



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

Approved by FDA on 11-15-93

Mfr report #
UF/Dis. report #
FDA use only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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### A. Patient information

1. Patient Identifier [redacted]	2. Age at time of event: 64 yrs or Date of birth:	3. Sex (X) female ( ) male	4. Weight unk lbs or kgs
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### 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)	( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/damage ( ) other:
3. Date of event (mo/day/yr) 4/13/01	4. Date of this report (mo/day/yr) 07/12/01

5. Describe event or problem

Consumer report received via Internet alleges that the use of an Extra Strength TYLENOL® acetaminophen product was associated with DEATH (died from acetaminophen toxicity) in his mother. Addl info rec'd 7/11/01: Phone call to consumer revealed that his mother was 64 years old at time of death. According to consumer, mother had been taking 1000 mg Extra Strength TYLENOL® three to four times a day for an unknown duration of time for general pain and pain from hemorrhoids. On 4/13/01, consumer reports he found his mother passed out on the floor (SYNCOPE) of her home. According to consumer, he rushed her to the local hospital where she was treated with unspecified IV medications. Consumer alleges that mother was transferred to a trauma center that weekend where her liver failed (LIVER FAILURE) and she had brain swelling (BRAIN EDEMA). On 4/15/01, she died at the center. According to consumer, medical examiner attributed his mother's death to acetaminophen toxicity.

6. Relevant tests/laboratory data, including dates

consumer reports "blood toxicology showed 24 mg/L (APAP level) with the sample being taken 36 to 48 hours after she could have taken her last dose"

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

menopause, anxiety; "allergic to alot of medications and antibiotics"

### C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 Extra Strength TYLENOL product #2	3. Therapy dates (if unk, own, give duration) #1 unknown dates and duration #2
2. Dose, frequency & route used #1 1000 mg, tid-qid, po #2	4. Diagnosis for use (indication) #1 general pain and pain from hemorrhoids #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) unspecified hormone replacement therapy, XANAX®

### 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) 07/07/01
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 (X) 15-day ( ) 10-day ( ) periodic (X) Initial ( ) follow-up #	8. Adverse event term(s) DEATH SYNCOPE LIVER FAILURE EDEMA BRAIN
9. Mfr. report number 1591366A	

### E. Initial reporter

1. Name, address & phone # DSS JUL 17 2001	2. Health professional? ( ) Yes ( ) No	3. Occupation	4. Initial reporter also sent report to FDA ( ) Yes ( ) No ( ) Unk
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Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

JUL 16 2001