



**San Francisco Health Plan**

**Phone: 800-626-0072**

**Fax: 866-511-2202**

**Prescriber Information**

Name: \_\_\_\_\_ Specialty: \_\_\_\_\_

DEA/NPI: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

**Pharmacy Information**

Name: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

**Patient Information**

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Member ID: \_\_\_\_\_

**Medication Information:**

Name and Strength of Drug: \_\_\_\_\_ Quantity & Dosing: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ Duration of Therapy: \_\_\_\_\_

Medication Request  New  Renewal ---Renewal Original Rx Date: \_\_\_\_\_

**Prior Authorization Criteria for Brand Medications**

You must answer ALL questions		
1. Has the patient experienced an allergy, adverse event, or therapeutic failure to the generic version? (Document drug, manufacturer, dates of trials, and description of failures below) _____ _____ _____ _____	Y	N
2. Is the patient currently taking the requested medication? (If yes, please describe how the medication was supplied) _____ _____ _____	Y	N

Please submit a completed FDA MedWatch form to the FDA and attach a copy to PA request. Also include any relevant clinical notes documenting the allergy, adverse event, or therapeutic failure to generic medication, including any pertinent lab values.

*Information given on this form is accurate as of this date.*

**Prescriber or Authorized Signature**

\_\_\_\_\_

**Date** \_\_\_\_\_

I understand that Informed Rx's use or disclosure of individually identifiable health information, whether furnished by me or obtained by another source such as medical providers, shall be in accordance with federal privacy regulations under HIPAA (Health Insurance Portability and Accountability Act of 1996).

# MEDWATCH

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

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

FDA USE ONLY

Triage unit  
sequence #

## The FDA Safety Information and Adverse Event Reporting Program

### A. PATIENT INFORMATION

1. Patient Identifier  In confidence	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
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### B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1.  Adverse Event     Product Problem (e.g., defects/malfunctions)  
 Product Use Error     Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event  
(Check all that apply)

Death: \_\_\_\_\_ (mm/dd/yyyy)     Disability or Permanent Damage  
 Life-threatening     Congenital Anomaly/Birth Defect  
 Hospitalization - initial or prolonged     Other Serious (Important Medical Events)  
 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)

Yes     No     Returned to Manufacturer on: \_\_\_\_\_ (mm/dd/yyyy)

### D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 \_\_\_\_\_  
#2 \_\_\_\_\_

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)

#1 \_\_\_\_\_  
#2 \_\_\_\_\_

4. Diagnosis or Reason for Use (Indication)

#1 \_\_\_\_\_  
#2 \_\_\_\_\_

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?

#1  Yes     No     Doesn't Apply  
#2  Yes     No     Doesn't Apply

8. Event Reappeared After Reintroduction?

#1  Yes     No     Doesn't Apply  
#2  Yes     No     Doesn't Apply

9. NDC # or Unique ID

### E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

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 #	Other #	

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?  
 Yes     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

Phone # \_\_\_\_\_    E-mail \_\_\_\_\_

2. Health Professional?    3. Occupation    4. Also Reported to:

Yes     No     Manufacturer  
 User Facility  
 Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

PLEASE TYPE OR USE BLACK INK

# ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: <http://www.fda.gov/medwatch/report/consumer/instruct.htm>

## Report adverse events, product problems or product use errors with:

- Medications (*drugs or biologics*)
- Medical devices (*including in-vitro diagnostics*)
- Combination products (*medication & medical devices*)
- Human cells, tissues, and cellular and tissue-based products
- Special nutritional products (*dietary supplements, medical foods, infant formulas*)
- Cosmetics

## Report product problems - quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

## Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization - initial or prolonged
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

## Report even if:

- You're not certain the product caused the event
- You don't have all the details

## How to report:

- Just fill in the sections that apply to your report
- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (*or both*)

## Other methods of reporting:

- 1-800-FDA-0178 -- To FAX report
- 1-800-FDA-1088 -- To report by phone
- [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) -- To report online

**If your report involves a serious adverse event with a device** and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

**If your report involves a serious adverse event with a vaccine** call 1-800-822-7967 to report.

**Confidentiality:** The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

*The public reporting burden for this collection of information has been estimated to average 36 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:*

Department of Health and Human Services  
Food and Drug Administration - MedWatch  
10903 New Hampshire Avenue  
Building 22, Mail Stop 4447  
Silver Spring, MD 20993-0002

Please **DO NOT**  
**RETURN** this form  
to this address.

**OMB statement:**  
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

FORM FDA 3500 (10/05) (Back)

Please Use Address Provided Below -- Fold in Thirds, Tape and Mail

## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

**Official Business**  
Penalty for Private Use \$300



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IF MAILED  
IN THE  
UNITED STATES  
OR APO/FPO

## BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

### MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20852-9787

