

er & Gamble  
latory Affairs

Mfr report #	1738458
UF/Dist report #	
FDA Use Only	

3446113-2-00-01\*

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<b>A. Patient information</b>			
1. Patient identifier	2. Age at time of event: 15 Years or Date of birth: [REDACTED]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 108 lbs or kgs
In confidence			
<b>B. Adverse event or product problem</b>			
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 checked="" 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 type="checkbox"/> other: Major Clinical Significance			
3. Date of event 12/15/97* (mo/day/yr)		4. Date of this report 01/06/00 (mo/day/yr)	
5. Describe event or problem			
AN ATTORNEY REPORTED THAT A 15 YEAR OLD FEMALE TOOK NYQUIL IN CONJUNCTION WITH TYLENOL SINUS AND EXTRA STRENGTH TYLENOL FOR THREE AND ONE HALF DAYS BEGINNING APPROXIMATELY 11-DEC-1997 TO TREAT FLU SYMPTOMS. SHE REMEMBERED CONSUMING AT LEAST ONE HALF OF AN UNSPECIFIED SIZE BOTTLE OF NYQUIL AND TWO TO FOUR EXTRA STRENGTH TYLENOL AND TYLENOL SINUS EVERY THREE TO FOUR HOURS BEFORE SHE BECAME EXTREMELY AGITATED AND INCOHERENT AND EXPERIENCED SEVERE ABDOMINAL PAIN, VOMITING, AND DEHYDRATION ON 15-DEC-1997. SHE WAS SEEN BY HER FAMILY PHYSICIAN WHO SENT HER TO THE LOCAL HOSPITAL TO BE EVALUATED. THE PATIENT PRESENTED AT THE EMERGENCY ROOM (19:45) WITH ADDITIONAL SYMPTOMS INCLUDING DISTENSION AND GENERALIZED TENDERNESS IN THE AREA OF HER ABDOMEN, NAUSEA, DISCOMFORT, SORE THROAT, SWOLLEN PHARYNX, INCREASED SLEEPINESS, LETHARGY, AND A HIGH WHITE BLOOD CELL COUNT. THE PATIENT BECAME SLIGHTLY COMBATIVE AND CONFUSED AT 21:50. HER LIVER ENZYMES WERE ELEVATED AT 22:15 AND IT WAS DECIDED THAT SHE NEEDED INTENSIVE CARE MONITORING. THE TRANSPORT TEAM NOTED ADDITIONAL SYMPTOMS OF ANOREXIA, GENERALIZED PAIN ALL OVER HER BODY, THE FEELING OF DIZZINESS, AND VERY DRY ORAL MUCOSA, THROAT, TONGUE AND LIPS. THE DISCHARGE SUMMARY CONCLUDED THAT THE PATIENT APPEARED TO BE VERY ILL AND FELT DIZZY WITH A HEADACHE WHILE AT HER PHYSICIAN'S OFFICE. HER URINALYSIS			
(Cont.)			
6. Relevant tests/laboratory data, including dates			
See Section B.6 on continuation sheet			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
Pregnant: No No known allergies Race: Caucasian Medical History: Date: UNK : FAMILY HX-CONDITION NEC STATUS Pending (In Process) Comment: A BROTHER WITH TOURETTES SYNDROME AND A SISTER WITH DOWNS SYNDROME			

<b>C. Suspect medication(s)</b>			
1. Name (give labeled strength & mfr/labeler, if known) (Cont.)			
#1 NyQuil Adult Liquid, Version/Flavor Unknown			
#2 TYLENOL (PARACETAMOL)			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from to (or best estimate)	
#1 UNKNOWN; Oral		#1 12/11/97* / 12/15/97*	
#2 UNKNOWN; Oral		#2 12/11/97* / 12/15/97*	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 FLU W RESP MANIFEST NEC		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 FLU W RESP MANIFEST NEC		#2 <input checked="" type="checkbox"/> yes <input 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 type="checkbox"/> doesn't apply			
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input 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)			
1. EMETROL; Route: Oral; UNK / UNK			

<b>G. All manufacturers</b>	
1. Contact office - name/address (& mfring site for devices)	2. Phone number
Procter & Gamble Regulatory Affairs 8700 Mason-Montgomery Road Mason, OH 45040	(513) 622-2013
<b>DSS</b>	
JAN 21 2000	
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 FDA (mo/day/yr)	(A) NDA#
12/29/98	
6. If IND, protocol#	IND#
N/A	N/A
7. Type of report (check all that apply)	PLA#
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up#	
9. Mfr. report number	pre-1938 <input type="checkbox"/> yes
1738458	OTC product <input checked="" type="checkbox"/> yes
8. Adverse event term(s)	
LIVER FAIL/ ABDO ENLARGE/ AGITATION/ ANOREXIA/ ATELECTASIS/ CHEILITIS/ COAGUL DIS/	
(Cont.)	

<b>E. Initial reporter</b>			
1. Name, address & phone#			
[REDACTED] COUNSELLORS AT LAW			
[REDACTED] PO BOX [REDACTED]			
United States			
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			

**FDA**  
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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.

\* : if present, indicates approximate date or period