CVS specialty™

CVSProductSafety@CVSCaremark.com

Fax

To:	**CVSProductSafety**	**From:**	
Date:	Mon, Mar 12 2018 07:11:49 PM	Pages:	1 of 2
Subject:	MFG_DRUG_Test Fax with values_Manufacturer_94		

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier / Patient Initials	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
CATS1/sa	03/08/2001	[X] Female [ ] Male	_____ lb or _____ kg
In confidence			

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

2. Outcome Attributed to Adverse Event (Check all the apply)

[ ] Death: XX / XX / XX (mm/dd/yyyy)
[X] Disability or Permanent Damage
[ ] Life-threatening
[ ] Congenital Anomaly/Birth Defect
[ ] Hospitalization – initial or prolonged
[ ] Other Serious (Important Medical Events)
[ ] Required Intervention to Prevent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
XX / XX / XX	03 / 08 / 2018

5. Describe Event, Problem or Product Use Error

Sdfa

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.)

Reported to CVS/Caremark by: [X] Patient/Caregiver [ ] Health Professional

Physician Name: sgdf sag

Address: asdvb asdfvbda AL 12365

Phone: 321-145-8889 Fax:

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

[ ] Yes [X] No [ ] Return to Manufacturer on: XX / XX / XX (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

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

#1 Name: ALDURAZYME
Strength: 2.9 MG/5ML
Manufacturer: GENZYME

#2 Name:
Strength:
Manufacturer:

2.	Dose or Amount	Frequency	Route
#1	asfvbda	1	asvfd
#2			

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

#1 From XX / XX / XX to XX / XX / XX
#2 From / / to / /

4. Diagnosis or Reason for Use (Indication)

#1 asfv
#2

5. Event Abated After Use Stopped or Dose Reduced?

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

6. Lot #

#1 afbdf
#2

7. Expiration Date

#1 XX / XX / XX
#2 / /

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
		[ ] Health Professional [ ] Lay User/Patient [ ] 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

Name:
Address:

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: CVS/Caremark Specialty Pharmacy
Store Number: 48036

Phone #	E-mail
	cvsproductsafety@cvscaremark.co

2. Health Professional?	3. Occupation	4. Also Reported to:
[X] Yes [ ] No	Clinician	[ ] Manufacturer [ ] User Facility [ ] Distribution/Importer

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