



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

MEDWATCH
FORM 3500A

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

Form Approved: OMB No. 0910-0291

Expires: 09-30-2027

See PRA statement on page 9.

Mfr report # 2000

UF/Importer Report #

Exemption/Variance/
Alternative #

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jan-1900.

A. PATIENT INFORMATION

1. Patient Identifier (In confidence)

123456

2. Age 80

☒ Year(s) ☐ Month(s)☐ Week(s) ☐ Day(s)

or Date of Birth (e.g., 01-Jan-1900)

3. Sex

☒ Male☐ Female

4. Weight 160

☐ lb☐ kg

5. Race and/or Ethnicity (Select all that apply)

☒ American Indian or Alaska Native☐ Asian☐ Black or African American☐ Hispanic or Latino☐ Middle Eastern or North African☐ Native Hawaiian or Pacific Islander☐ White

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Type of Report (Check all that apply)

☒ Adverse Event☐ Product Problem
(e.g., defects/malfunctions)

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

☐ Death - Date of death (e.g., 01-Jan-1900):☒ Life-threatening☐ Hospitalization (Initial or prolonged)☐ Required Intervention to Prevent Permanent Impairment/Damage☐ Disability or Permanent Damage☐ Congenital Anomaly/Birth Defects☐ Other Serious or Important Medical Events

3. Date of Event (e.g., 01-Jan-1900)

01-Jan-2026

4. Date of this Report (e.g., 01-Jan-1900)

02-Jan-2026

5. Describe Event or Problem

Characters Remaining (max. 10,000):

Describing Event or Problem. This is a test run.

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

* Please see instructions

6. Relevant Test/Laboratory Data**Low Test Range****High Test Range****Date (e.g., 01-Jan-1900)**

Serum test	10	100	02-Jan-2026

Additional Comments

Characters Remaining (max. 2,000):

Additional comments not available.

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

Characters Remaining (max. 2,000):

Patient's relevant history: allergies

C. SUSPECT PRODUCTS

SUSPECT PRODUCT #1

1. Name, Strength, Manufacturer/Compounder

Product Name	Strength	Unit
<input type="text" value="Baboon"/>	<input type="text" value="200"/>	<input type="text" value="MILLIGRAM(S) - MG"/>
NDC # or Unique ID	Manufacturer/Compounder Name	
<input type="text" value="6000700"/>	<input type="text" value="Tesla"/>	
Lot #	FEI # for cosmetics	
<input type="text" value="764998"/>	<input type="text"/>	

2. Dose or Amount

Frequency

Route

<input type="text" value="1000"/>	<input type="text" value="BID"/>	<input type="text" value="Oral"/>
Unit	Other Frequency	Other Route
<input type="text" value="MILLIGRAM(S) - MG"/>	<input type="text"/>	<input type="text"/>

3. Treatment/Therapy/Usage Dates *(Give best estimate of length of treatment/usage (start/stop) or date of dose reduction.)*

Therapy/Usage started on (e.g., 01-Jan-1900)	<input type="text" value="12-12-2025"/>	OR	Duration	<input type="text"/>
Therapy/Usage stopped on (e.g., 01-Jan-1900)	<input type="text" value="12-25-2025"/>		Unit	<input type="text" value="--"/>
Dose Reduced on (e.g., 01-Jan-1900)	<input type="text" value="500"/>			

4. Diagnosis for use *(Indication)*

Treatment of ATTR-CM

5. Product Type *(Check all that apply)*

Drug or Biologic

- ☒ Brand
- ☐ Generic or Biosimilar
- ☐ Over-the-Counter (OTC)
- ☐ Compounded product
(By a Pharmacy or an Outsourcing Facility)

Cosmetics *(Select one)*

- ☐ Cosmetics for professional use only
- ☐ Cosmetics sold on a retail basis

Other Product Types

- ☐ Cannabinoid hemp products
(Such as products containing CBD)
- ☐ Other

6. Expiration Date *(e.g., 01-Jan-1900)*

7. Event Abated after use Stopped or Dose Reduced?

☐ Yes
 ☐ No
 ☒ Doesn't Apply

8. Event Reappeared after Reintroduction?

☐ Yes
 ☐ No
 ☐ Doesn't Apply

SUSPECT PRODUCT #2**1. Name, Strength, Manufacturer/Compounder**

Product Name	Strength	Unit
<input type="text"/>	<input type="text"/>	<input type="text"/>
NDC # or Unique ID	Manufacturer/Compounder Name	
<input type="text"/>	<input type="text"/>	
Lot #	FEI # for cosmetics	
<input type="text"/>	<input type="text"/>	

2. Dose or Amount**Frequency****Route**

<input type="text"/>	<input type="text"/>	<input type="text"/>
Unit	Other Frequency	Other Route
<input type="text"/>	<input type="text"/>	<input type="text"/>

3. Treatment/Therapy/Usage Dates (Give best estimate of length of treatment/usage (start/stop) or date of dose reduction.)

Therapy/Usage started on (e.g., 01-Jan-1900)	<input type="text"/>	OR	Duration	<input type="text"/>
Therapy/Usage stopped on (e.g., 01-Jan-1900)	<input type="text"/>		Unit	<input type="text"/>
Dose Reduced on (e.g., 01-Jan-1900)	<input type="text"/>		<input type="text"/>	

4. Diagnosis for use (Indication)**5. Product Type** (Check all that apply)**Drug or Biologic**

- ☐ Brand
☐ Generic or Biosimilar
☐ Over-the-Counter (OTC)
☐ Compounded product
(By a Pharmacy or an Outsourcing Facility)

Cosmetics (Select one)

- ☐ Cosmetics for professional use only
☐ Cosmetics sold on a retail basis

Other Product Types

- ☐ Cannabinoid hemp products
(Such as products containing CBD)
☐ Other

6. Expiration Date
(e.g., 01-Jan-1900)**7. Event Abated after use Stopped or Dose Reduced?**

☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared after Reintroduction?

☐ Yes ☐ No ☐ Doesn't Apply

9. List Medical Product and Treatment Given at the Same Time of the Event and Date *(Do not include treatment for initial event)*

	Product Name	Therapy/Usage Start Date <i>(e.g., 01-Jan-1900)</i>	Therapy/Usage Stop Date <i>(e.g., 01-Jan-1900)</i>
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

D. SUSPECT MEDICAL DEVICE

1. Brand Name	2a. Procode	2b. Common Device Name

3. Manufacturer Name, City, State, and Country

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4. Model #	Lot #	Catalog #

Expiration Date <i>(e.g., 01-Jan-1900)</i>	Serial #

Unique Device Identifier (UDI) #

Characters Remaining (max. 1,000):

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5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Patient/Consumer <input type="checkbox"/> Other <input style="width: 150px;" type="text"/>	6a. If Implanted, Give Date <i>(e.g., 01-Jan-1900)</i> <input style="width: 100%;" type="text"/>	6b. If Explanted, Give Date <i>(e.g., 01-Jan-1900)</i> <input style="width: 100%;" type="text"/>
7a. Is this a single-use device that was reprocessed and reused on a patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	7b. If yes, enter the name and address of the reprocessor <input style="width: 100%; height: 40px;" type="text"/>	
8. Was this device ever serviced by a third-party servicer? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	9. Is this Device Available for Evaluation? <i>(Do not send to FDA)</i> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to manufacturer <i>(01-Jan-1900)</i> <input style="width: 80px;" type="text"/>	

10. Concomitant Medical Products and Therapy/usage Dates <i>(Exclude treatment of event)</i>			
	Product Name	Therapy/Usage Start Date <i>(e.g., 01-Jan-1900)</i>	Therapy/Usage End Date <i>(e.g., 01-Jan-1900)</i>
1.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
2.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
3.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
4.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
5.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
6.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
7.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
8.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
9.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>
10.	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>

E. INITIAL REPORTER

1. Name and Address			
Last Name		First Name	
<input style="width: 95%;" type="text" value="Chan"/>		<input style="width: 95%;" type="text" value="Jackie"/>	
Address			
<input style="width: 95%;" type="text" value="Headen Way"/>			
City		State/Province/Region	ZIP/Postal Code
<input style="width: 95%;" type="text" value="San Francisco"/>		<input style="width: 95%;" type="text" value="CA"/>	<input style="width: 95%;" type="text" value="95054"/>
Country			
<input style="width: 95%;" type="text" value="UNITED STATES"/>			
Phone #		Email	
<input style="width: 95%;" type="text"/>		<input style="width: 95%;" type="text" value="jackiechan@gmail.com"/>	
2. Health Professional? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		3. Occupation <i>(Select list)</i> <input style="width: 150px;" type="text" value="Physician"/>	
4. Initial reporter also sent report to FDA? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown			

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

1. Check One <input type="checkbox"/> User Facility <input type="checkbox"/> Importer		2. User Facility/Importer Report Number <input style="width:150px" type="text"/>	
3. User Facility or Importer Name/Address/Email <div style="border:1px solid black; height:80px; width:100%;"></div>		4. Contact Person <div style="border:1px solid black; height:20px; width:100%;"></div>	
		5. Phone Number <div style="border:1px solid black; height:20px; width:100%;"></div>	
		6. Date User Facility or Importer Became Aware of Event (e.g., 01-Jan-1900) <div style="border:1px solid black; height:20px; width:100%;"></div>	
		7. Type of Report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up # <div style="border:1px solid black; width:50px; height:20px; display:inline-block;"></div>	
8. Approximate Age of Device <input type="checkbox"/> Year(s) <div style="border:1px solid black; width:40px; height:20px; display:inline-block;"></div> <input type="checkbox"/> Month(s) <div style="border:1px solid black; width:40px; height:20px; display:inline-block;"></div>			
9. Adverse Event Problem (Refer to coding manual) Health Effect – Clinical Code Health Effect – Impact Code Medical Device Problem Code Component Code <div style="border:1px solid black; height:20px; width:100%;"></div>			
10. Report Sent to FDA? (If Yes, enter date (e.g., 01-Jan-1900)) <input type="checkbox"/> Yes <input type="checkbox"/> No <div style="border:1px solid black; width:50px; height:20px; display:inline-block;"></div>		11. Location Where Event Occurred <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Other (Specify) <input type="checkbox"/> Home <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Hospital <input type="checkbox"/> Nursing Home <div style="border:1px solid black; width:100px; height:30px; display:inline-block;"></div>	
12. Report Sent to Manufacturer? (If Yes, enter date (e.g., 01-Jan-1900)) <input type="checkbox"/> Yes <div style="border:1px solid black; width:50px; height:20px; display:inline-block;"></div> <input type="checkbox"/> No		13. Manufacturer Name/Address <div style="border:1px solid black; height:40px; width:100%;"></div>	

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility or Responsible Person Name Email Address Phone Number <div style="border:1px solid black; height:20px; width:100%;"></div> <div style="border:1px solid black; height:20px; width:100%;"></div> <div style="border:1px solid black; height:20px; width:100%;"></div> Address <div style="border:1px solid black; height:20px; width:100%;"></div> Compounding Outsourcing Facility 503B? Outsourcing Facility <input type="checkbox"/> Check box if applicable <div style="border:1px solid black; width:150px; height:20px; display:inline-block;"></div>				
2. Report Source (Check all that apply) <input checked="" type="checkbox"/> Foreign <input type="checkbox"/> Literature <input type="checkbox"/> Health Professional <input type="checkbox"/> Company Representative <input type="checkbox"/> Study <input type="checkbox"/> Consumer <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer <input type="checkbox"/> Other (Please list) <div style="border:1px solid black; height:20px; width:100%;"></div>				3. Date Received by Manufacturer or Responsible Person (e.g., 01-Jan-1900) <div style="border:1px solid black; height:20px; width:100%;"></div>
4. NDA # ANDA/Pre-ANDA # IND # BLA # PMA/510(k) # <div style="border:1px solid black; height:20px; width:100%;"></div>				
Check all that apply: <input type="checkbox"/> Combination product <input type="checkbox"/> Pre-ANDA <input type="checkbox"/> Pre-1938 <input type="checkbox"/> OTC <input type="checkbox"/> Compounded Product				
5. If IND/Pre-ANDA, Give Protocol # <div style="border:1px solid black; height:20px; width:100%;"></div>		6. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> Non-expedited (periodic) <input type="checkbox"/> Follow-up # <div style="border:1px solid black; width:50px; height:20px; display:inline-block;"></div> <input type="checkbox"/> 7-day <input type="checkbox"/> 30-day <input type="checkbox"/> Initial		
7. Adverse Event Term(s) <div style="border:1px solid black; height:20px; width:100%;"></div>			8. Manufacturer Report Number <div style="border:1px solid black; height:20px; width:100%;"></div>	

H. DEVICE MANUFACTURERS ONLY**1. Type of Reportable Event** (Check all that apply)

- ☐ Death ☐ Summary Report
☐ Serious Injury No. of events summarized
☐ Malfunction

2. If Follow-up, What Type?

- ☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?

- ☐ Yes ☐ No

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 Code

Investigation Findings Code

Investigation Conclusions Code

7. If Remedial Action Initiated, Check Type

- ☐ Recall ☐ Relabeling ☐ Patient Monitoring
☐ Repair ☐ Notification ☐ Modification/Adjustment
☐ Replace ☐ Inspection ☐ Other:

8. Usage of Device

- ☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(g), list FDA-assigned recall number or include a statement:**10. Related Report Number****11. Additional Manufacturer Narrative**

Characters Remaining (max. 450):

PRIVACY ACT STATEMENT

Authority: The information collected in this form is provided to comply with the Privacy Act of 1974 (P.L. 93-579) for individuals seeking non-employee student, post-graduate or senior scientist training opportunities from the Food and Drug Administration. Purpose and Uses: All information collected in this form is required to begin the Traineeship. Completed forms are used by the Staff to meet program selection and on-boarding requirements. Information is also shared with the FDA personnel authorized to administer the program. Effects of nondisclosure: Disclosure of the information is voluntary; however, collection of this information is necessary to continue with the FDA.

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Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."