VENTURA COUNTY
HEALTH CARE PLAN

Dispense as Written (DAW) Drug Policy

Effective Date: 01/28/2020
Date Developed: 12/18/2019 by Howard Taekman, MD
Date Approved by P&T Committee: 2/2/21, 2/1/22, 1/31/23

Ventura County Health Care Plan will review and approve requests for brand name medication where the prescribing physician has requested "Dispense as Written" or "DAW" and consider its use as medically necessary when the following criteria have been met.

Pre-Authorization Criteria:

Approve if the Brand product being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction **AND** has a completed FDA MedWatch form and submitted to FDA.

The completed FDA MedWatch form must be included with this request (see attachment 1). A copy of the FDA MedWatch form may be obtained online at:
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

Attachment: Med Watch Consumer Voluntary Reporting (Form FDA 3500B)
Revision History:

Date Developed: 12/18/19 by H. Taekman, MD and R. Sterling, MD
Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/18/20
Date Reviewed/No Updates: 2/2/21 by H. Howard, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/2/21
Date Reviewed/No Updates: 2/1/22 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/1/22
Date Reviewed/No Updates: 1/31/23 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/31/23

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	New
2/2/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review

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Attachment 1: Med Watch Consumer Voluntary Reporting (Form FDA 3500B)

FDA

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
Consumer Voluntary Reporting
(FORM FDA 3500B)

Form Approved: OMB No. 0910-0291
Expiration Date: 11/30/2021
(See PRA Statement below)

When do I use this form?

- You were hurt or had a bad side effect (including new or worsening symptoms) after taking a drug or using a medical device or product.
- You used a drug, product, or medical device incorrectly which could have or led to unsafe use.
- You noticed a problem with the quality of the drug, product or medical device.
- You had problems with how a drug worked after switching from one maker to another maker.

Don't use this form to report:

- Vaccines – report problems to the Vaccine Adverse Event Reporting System (VAERS).
- Investigational drugs or medical devices (those being studied) – report problems to your doctor or to the contact person listed in the clinical trial.

Will the information I report be kept private?

The FDA recognizes that privacy is an important concern, so you should know:

- We ask only for the name and contact information of the person filling out the form in case we need more information.
- Your name and contact information may be shared with the company that makes the product to help them better understand the problem you are reporting, unless you request otherwise (see Section F).

What types of products should I use this form for?

- Drugs, including prescription or over-the-counter medicines, and biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- Medical devices, including any health-related kit, test, tool, or piece of equipment (such as breast implants, pacemakers, diabetes glucose-test kits, hearing aids, breast pumps, and many others)
- Cosmetics such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos
- Foods (including beverages and ingredients added to foods)

Are there specific instructions for filling out the form?

- Fill in as much information as possible and send in the report even if you do not have all the information.
- You can fill out this form yourself or have someone fill it out for you. If you need help, you may want to talk with your health professional.
- Feel free to include or attach an image of the product. Please do not send the products to the FDA.

How will I know the FDA has received my form?

- You will receive a reply from the FDA after we receive your report. We will personally contact you only if we need additional information.
- Your report will become part of a database so that it can be reviewed and compared to other reports by an FDA safety evaluator who will determine what steps to take.

How can I contact the FDA if I have questions?

Toll-free line: 1-800-332-1088
To report online: www.fda.gov/medwatch/report.htm

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 30 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 the address to the right:

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 number."

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

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF ADDRESS.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
Consumer Voluntary Reporting
(FORM FDA 3500B)

Form Approved: OMB No. 0910-0291
Expiration Date: 9/30/2018
(See PRA Statement on preceding general information page)

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.*

Section A – About the Problem

1. What kind of problem was it? *(Check all that apply)*

- ☐ Were hurt or had a bad side effect *(including new or worsening symptoms)*
- ☐ Used a product incorrectly which could have or led to a problem
- ☐ Noticed a problem with the quality of the product
- ☐ Had problems after switching from one product maker to another maker

2. Did any of the following happen? *(Check all that apply)*

- ☐ Hospitalization – admitted or stayed longer
- ☐ Required help to prevent permanent harm
- ☐ Disability or health problem
- ☐ Birth defect
- ☐ Life-threatening
- ☐ Death *(include date)(dd-mmm-yyyy)*: - -
- ☐ Other serious/important medical incident *(Please describe below)*

3. Date the problem occurred *(dd-mmm-yyyy)*
- -

4. Tell us what happened and how it happened. *(Include as many details as possible FDA may reach out to you for any additional documents if necessary)*

Continuation Page

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

Additional Comments

For a problem with a product, including

- prescription or over-the-counter medicine
- biologics, such as blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

Go to Section C

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Section A – About the Problem *(continued)*

For a problem with a medical device, including

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

Go to Section D (Skip Section C)

For more information, visit http://www.fda.gov/MedWatch	**Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

Section B – Product Availability

1. Do you still have the product in case we need to evaluate it? *(Do not send the product to FDA. We will contact you directly if we need it.)* ☐ Yes ☐ No	2. Do you have a picture of the product? *(check yes if you are including a picture)* ☐ Yes

Section C – About the Products

1. This report is about ☐ Drug ☐ Cosmetic, Dietary Supplement or Food/Medical Food

2. Name(s) of the product as it appears on the box, bottle, or package *(Include as many names as you see)*

3. Check if therapy is on-going ☐

4. Name(s) of the company that makes (or compounds) the product

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

☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar

6. Expiration date *(dd-mmm-yyyy)* - -	7. Lot number	8. NDC number

9. Strength *(for example, 250 mg per 500 mL or 1 g)*	10. Quantity *(for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)*	11. Frequency *(for example, twice daily or at bedtime)*	12. How was it taken or used *(for example, by mouth, injection, or on the skin)*?

13a. Date the person first started taking or using the product *(dd-mmm-yyyy)*: - -

13b. Date the person stopped taking or using the product *(dd-mmm-yyyy)*: - -

14. Give best estimate of duration

15. Why was the person using the product? *(such as, what condition was it supposed to treat)*

16. Did the problem stop after the person reduced the dose or stopped taking or using the product? ☐ Yes ☐ No

17. Did the problem return if the person started taking or using the product again? ☐ Yes ☐ No ☐ Didn't restart

Go to Section E (Skip Section D)

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Section D – About the Medical Device

1. Name of medical device

2. Name of the company that makes the medical device

3. Model number	4. Catalog number	5. Lot number	6. Serial number	7. UDI number	8. Expiration date *(dd-mmm-yyyy)*
					- -

9. Was someone operating the medical device when the problem occurred?
☐ Yes ☐ No

If yes, who was operating it?
☐ The person who had the problem ☐ A health professional *(such as a doctor, nurse, or aide)*
☐ Someone else *(Please explain who)*

10. For implanted medical devices ONLY *(such as pacemakers, breast implants, etc.)*
Date the implant was put in *(dd-mmm-yyyy)* - -
Date the implant was taken out *(If relevant) (dd-mmm-yyyy)* - -

Go to Section E

Section E – About the Person Who Had the Problem

1. Person's Initials

2. Gender
☐ Female ☐ Male
☐ Intersex ☐ Transgender
☐ Prefer not to disclose

3. Age *(specify unit of time for age)*
☐ Year(s) ☐ Month(s)
☐ Week(s) ☐ Day(s)

4. Date of Birth *(dd-mmm-yyyy)* - -

5. Weight *(Specify lbs or kg)*
☐ lb ☐ kg

6. Ethnicity *(Choose only one)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

7. Race *(Choose all that apply)*
☐ American Indian or Alaskan Native
☐ Native Hawaiian or Other Pacific Islander
☐ Asian
☐ White
☐ Black or African American

8. List known medical conditions. *(Such as diabetes, high blood pressure, cancer, heart disease, or others)*

9. Please list all allergies *(such as to drugs, foods, pollen or others)*

10. List any other important information about the person *(such as smoking, pregnancy, alcohol use, etc.)*

11. List all current prescription medications and medical devices being used.
Continuation Page

12. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
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Go to Section F

For more information, visit *http://www.fda.gov/MedWatch*

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Section F – About the Person Filling Out This Form		
We will contact you only if we need additional information.		
1. Last name	2. First name	
3. Number/Street	4. City and State/Province	
5. ZIP or Postal code	6. Country	
7. Telephone number	8. Email address	9. Today's date *(dd-mmm-yyyy)*
10. Did you report this problem to the company that makes the product (the manufacturer/compounder)? ☐ Yes ☐ No		
11. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐		

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA. Mail or fax the form to: MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852; FAX: 800-332-0178 (toll-free).

Thank you for helping us protect the public health.

For more information, visit *http://www.fda.gov/MedWatch*	**Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

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Continued Entries
CONTINUED ENTRY FOR: Tell us what happened and how it happened. *(Include as many details as possible)*
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CONTINUED ENTRY FOR: List all current prescription medications and medical devices being used.
Back to Form
CONTINUED ENTRY FOR: List all over-the-counter medications and any vitamins, minerals, and herbal remedies being used.
Back to Form