3 days #2 | | | |
| 1. X Adverse event and/or Product problem (e.g., defects/malfunctions) | | | | 4. Diagnosis for use (indication) #1 fever #2 | | 5. Event abated after use stopped or dose reduced #1 (X) Yes () No () N/A #2 () Yes () No () N/A | |
| 2. Outcomes attributed to adverse event (check all that apply) | | | | 6. Lot # (if known) #1 BHM071 #2 | | 7. Exp. date (if known) #1 unknown #2 | |
| () death (m/day/yr) () life-threatening (X) hospitalization - initial or prolonged | | | | () disability () congenital anomaly () required intervention to prevent permanent impairment/damage (X) other: recovered | | 8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A | |
| 3. Date of event (m/day/yr) 12/11/98 | | 4. Date of this report (m/day/yr) 02/10/99 | | 9. NDC # - for product problems only (if known) | | | |
| 5. Describe event or problem | | | | 10. Concomitant medical products and therapy dates (exclude treatment of event) none | | | |
| Pharmacist's report of ACCIDENTAL OVERDOSE allegedly associated with Infants' TYLENOL® acetaminophen Concentrated Drops in a child. Pharmacist reports child was taken to ER. Addl info rec'd 12/15/98: According to consumer on 12/11/98, she contacted her son's MD because he had a fever. MD reportedly recommended 1 tsp of TYLENOL® q4h. Consumer reports administering doses of Infants' TYLENOL® Concentrated Drops, rather than Children's TYLENOL® Elixir. On 12/13/98, son began experiencing sx's of DIARRHEA, NERVOUSNESS (irritable), SOMNOLENCE (more tired than usual) & VOMITING. At same time of sx's, consumer reports son was infected by RSV. Later that day, pharmacist recommended taking son to ER. In ER, son's blood analysis reportedly revealed ABNORMAL LIVER FUNCTION TEST (abnormal liver enzymes). Pt tx'd w/NAC & admitted to hosp on 12/13/98 for observation. On 12/14/98, pt d/c'd home w/instructions to complete NAC tx. Addl info rec'd 2/9/99: Data follow-up form indicates son was given 1 tsp q4-6 hrs. Son also had sx of JAUNDICE & was tx'd w/NAC for 36 hrs. | | | | G. All manufacturers | | | |
| 6. Relevant tests/laboratory data, including dates | | | | 1. Contact office - name/address (& mfring site for devices) | | 2. Phone number | |
| 12/13/98: unspecified abnormal liver enzymes; 12/16/98: f/u blood analysis performed & results pending | | | | McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034 | | 215-273-7820 | |
| 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) prior history of fever; consumer reportedly measured fever of 102 in son on 12/11/98 | | | | 4. Date received by manufacturer (m/day/yr) 02/09/99 | | 3. Report source (check all that apply) | |
| | | | | 5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes | | () foreign () study () literature (X) consumer (X) health professional () user facility () company representative () distributor () other: | |
| 8. Adverse event term(s) | | | | 6. If IND, protocol # | | 7. Type of report (check all that apply) | |
| OVERDOSE ACCID DIARRHEA NERVOUSNESS SOMNOLENCE VOMITING LIVER FUNC ABNO JAUNDICE | | | | () 5-day (X) 15-day () 10-day () periodic () Initial (X) follow-up # 2 | | 9. Mfr. report number 1086122A | |
| E. Initial reporter | | | | F. Initial reporter | | | |
| 1. Name, address & phone # Mr. _____ RPh _____ Pharmacy _____ Road _____ | | | | 2. Health professional? (X) Yes () No | | 3. Occupation pharmacist | |
| 4. Initial reporter also sent report to FDA () Yes () No (X) Unk | | | | Submission of this report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event. | | | |

RECEIVED
FEB 18 1999
BY:

DSS

FEB 22 1999

