U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (2/19)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 11/30/2021
See PRA statement on reverse.

Mfr Report # AGI-30112021-74

UF/Importer Report #

FDA Use Only

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2018.

A. PATIENT INFORMATION

1. Patient Identifier
PATT

In confidence

2. Age
31 ☒ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth:
01-Jan-1990

3.Gender
☐ Female
☒ Male
☐ Intersex
☐ Transgender
☐ Prefer not to disclose

4. Weight
☐ lb
☐ kg

5. Ethnicity
☒ Hispanic/Latino
☐ Not Hispanic/Latino

6. Race
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacifc Islander

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Type of Report
☐ Adverse event ☐ Product problem *(e.g. defects/malfunctions)*

2. Outcome Attributed to Adverse Event (check all that apply)
☐ Death Date of death :
☒ Life-threatening
☐ Hospitalization (initial or prolonged)
☒ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

3. Date of Event *(dd-mmm-yyyy)*
30-Nov-2021

4. Date of this Report *(dd-mmm-yyyy)*
30-Nov-2021

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data **Date** *(dd-mmm-yyyy)*

7. Other Relevant History, Including Preexisting Medical Conditions
(e.g.,allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

C. SUSPECT PRODUCTS

1. Name, Strength, Manufacturer/Compounder

#1 – Name and Strength Crocin	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

2. List Medical Product and Treatment Given at the Same Time Of the Event and Date
No concomitants used/reported

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributer, manufacturer or product caused or contributed to the event.

3. Dose **Frequency** **Route Used**
#1
#2

4. Treatment Dates/Therapy Dates *(give length of treatment (start/stop) or your best estimate.)*
#1 Start
#1 Stop
#2 Start
#2 Stop

5. Diagnosis for Use *(Indication)*
#1
#2

6. Product Type *(Check all that apply)*
#1 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
#2 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar

7. Expiration Date
#1
#2

8. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

D. 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**
☐ Health Professional
☐ Patient/Consumer
☐ Other _____

Catalog # **Expiration Date**

Serial # **Unique Identifier (UDI) #**

6a. If Implanted , Give Date **6b. If Explanted, Give Date**

7a. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

7b. If Yes, Enter Name and Address of Reprocessor

8. Was this device serviced by a third party?
☐ Yes ☐ No ☐ Unknown

9. Device Available for Evaluation ?
☐ Yes ☐ No ☐ Returned to Manufacturer on : _____

10. Concomitant Medical Products and Therapy Dates

E. INITIAL REPORTER

1. Name and Address

Last Name : TEST First Name : TEST

Address :

City : State/Province/Region:

ZIP/Postal Code: Country: UNITED STATES OF AMERICA

Phone #: Email :

2. Health Professional? ☒ Yes ☐ No

3. Occupation
Physician

4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No ☐ Unk

MEDWATCH

FORM FDA 3500A (2/19) *(continued)*

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FDA Use Only

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One
☐ User Facility ☐ Importer

2. User Facility/Importer Reporter Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event

7. Type of Report
☐ Initial
☐ Follow-up #

8. Date of This Report

9. Approximate Age of Device

10. Adverse Event Problem
Health Effect - Clinical Code
Health Effect - Impact Code
Medical Device Problem Code
Component Code

11. Report Sent to FDA?
☐ Yes
☐ No

12. Location Where Event Occurred

13. Report Sent to Manufacturer?
☐ Yes
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility

Name : PTEST1

Email Address : udupi.purohit@arisglobal.com

Address : PTEST1, TEST, MYSORE, MYSORE, AMERICAN SAMOA, 12345

Phone Number : continued

Compounding Outsourcing Facility 503B? ☐ Check box if applicable

Outsourcing Facility : PTEST1

2. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☒ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor/Importer
☐ Other (Please list):

3. Date Received by Manufacturer *(dd-mmm-yyyy)*
30-Nov-2021

4.
NDA #
ANDA #
IND #
BLA #
PMA/ 510(k) #

Check all that apply:
Combination Product ☐
PreANDA ☐
Pre-1938 ☐
OTC ☐
Compounded Product ☐

5. If IND/PreANDA, Give Protocol #

6. Type of Report (Check all that apply)
☐ 5-Day ☐ Periodic
☐ 7-Day ☒ Initial
☐ 15-Day ☐ Follow-Up :
☐ 30-Day

7. Adverse Event Term(s)
fever (Fever(10016558) , Pyrexia(10037660))

8. Manufacturer Report Number
AGI-30112021-74

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Summary Report
No. of events summarized

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evalution

3. Device Evaluated by Manufacturer?
☐ Yes ☐ No
(Attach page to explain why not) or provide code:

☐ Not Returned to Manufacturer
☐ Evaluation Summary Attached

4. Device Manufacture Date

5. Labeled for Single Use?
☐ Yes ☐ No

6. Adverse Event Problem (Refer to coding manual)
Health Effect - Clinical Code
Health Effect - Impact Code
Medical Device Problem Code
Component Code
Type of Investigation
Investigation Findings
Investigation Conclusions

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Others :
☐ Notification
☐ Inspection
☐ Patient Montitoring
☐ Modification/ Adjustment

8. Usage of Device
☐ Initial Use of Device
☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction / removal reporting number :

10.Additional Manufacturer Narrative

11. Correction Data

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 contact number."

C. SUSPECT AND OTHER PRODUCT(S) (Cont..)

Seq No. : 1
C.1. Name, Strength, Manufacturer/Compounder (from product label)
C.1.1. Name and Strength : Crocin (CROCIN , test) (Suspect)

EVENT INFORMATION

Seq No. : 1
Reported Term : fever
Onset Date : 30-Nov-2021
Event Type : Adverse Event/Reaction
OutCome : Recovering/Resolving
Country Of Detection : UNITED STATES OF AMERICA
Severity : Severe

Event Seriousness

Seriousness : Yes
Death? : No
Required Intervenation : No Information
Life Threatening? : Yes
Congenital Anomaly/Birth Defect? : No Information
Caused/Prolonged Hospitalization : No Information
Disability/Permanent Damage? : No Information
Other Medically Important Condition : Yes

Other Medically Important Condition Info

Test

G. ALL MANUFACTURERS

G.2. Phone Number

1111-11111-123456