

[Reset Form](#)**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)

3. Sex

- Male
 Female

or Date of Birth (e.g., 01-Jan-1900)**4. Weight**

160

- lb
 kg

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

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

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): Disability or Permanent Damage
 Life-threatening Congenital Anomaly/Birth Defects
 Hospitalization (Initial or prolonged) Other Serious or Important Medical Events
 Required Intervention to Prevent Permanent Impairment/Damage

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

5. Describe Event or Problem (Cont.)

Characters Remaining (max. 10,000):

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
Baboon	200	MILLIGRAM(S) - MG
NDC # or Unique ID	Manufacturer/Compounder Name	
6000700	Tesla	
Lot #	FEI # for cosmetics	
764998		

2. Dose or Amount

Frequency

Route

1000	BID	Oral
Unit	Other Frequency	
MILLIGRAM(S) - MG		

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)

12-12-2025

Therapy/Usage stopped on (e.g., 01-Jan-1900)

12-25-2025

OR

Duration

Dose Reduced on (e.g., 01-Jan-1900)

500

Unit

-

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
--------------	----------	------

NDC # or Unique ID	Manufacturer/Compounder Name
--------------------	------------------------------

Lot #	FEI # for cosmetics
-------	---------------------

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

	--	
--	----	--

Unit	Other Frequency	Other Route
------	-----------------	-------------

--		
----	--	--

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)

Therapy/Usage stopped on (e.g., 01-Jan-1900)

Duration

Dose Reduced on (e.g., 01-Jan-1900)

Unit

--

OR**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 (e.g., 01-Jan-1900)	Therapy/Usage Stop Date (e.g., 01-Jan-1900)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

D. SUSPECT MEDICAL DEVICE

1. Brand Name	2a. Procode	2b. Common Device Name
<input type="text"/>	<input type="text"/>	<input type="text"/>
3. Manufacturer Name, City, State, and Country <input type="text"/>		
4. Model # <input type="text"/>	Lot # <input type="text"/>	Catalog # <input type="text"/>
Expiration Date (e.g., 01-Jan-1900) <input type="text"/>		Serial # <input type="text"/>
Unique Device Identifier (UDI) # <input type="text"/>		Characters Remaining (max. 1,000): <input type="text"/>

5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Patient/Consumer <input type="checkbox"/> Other _____	6a. If Implanted, Give Date (e.g., 01-Jan-1900) _____	6b. If Explanted, Give Date (e.g., 01-Jan-1900) _____
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 _____	
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? (Do not send to FDA) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to manufacturer (01-Jan-1900) _____	

10. Concomitant Medical Products and Therapy/usage Dates (Exclude treatment of event)

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

E. INITIAL REPORTER

1. Name and Address

Last Name	First Name	
Chan	Jackie	
Address		
Headen Way		
City	State/Province/Region	ZIP/Postal Code
San Francisco	CA	95054
Country		
UNITED STATES		
Phone #	Email	
	jackiechan@gmail.com	

2. Health Professional?
 Yes No

3. Occupation (Select list)

Physician

4. Initial reporter also sent report to FDA?
 Yes No 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				
3. User Facility or Importer Name/Address/Email	4. Contact Person				
	5. Phone Number				
6. Date User Facility or Importer Became Aware of Event (e.g., 01-Jan-1900)	7. Type of Report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up #				
8. Approximate Age of Device <input type="checkbox"/> Year(s) <input type="checkbox"/>	<input type="checkbox"/> Month(s) <input type="checkbox"/>				
9. Adverse Event Problem (Refer to coding manual)					
Health Effect – Clinical Code	Health Effect – Impact Code	Medical Device Problem Code	Component Code		
10. Report Sent to FDA? (If Yes, enter date (e.g., 01-Jan-1900))		11. Location Where Event Occurred			
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Ambulatory Surgical Facility	<input type="checkbox"/> Outpatient Treatment Facility		
		<input type="checkbox"/> Home	<input type="checkbox"/> Outpatient Diagnostic Facility		
		<input type="checkbox"/> Hospital	<input type="checkbox"/> Nursing Home		
12. Report Sent to Manufacturer? (If Yes, enter date (e.g., 01-Jan-1900))		13. Manufacturer Name/Address			
<input type="checkbox"/> Yes					
<input type="checkbox"/> No					
G. ALL MANUFACTURERS					
1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility or Responsible Person					
Name	Email Address	Phone Number			
ThermoFisher	thermo@gmail.com				
Address					
Zanker road, San Jose CA					
Compounding Outsourcing Facility 503B?	Outsourcing Facility				
<input type="checkbox"/> Check box if applicable					
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)					
3. Date Received by Manufacturer or Responsible Person (e.g., 01-Jan-1900)					
4. NDA #	ANDA/Pre-ANDA #	IND #	BLA #	PMA/510(k) #	
4855859					
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 #		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 #
		<input type="checkbox"/> 7-day	<input type="checkbox"/> 30-day	<input type="checkbox"/> Initial	
7. Adverse Event Term(s)			8. Manufacturer Report Number		
rash			43643274		

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event (Check all that apply) <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="flex: 1;"> <input type="checkbox"/> Death <input type="checkbox"/> Serious Injury <input type="checkbox"/> Malfunction </div> <div style="flex: 1;"> <input type="checkbox"/> Summary Report No. of events summarized <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-top: 0.5em;"></div> </div> </div>	2. If Follow-up, What Type? <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="flex: 1;"> <input type="checkbox"/> Correction <input type="checkbox"/> Additional Information <input type="checkbox"/> Response to FDA Request <input type="checkbox"/> Device Evaluation </div> </div>	3. Device Evaluated by Manufacturer? <div style="display: flex; justify-content: space-around; align-items: center;"> <input type="checkbox"/> Yes <input type="checkbox"/> No </div>
4. Device Manufacture Date <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div>	5. Labeled for Single Use? <div style="display: flex; justify-content: space-around; align-items: center;"> <input type="checkbox"/> Yes <input type="checkbox"/> No </div>	
6. Adverse Event Problem (Refer to coding manual) <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="flex: 1;"> Health Effect – Clinical Code <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div> </div> <div style="flex: 1;"> Health Effect – Impact Code <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div> </div> <div style="flex: 1;"> Medical Device Problem Code <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div> </div> <div style="flex: 1;"> Component Code <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div> </div> </div> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="flex: 1;"> Type of Investigation Code <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div> </div> <div style="flex: 1;"> Investigation Findings Code <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div> </div> <div style="flex: 1;"> Investigation Conclusions Code <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div> </div> </div>		
7. If Remedial Action Initiated, Check Type <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="flex: 1;"> <input type="checkbox"/> Recall <input type="checkbox"/> Repair <input type="checkbox"/> Replace </div> <div style="flex: 1;"> <input type="checkbox"/> Relabeling <input type="checkbox"/> Notification <input type="checkbox"/> Inspection </div> <div style="flex: 1;"> <input type="checkbox"/> Patient Monitoring <input type="checkbox"/> Modification/Adjustment <input type="checkbox"/> Other: <input style="width: 100px;" type="text"/> </div> </div>		8. Usage of Device <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="flex: 1;"> <input type="checkbox"/> Initial Use of Device <input type="checkbox"/> Reuse <input type="checkbox"/> Unknown </div> </div>
9. If action reported to FDA under 21 USC 360i(g), list FDA-assigned recall number or include a statement: <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div>		10. Related Report Number <div style="border: 1px solid black; width: 100%; height: 1.2em; margin-bottom: 0.5em;"></div>
11. Additional Manufacturer Narrative Characters Remaining (max. 450): <div style="border: 1px solid black; width: 100%; height: 4em; margin-top: 0.5em;"></div>		

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.

PRA Info

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 15 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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."