

# MEDWATCH

For VOLUNTARY reporting of  
adverse events, product problems and  
product use errors

## The FDA Safety Information and Adverse Event Reporting Program

Page 1 of \_\_\_\_\_

FDA USE ONLY	
Triage unit sequence #	

A. PATIENT INFORMATION			
1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight _____ lb or _____ kg
In confidence			

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	
Check all that apply: <input type="checkbox"/> Adverse Event <input type="checkbox"/> Product Problem (e.g., defects/malfunctions) <input type="checkbox"/> Product Use Error <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine	
2. Outcomes Attributed to Adverse Event (Check all that apply) <input type="checkbox"/> Death: _____ (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)	
3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)

5. Describe Event, Problem or Product Use Error	
6. Relevant Tests/Laboratory Data, Including Dates	
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)	

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label) #1 Name: _____ Strength: _____ Manufacturer: _____
#2 Name: _____ Strength: _____ Manufacturer: _____

2. Dose or Amount	Frequency	Route
#1		
#2		
3. Dates of Use (If unknown, give duration) from/to (or best estimate) #1 _____ #2 _____		5. Event Abated After Use Stopped or Dose Reduced? #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
4. Diagnosis or Reason for Use (Indication) #1 _____ #2 _____		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
6. Lot # #1 _____ #2 _____	7. Expiration Date #1 _____ #2 _____	
9. NDC # or Unique ID		

E. SUSPECT MEDICAL DEVICE		
1. Brand Name		
2a. Common Device Name		2b. Procode
3. Manufacturer Name, City and State		
4. Model #	Lot #	5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other:
Catalog #	Expiration Date (mm/dd/yyyy)	
Serial #	Unique Identifier (UDI) #	
6. If Implanted, Give Date (mm/dd/yyyy)		7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? <input type="checkbox"/> Yes <input type="checkbox"/> No		
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor		

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)			
1. Name and Address Name: _____ Address: _____  City: _____ State: _____ ZIP: _____			
Phone #		E-mail	
2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation		4. Also Reported to: <input type="checkbox"/> Manufacturer <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input type="checkbox"/>			

PLEASE TYPE OR USE BLACK INK