



3460246-6-00-01

**Procter & Gamble
Regulatory Affairs**

Mfr report #	1743742
UF/Dat report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

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A. Patient information			
1. Patient Identifier	2. Age at time of event: 17 Years or Date of birth: 01/12/1977	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
In confidence			
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g. defects/malfunctions)			
2. Outcome attributed to adverse event (check all that apply)			
<input type="checkbox"/> death _____ (mo/day/yr)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input checked="" type="checkbox"/> hospitalization - initial or prolonged		<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage	
		<input checked="" type="checkbox"/> other: Major Clinical Significance	
3. Date of event 03/01/94* (mo/day/yr)		4. Date of this report 02/11/00 (mo/day/yr)	
5. Describe event or problem			
<p>AN ATTORNEY REPRESENTING A CLIENT REPORTED THAT THE 17 YEAR OLD FEMALE TOOK UNSPECIFIED DAILY DOSES OF NYQUIL AND TYLENOL DURING THE MONTHS OF FEBRUARY AND MARCH 1994 AND DEVELOPED ACETAMINOPHEN TOXICITY CAUSING LIVER AND BRAIN DAMAGE BEGINNING APPROXIMATELY 01-MAR-1994. SHE EXPERIENCED FULMINANT HEPATIC FAILURE, ENCEPHALOPATHY, CEREBRAL INFARCT, PNEUMOTHORAX, PNEUMONIA, PERMANENT LUNG DAMAGE, AND SCARRING OF HER SCALP AND TORSO; SHE EXPERIENCED SEVERE PAIN AND NERVOUSNESS AS A RESULT OF THE SYMPTOMS. HIS CLIENT WAS REQUIRED TO UNDERGO MEDICAL, SURGICAL AND NURSING CARE AND UNSPECIFIED TREATMENT TO TREAT THE SYMPTOMS. THE STATUS OF EACH SYMPTOM WAS NOT MENTIONED AT THE TIME OF THE REPORT ON 27-JAN-2000 BUT THE ATTORNEY MENTIONED THAT HIS CLIENT SUSTAINED PERMANENT LIVER, BRAIN AND LUNG DAMAGE WHICH HAD CAUSED HER TO BE AT RISK FOR HEPATIC, RENAL AND RESPIRATORY FAILURE. THE USE AND FUNCTION OF THE INJURED PARTS AND ABILITY TO EARN WAGES HAD BEEN AND WILL BE IN THE FUTURE IMPAIRED. NO FURTHER INFORMATION WAS PROVIDED.</p>			
6. Relevant tests/laboratory data, including dates			
Unknown			
7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
<p>Allergies: UNK Race: Unknown Medical History: Unknown</p>			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 NyQuil, Version/Form/Flavor Unknown			
#2 TYLENOL (PARACETAMOL)			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) <small>from to (or best estimate)</small>	
#1 UNKNOWN: Oral		#1 02/01/94* / 03/31/94*	
#2 UNKNOWN: Oral		#2 02/01/94* / 03/31/94*	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 UNK		#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 UNK		#2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot# (if known)		7. Exp. date (if known)	
#1 UNKNOWN		#1 UNK	
#2 UNKNOWN		#2 UNK	
8. Event reappeared after reintroduction			
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			
9. NDC# - for product problems only (if known)			
N/A			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
Unknown			

G. All manufacturers			
1. Contact office - name/address (& mailing site for devices)		2. Phone number (513) 622-2013	
Procter & Gamble Regulatory Affairs 8700 Mason-Montgomery Road Mason, OH 45040		3. Report source (check all that apply)	
		<input type="checkbox"/> foreign	
		<input type="checkbox"/> study	
		<input type="checkbox"/> literature	
		<input checked="" type="checkbox"/> consumer	
		<input type="checkbox"/> health professional	
		<input type="checkbox"/> user facility	
		<input type="checkbox"/> company representative	
		<input type="checkbox"/> distributor	
		<input type="checkbox"/> other:	
4. Date received by manufacturer (mo/day/yr) 01/27/00		5. (A)NDA# _____	
6. If IND, protocol# N/A		IND# N/A	
7. Type of report (check all that apply)		pre-1938 <input type="checkbox"/> yes	
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day		OTC product <input checked="" type="checkbox"/> yes	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic		8. Adverse event term(s)	
<input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up# _____		BRAIN SYND ACUTE/ ATROPHY SKIN/ ENCEPHALOPATHY/ INFARCT CEREBR/ LIVER DAMAGE/ LIVER FAIL/ LUNG DIS/	
9. Mfr. report number 1743742			

FEB 22 2000

(Cont.)

E. Initial reporter			
1. Name, address & phone#			
[REDACTED]			
DSS			
FEB 22 2000			
2. Health professional?		3. Occupation	
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no		Legal	
4. Initial reporter also sent report to FDA			
<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> 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.

* : if present, indicates approximate date or period

**Medication
Experience Report**
(continued)

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3.8 Adverse event term(s) (Continued)

NERVOUSNESS / OVERDOSE / PAIN / PNEUMONIA / PNEUMOTHORAX



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DSS

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