



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

Approved by FDA on 11/18/93

Mfr report # \_\_\_\_\_

UF/Dist report # \_\_\_\_\_

FDA use only

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|   |  |  |                                   |  |  |  |  |
|---|--|--|-----------------------------------|--|--|--|--|
| <b>A. Patient information</b>   |  |  |                                   | <b>C. Suspect medication(s)</b>  |  |  |  |
| 1. Patient identifier<br>unknown<br>In confidence   | 2. Age at time of event:<br>or 20 yrs<br>Date of birth: 02/18/1979 | 3. Sex<br>(X) female<br>( ) male               | 4. Weight<br>unk lbs<br>or<br>kgs | 1. Name (give labeled strength & mfr/labeler, if known)<br>#1 unspecified TYLENOL product<br>#2  |  | 2. Dose, frequency & route used<br>#1 "overdose", po<br>#2   |  |
| <b>B. Adverse event or product problem</b>  |  |  |                                   | 3. Therapy dates (if unknown, give duration) from/to (or best estimate)<br>#1 unknown dates or duration<br>#2  |  |  |  |
| 1. X Adverse event and/or Product problem (e.g., defects/malfunctions)  |  |  |                                   | 4. Diagnosis for use (indication)<br>#1 unknown<br>#2  |  | 5. Event abated after use stopped or dose reduced<br>#1 ( ) Yes ( ) No (X) N/A<br>#2 ( ) Yes ( ) No ( ) N/A  |  |
| 2. Outcomes attributed to adverse event (check all that apply)<br>(X) death (mo/day/yr) 02/12/00<br>( ) life-threatening<br>( ) hospitalization - initial or prolonged<br>( ) other:  |  |  |                                   | 6. Lot # (if known)<br>#1 unknown<br>#2  |  | 7. Exp. date (if known)<br>#1 unknown<br>#2  |  |
| 3. Date of event<br>(mo/day/yr) 2/11/00   |  | 4. Date of this report<br>(mo/day/yr) 03/06/00 |                                   | 8. Event reappeared after reintroduction<br>#1 ( ) Yes ( ) No (X) N/A<br>#2 ( ) Yes ( ) No ( ) N/A   |  |  |  |
| 5. Describe event or problem<br><br>Consumer report received via Internet of DEATH (she passed away) allegedly associated with the use of an unspecified TYLENOL® acetaminophen product in her 20 year old daughter. According to report, on an unspecified date, her daughter took an OVERDOSE of TYLENOL. On 2/11/00, "her liver died" (LIVER FAILURE) and on 2/12/00, "she was gone." No further information was provided. |  |  |                                   | 9. NDC # - for product problems only (if known)<br>- -   |  |  |  |
| 6. Relevant tests/laboratory data, including dates<br>unknown   |  |  |                                   | 10. Concomitant medical products and therapy dates (exclude treatment of event)<br>unknown   |  |  |  |
| 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)<br>unknown   |  |  |                                   | <b>G. All manufacturers</b>  |  |  |  |
|   |  |  |                                   | 1. Contact office - name/address (& mfring site for devices)<br>McNeil Consumer Healthcare<br>Medical Affairs<br>7050 Camp Hill Road<br>Ft. Washington, PA 19034 |  | 2. Phone number<br>215-273-7303  |  |
|   |  |  |                                   | 4. Date received by manufacturer (mo/day/yr) 03/04/00  |  | 3. Report source (check all that apply)<br>( ) foreign<br>( ) study<br>( ) literature<br>(X) consumer<br><br>( ) health professional<br>( ) user facility<br><br>( ) company representative<br>( ) distributor<br>(X) other:<br>Internet |  |
|   |  |  |                                   | 6. If IND, protocol #  |  | 5. (A) NDA # 19-872<br>IND #<br>PLA #<br>pre-1938 ( ) Yes<br>OTC product (X) Yes   |  |
|   |  |  |                                   | 7. Type of report (check all that apply)<br>( ) 5-day (X) 15-day<br>( ) 10-day ( ) periodic<br>(X) Initial ( ) follow-up #                                       |  | 8. Adverse event term(s)<br>DEATH OVERDOSE<br>LIVER FAILURE  |  |
|   |  |  |                                   | 9. Mfr. report number<br>1325474A  |  |  |  |
|   |  |  |                                   | <b>E. Initial reporter</b>   |  |  |  |
|   |  |  |                                   | 1. Name, address & phone #<br><br>DSS<br>MAR - 9 2000<br>MAR X 8 2000  |  |  |  |
| 2. Health professional?<br>( ) Yes ( ) No   |  | 3. Occupation                                  |                                   | 4. Initial reporter also sent report to FDA<br>( ) 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.