



McNeil
 Consumer Healthcare
 McNeil Consumer Healthcare
 2000 North Washington, PA 15034-2299

Approved by FDA on 11/15/93

| |
|-----------------|
| Mfr report # |
| UF/Out report # |
| FDA use only |

Page ___ of ___

| A. Patient information | | | | C. Suspect medication(s) | |
|--|--|--|-----------------------------------|---|--|
| 1. Patient Identifier unknown In confidence | 2. Age at time of event: or fetus Date of birth: | 3. Sex (X) female () male | 4. Weight 3.6 lbs or kgs | 1. Name (give labeled strength & mfr/labeler, if known) #1 Extra Strength TYLENOL product #2 | |
| B. Adverse event or product problem | | | | 2. Dose, frequency & route used #1 maternal ingestion #2 | |
| 1. X Adverse event and/or Product problem (e.g., defects/malfunctions) | | | | 3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates; 5 days #2 | |
| 2. Outcomes attributed to adverse event (check all that apply) | | | | 4. Diagnosis for use (indication) #1 mother's toothache #2 | |
| (X) death (mo/day/yr) 1/23/00 () life-threatening (X) hospitalization - initial or prolonged () other: | | | | 5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A | |
| 3. Date of event (mo/day/yr) 1/23/00 | | 4. Date of this report (mo/day/yr) 03/23/00 | | 6. Lot # (if known) #1 unknown #2 | |
| 5. Describe event or problem | | | | 7. Exp. date (if known) #1 unknown #2 | |
| Notification received via Company Sales Representative from a physician of DEATH allegedly associated with an Extra Strength TYLENOL [®] acetaminophen product in a patient. According to representative, mother (Mfr. Report #1311827A) ingested 100 Extra Strength TYLENOL [®] Tablets (50 g) over 4 days for a toothache. Mother was reportedly in 29th week of pregnancy and the fetus died (DEATH). | | | | 8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A | |
| Addl info rec'd 3/23/00: Physician's comments on MedWatch Form indicate that event occurred on 1/23/00. The level of acetaminophen in the fetus's liver was 8.5 ug/g and centrilobular necrosis (LIVER NECROSIS) was noted in the liver. Otherwise, no other abnormalities noted. According to physician's comments on MedWatch Form Mfr. Report #1311827A, mother ingested Extra Strength TYLENOL over 5 days, not 4 days as previously reported. | | | | 9. NDC # - for product problems only (if known) | |
| 6. Relevant tests/laboratory data, including dates | | | | 10. Concomitant medical products and therapy dates (exclude treatment of event) unknown | |
| unspecified date: acetaminophen level in liver=8.5 ug/g | | | | G. All manufacturers | |
| DSS APR 04 2000 | | | | 1. Contact office - name/address (& mfrng site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034 | |
| | | | | 2. Phone number 215-273-7303 | |
| 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) mother in 29th week of pregnancy | | | | 3. Report source (check all that apply) () foreign () study () literature () consumer (X) health professional () user facility () conv representative () distributor () other: | |
| 8. Adverse event term(s) DEATH NECROSIS LIVER | | | | 4. Date received by manufacturer (mo/day/yr) 03/23/00 | |
| 9. Mfr. report number 1312040A | | | | 5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes | |
| E. Initial reporter | | | | 6. If IND, protocol # | |
| 1. Name, address & phone # Dr. [REDACTED] [REDACTED] [REDACTED] | | | | 7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic () initial (X) follow-up # 1 | |
| 2. Health professional? (X) Yes () No | | | | 3. Occupation physician | |
| 3. Occupation | | | | 4. Initial reporter also sent report to FDA () Yes () No (X) Unk | |

APR 8 X 2000

