Introduction to FDA's MedWatch Adverse Event Reporting Program

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FDA Office of Health and Constituent Affairs

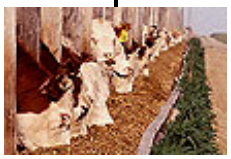
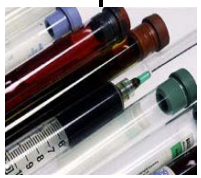
February 9, 2016

Webinar Hosted by CDER's Office of Communication, Division of Drug Information (DDI)

Learning Objectives

- Describe the FDA MedWatch Program.
- Identify the types of adverse events and product problems that should be reported to FDA.
- Explain how to submit a report to the FDA MedWatch Program.
- Summarize how to obtain safety information from FDA MedWatch.

Office of the Commissioner

- Office of Foods
  - 
    Center for **F**ood **S**afety & **A**pplied **N**utrition
  - 
    Center for **V**eterinary **M**edicine
- Office of Medical Products & Tobacco
  - 
    Center for **D**evices & **R**adiological **H**ealth
  - 
    Center for **B**iologics **E**valuation & **R**esearch
  - 
    Center for **D**rug **E**valuation & **R**esearch
  - 
    Center for **T**obacco **P**roducts
- Office of Global Reg. Ops & Policy
  - 
    Office of **R**egulatory **A**ffairs

FDA Regulates $1 Trillion Worth of Products a Year

Every morning when you wake up and

brush your teeth
put in your contact lenses
microwave your breakfast
take your medicine
feed your pet
select a lipstick
go grocery shopping
get a flu shot or a mammogram….

You have been touched by the
U. S. Food and Drug Administration.

Assessment Question 1

Which is *Not* Regulated by the FDA?

A) Aspirin

B) Anti-lice shampoo

C) Insect repellent

D) Lipstick

FDA MedWatch and Patient Safety

- Reports **IN**
  - Reports about problems with medical products come **IN** to MedWatch.
- Safety **OUT**
  - Safety information about medical products goes **OUT** to health professionals, patients, and consumers.

Your gateway for learning about important safety information and reporting serious problems with medical products.

MedWatch Milestones

2013

Mobile Technology

2010

Consumer Form 3500B available

Social Media

2000

E-List Subscribers

1996

MedWatch on the World Wide Web

1993

MedWatch Voluntary Reporting Form Launched

Why Report?

- Not all products have clinical data/trials before clearance to market
- Limitations of clinical trials to identify safety signals before marketing
- Number of patients tested may be too small to detect serious but rare problems
- Trials are brief

MedWatch
Reporting IN

- Anyone can report a serious problem.

Walla Walla, WA – Pharmacist
Sacramento, CA – Nurse
Houston, TX – Dentist
Tallahassee, FL – Consumer
Portland, ME – Physician Assistant

MedWatch
Reporting IN

- One person can make a difference.

MedWatch - What to Report


Drugs


Medical Devices


Biologics


Combination Products

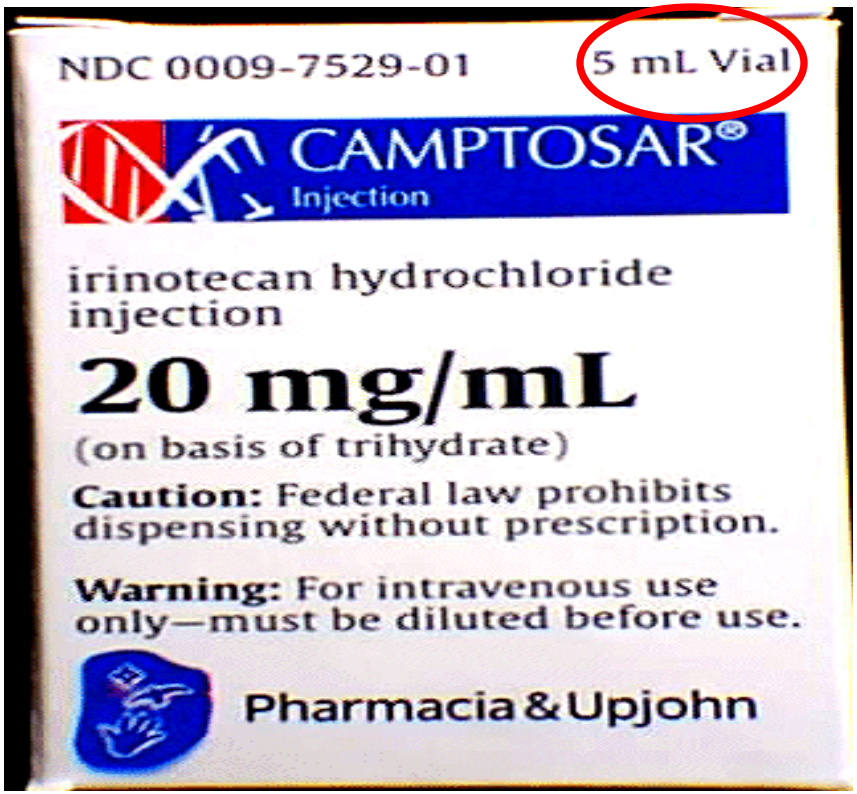

Special Nutritional Products

- Any event that:
  - Is fatal.
  - Is life-threatening.
  - Is permanently disabling.
  - Requires/ prolongs hospitalization.
  - Causes a birth defect.
  - Requires intervention to prevent permanent impairment or damage.
  - Potential for harm/close calls (drugs or devices).

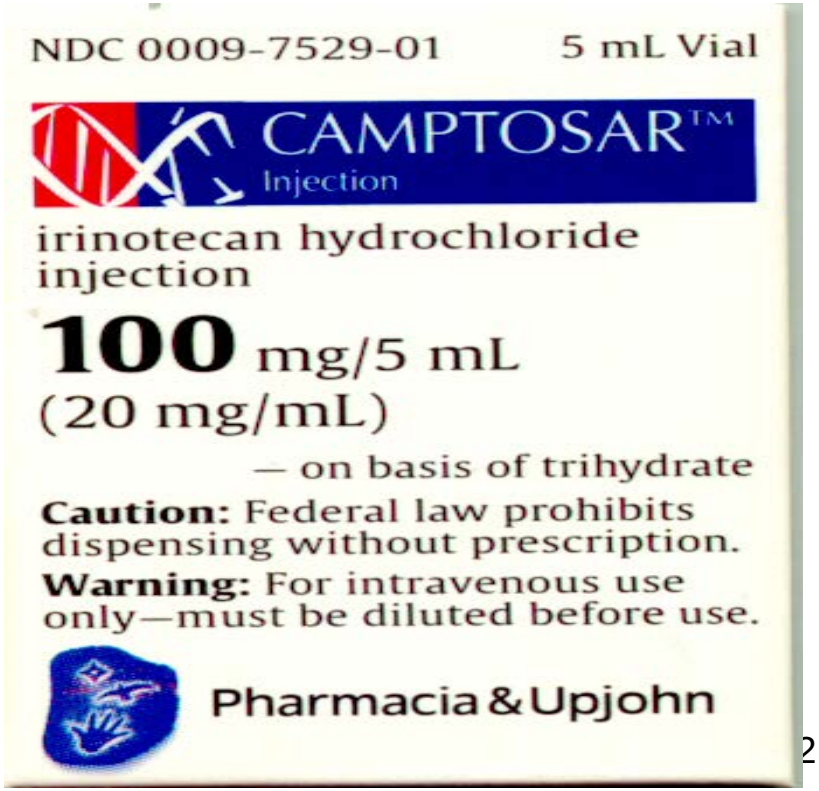
MedWatch - What to Report

Labels- Expression of Strength

Before

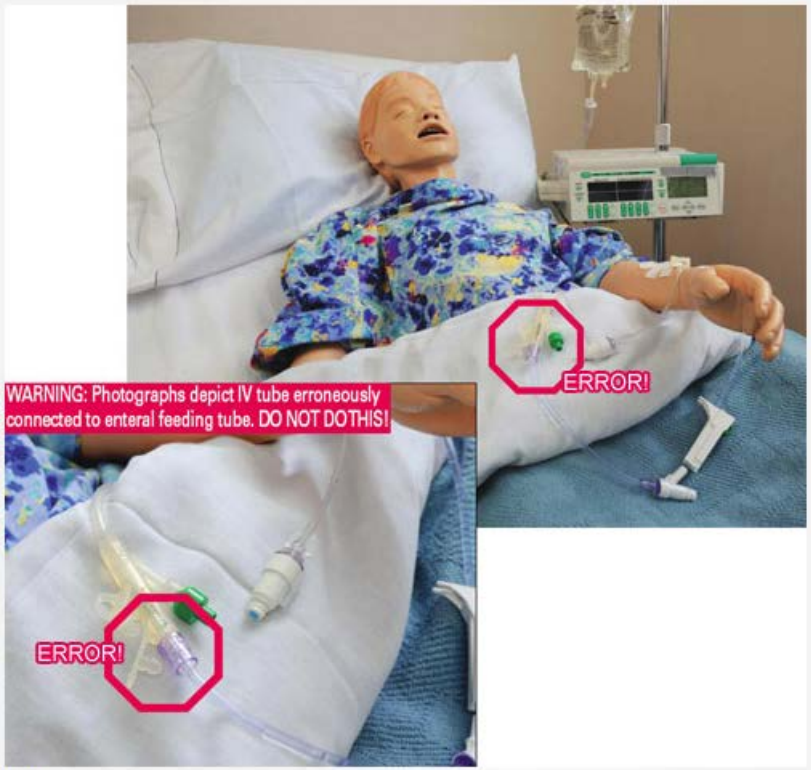


After



Reporting IN – Potential for Harm

IV tubing erroneously connected to enteral feeding tube



CASE STUDY

- A child had both a gastric feeding tube for nutrition and an IV for medicine and hydration
- When the child's gown was changed, a family member inadvertently attached the IV tubing to the gastric feeding tube
- The medicine was delivered through the feeding tube into the stomach
- There was no patient harm since the event was noted in a timely manner

POTENTIAL FOR HARM: Moderate

FDA is also interested in cases where the potential for harm exists

Such reports help FDA identify and better understand the risks associated with medical products

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/ucm313275.htm

Assessment Question 2

True or False. You must be a healthcare professional in order to submit a report to MedWatch.

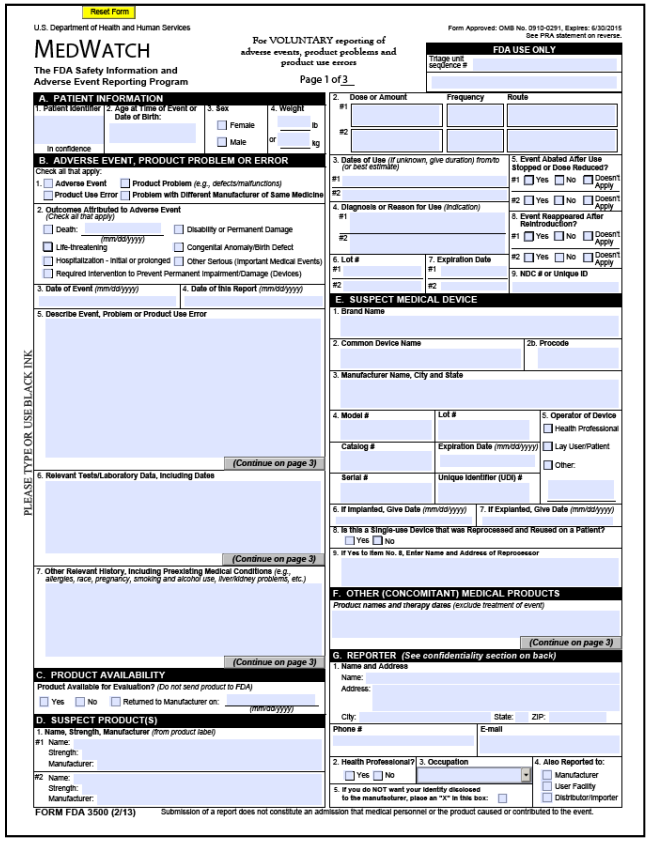
False

MedWatch- Reporting IN

- How to Report:
  - Online (www.fda.gov/medwatch/report.htm)
  - Download the form
    - Mail
    - Fax 1–800–332–0178
- For questions about the form:
  - 1–800–332–1088.

MedWatch Reporting - VOLUNTARY

Clinician Form 3500



Reset Form

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

Form Approved: OMB No. 0910-0291, Expires: 6/30/2016
See PRA statement on reverse.

Page 1 of 3

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION
1. Patient Identifier | 2. Age at time of Event or Date of Birth: | 3. Sex (Female / Male) | 4. Weight (lb / or kg)
In confidence

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. Adverse Event / Product Problem (e.g., defects/malfunctions) / Product Use Error / Problem with Different Manufacturer of Same Medicine
2. Outcomes Attributed to Adverse Event (Check all that apply)
Death (mm/dd/yyyy) / Disability or Permanent Damage / Life-threatening / Congenital Anomaly/Birth Defect / Hospitalization - initial or prolonged / Other Serious (Important Medical Events) / Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (mm/dd/yyyy) | 4. Date of this Report (mm/dd/yyyy)
5. Describe Event, Problem or Product Use Error
(Continue on page 3)
6. Relevant Tests/Laboratory Data, Including Dates
(Continue on page 3)
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
(Continue on page 3)

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
Yes / No / Returned to Manufacturer on: (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
#1 Name: Strength: Manufacturer:
#2 Name: Strength: Manufacturer:

2. Dose or Amount | Frequency | Route
#1
#2
3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1
#2
4. Diagnosis or Reason for Use (Indication)
#1
#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 #2
7. Expiration Date #1 #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 | 2b. Procode
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 # | Unique Identifier (UDI) #
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

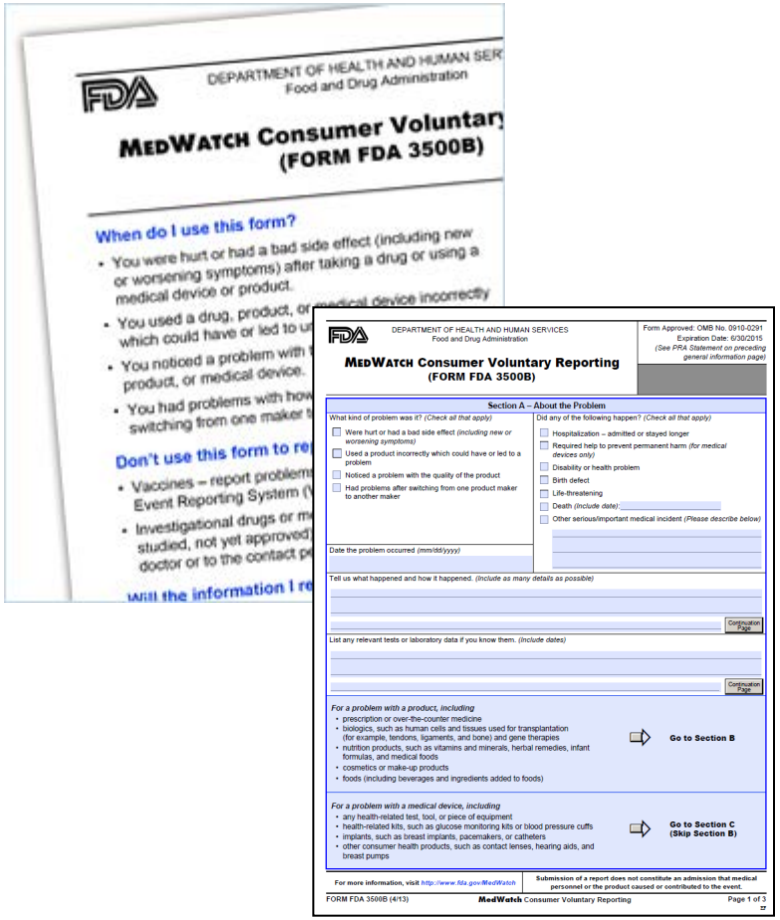
F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)
(Continue on page 3)

G. REPORTER (See confidentiality section on back)
1. Name and Address
Name:
Address:
City: State: ZIP:
Phone # | E-mail
2. Health Professional? Yes No | 3. Occupation | 4. Also Reported to: Manufacturer / User Facility / Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (2/13) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Consumer/Patient Form 3500B



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: 6/30/2015
(See PRA Statement on preceding general information page)

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 u
- You noticed a problem with t product, or medical device.
- You had problems with how switching from one maker t

Don't use this form to re
- Vaccines – report problem Event Reporting System (
- Investigational drugs or m studied, not yet approved doctor or to the contact pe

Will the information I re

Section A – About the Problem

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

Did any of the following happen? (Check all that apply)
Hospitalization – admitted or stayed longer
Required help to prevent permanent harm (for medical devices only)
Disability or health problem
Birth defect
Life-threatening
Death (Include date)
Other serious/important medical incident (Please describe below)

Date the problem occurred (mm/dd/yyyy)

Tell us what happened and how it happened. (Include as many details as possible)
Continuation Page

List any relevant tests or laboratory data if you know them. (Include dates)
Continuation Page

For a problem with a product, including
- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- 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 B

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 C (Skip Section B)

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

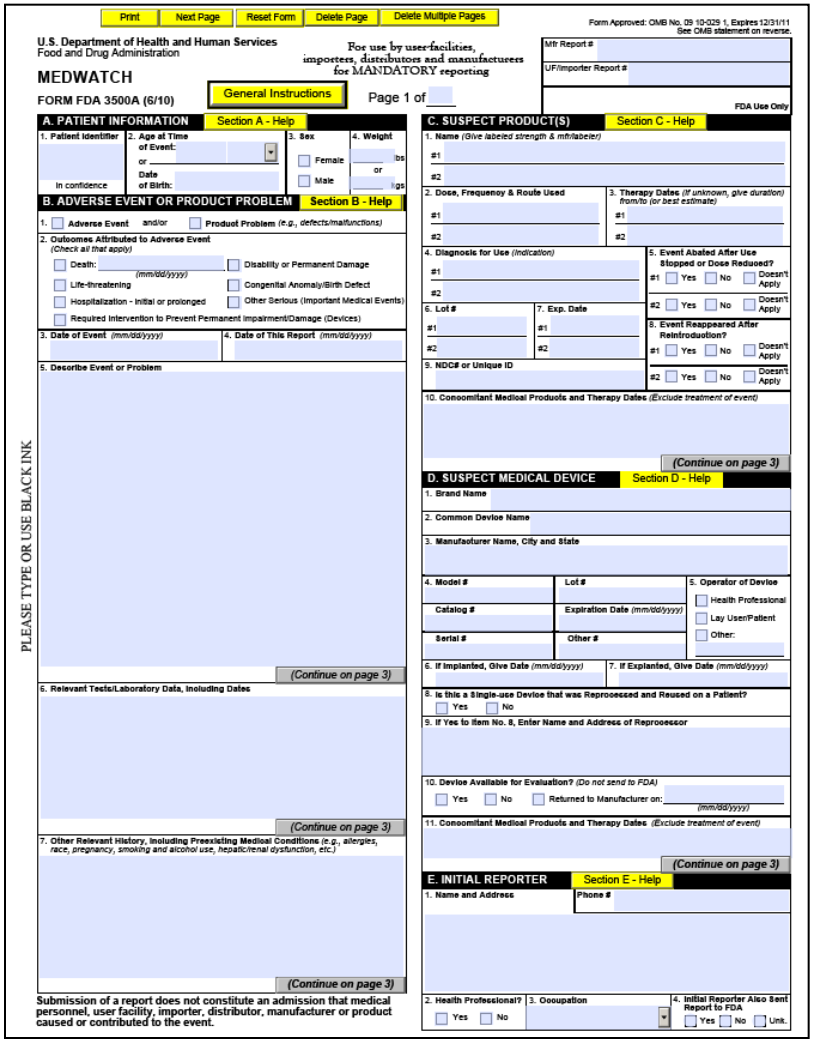
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FORM FDA 3500B (4/13) MedWatch Consumer Voluntary Reporting Page 1 of 3

MedWatch Reporting - MANDATORY

MANDATORY Form 3500A

- User Facilities (medical devices)
- Manufacturers
  - Drugs
  - Biologics
  - Human Cell and Tissue Products
  - OTC Products
  - Medical Devices



Print | Next Page | Reset Form | Delete Page | Delete Multiple Pages

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

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

MEDWATCH

FORM FDA 3500A (6/10)

General Instructions

Page 1 of

Mfr Report #

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION Section A - Help

1. Patient Identifier
2. Age at Time of Event: or Date of Birth:
3. Sex: Female / Male
4. Weight: lbs or kgs

In confidence

B. ADVERSE EVENT OR PRODUCT PROBLEM Section B - Help

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - Death: (mm/dd/yyyy)
   - Life-threatening
   - Hospitalization - initial or prolonged
   - Required intervention to Prevent Permanent Impairment/Damage (Devices)
   - Disability or Permanent Damage
   - Congenital Anomaly/Birth Defect
   - Other Serious (Important Medical Events)
3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)
5. Describe Event or Problem

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

(Continue on page 3)

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

C. SUSPECT PRODUCT(S) Section C - Help

1. Name (Give labeled strength & mfr/labeler)
2. Dose, Frequency & Route Used
3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
4. Diagnosis for Use (Indication)
5. Event Abated After Use Stopped or Dose Reduced? Yes / No / Doesn't Apply
6. Lot #
7. Exp. Date
8. Event Reappeared After Reintroduction? Yes / No / Doesn't Apply
9. NDC# or Unique ID
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE Section D - Help

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: Health Professional / Lay User/Patient / 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
10. Device Available for Evaluation? (Do not send to FDA) Yes / No / Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER Section E - Help

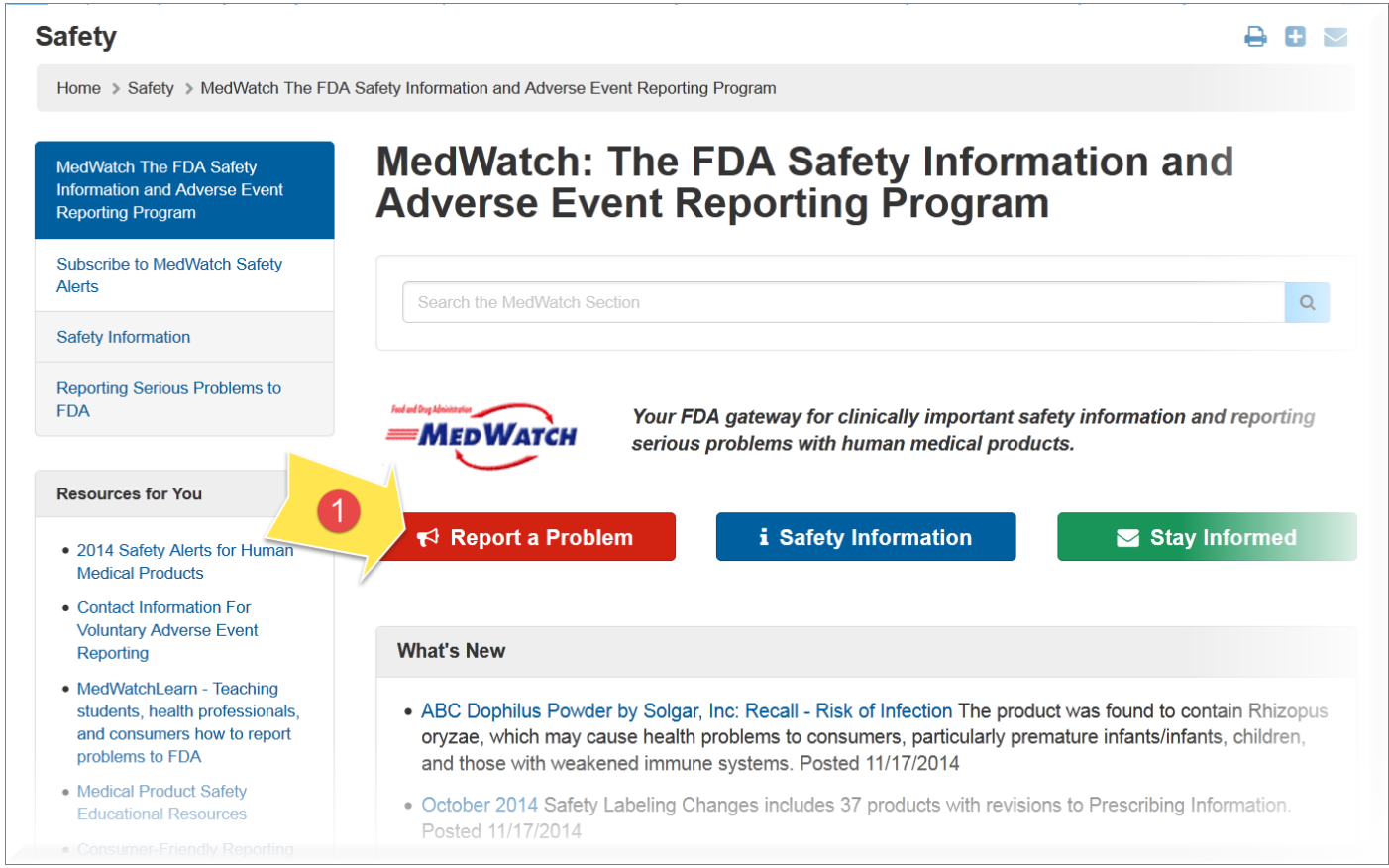
1. Name and Address
Phone #
2. Health Professional? Yes / No
3. Occupation
4. Initial Reporter Also Sent Report to FDA Yes / No / Unk.

Responsive Design

- First for FDA website
- Screen will adjust to device used to access web page: i.e. tablets, smart phone

How do I report?

Report A Problem



www.fda.gov/medwatch

MedWatch The FDA Safety Information and Adverse Event Reporting Program

MedWatch Online Voluntary Reporting Form

Welcome

What to Report to FDA MedWatch:

Use the MedWatch form to report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
- Medical devices (including in vitro diagnostic products)
- Combination products
- Special nutritional products (dietary supplements, infant formulas, and medical foods)
- Cosmetics
- Foods/beverages (including reports of serious allergic reactions)

2

Begin Report As a:

Health Professional

Consumer/Patient

Frequently Asked Questions

Reporting Online Mobile-Friendly

MedWatch Voluntary Report

3

1 About Problem | 2 About Device | 3 About Product | 4 About Patient | 5 About Reporter | 6 Review & Submit

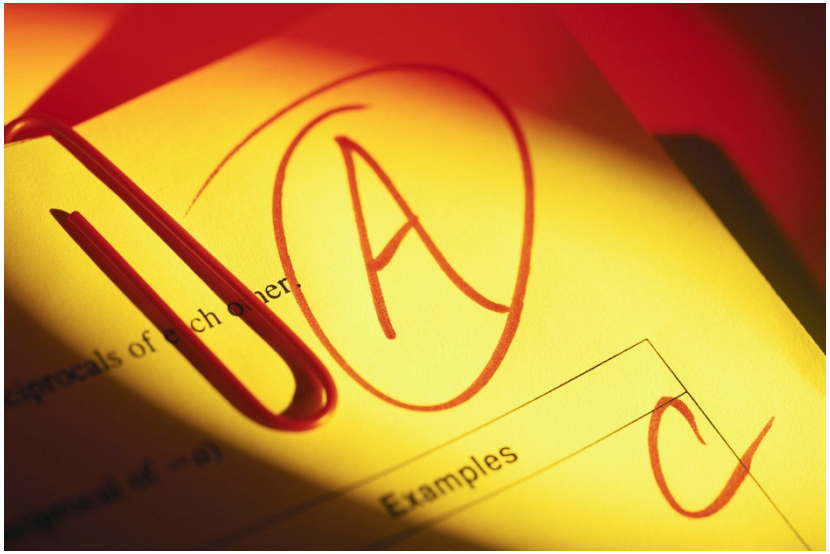
www.fda.gov/medwatch/report

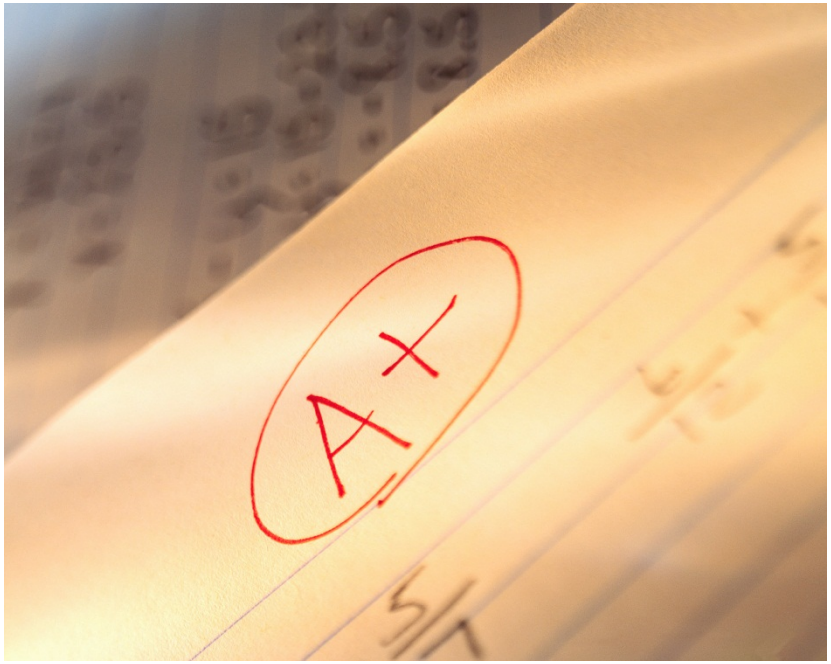
Assessment Question 3

The FDA will accept your adverse event report by which of the following methods?

A) Mail
B) Online submission
C) Fax
D) All of the Above

What makes a good report a





Great report ?

Reporting Tutorial – MedWatch*Learn*

- Online practice portal
  - Students/Health Professionals
  - Consumers Section
  - Learn how to fill out a MedWatch Report

www.fda.gov/medwatchlearn

Reporting Tutorial - MedWatch *Learn*

U.S Department of **Health & Human Services**

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Food and Drug Administration MEDWATCH

MEDWATCHLEARN

FDA **MedWatch*Learn*** teaches students, health professionals, and consumers how to complete the forms necessary to report
you have the opportunity to practice filling out ***FDA Form 3500*** *(for health professionals)* or ***FDA Form 3500B*** *(for consumers)*.

Learn more about MedWatch medical product safety or submit an actual report.

To start, select either "Students and Health Professionals" or "Consumers."

Students and Health Professionals
(FDA Form 3500)

Consumers
(FDA Form 3500B)

This site performs best with Internet Explorer 9 or higher, or recent versions of Firefox, Safari, and Chrome web browsers. If you
viewing or printing pages, try updating your browser to the latest available version.

Page Last Updated: 05/29/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
MedWatchLearn v1.0

Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No Fear Act | Site Map | Transp

What Happens to Your MedWatch Report?

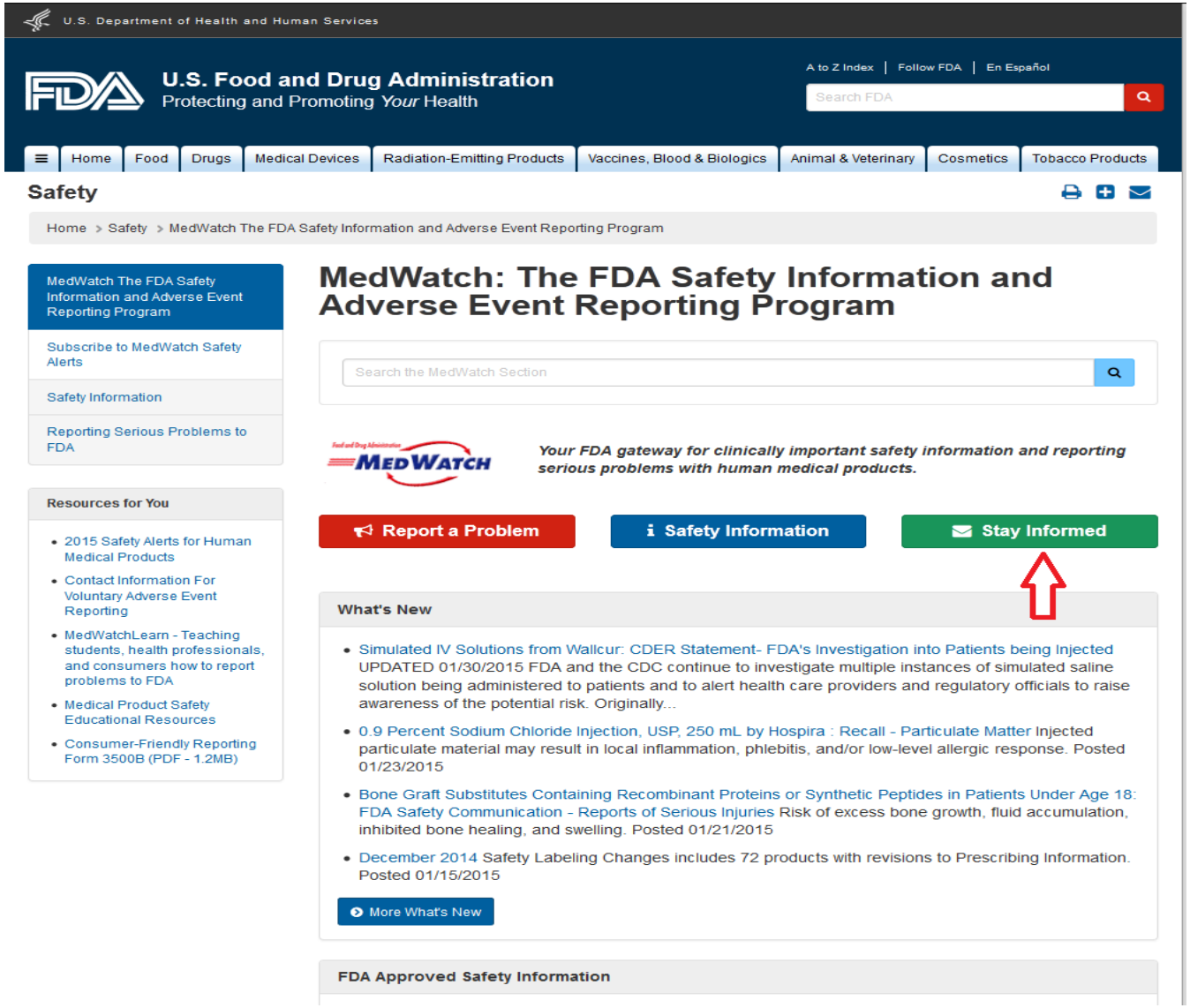
- Report is captured in a database.
- FDA safety evaluator reviews the report.
- FDA safety evaluator looks for similar reports.
- FDA review division may consult with manufacturer.
- FDA /manufacturer conducts further epidemiological studies or post-market clinical trials as needed.

How can MedWatch Reports Result in Product Changes?

- Update the product label.
- Include a Medication Guide.
- Request a change in the product's design, process, packaging, or distribution.
- Request a product recall.

MedWatch-Safety OUT

- Subscribe to MedWatch
  - E-list
  - Twitter
  - RSS feeds



MedWatch-Safety OUT

Example of Individual MedWatch Safety Alert

U.S. Department of Health and Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Safety

Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program > Safety Information > Safety Alerts for Human Medical Products

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Safety Information

Safety Alerts for Human Medical Products

2015 Safety Alerts for Human Medical Products

2014 Safety Alerts for Human Medical Products

2013 Safety Alerts for Human Medical Products

2012 Safety Alerts for Human Medical Products

Eszopiclone Containing Sleep Aids: Drug Safety Communication - Can Cause Next-Day Impairment

Including Lunesta and generics

[Posted 05/15/2014]

AUDIENCE: Pharmacy, Primary Care Medicine

ISSUE: FDA has notified health professionals and their medical care organizations of a new warning that the insomnia drug Lunesta (eszopiclone) can cause next-day impairment of driving and other activities that require alertness. FDA recommends a decreased starting dose of Lunesta to 1 mg at bedtime. Women and men are equally susceptible to impairment from Lunesta, so the recommended starting dose of 1 mg is the same for both. FDA approved changes to the Lunesta prescribing information and the patient Medication Guide to include these new recommendations. The drug labels for generic eszopiclone products will also be updated to include these changes.

BACKGROUND: A study of Lunesta found that the previously recommended dose of 3 mg can cause impairment to driving skills, memory, and coordination that can last more than 11 hours after receiving an evening dose (see Data Summary). Despite these driving and other problems, patients were often unaware they were impaired. The new lower recommended starting dose of 1 mg at bedtime will result in less drug in the blood the next day.

RECOMMENDATION: Health care professionals should follow the new dosing recommendations when starting patients on Lunesta. Patients should continue taking their prescribed dose of Lunesta and contact their health care professionals to ask about the most appropriate dose for them. FDA is continuing to evaluate the risk of impaired mental alertness with the entire class of sleep aid drugs, including over-the-counter drugs available without a prescription, and will update the public as new information becomes available.

[05/15/2014 - Drug Safety Communication - FDA]

Related MedWatch Alert:

[05/14/2013 - Zolpidem Containing Products]

Page Last Updated: 05/15/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

MedWatch- Safety OUT

Drug Safety Labeling Changes

June 2015

Drug Safety Labeling Changes

The summary view includes drug products with safety labeling changes to the BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, or PATIENT PACKAGE INSERT/MEDICATION GUIDE sections. The "quick view" table below provides the drug name and sections modified. Click on the drug name to go to the detailed view. The detailed view includes sections and subsections modified, a description of new or modified safety information in the BOXED WARNING, CONTRAINDICATIONS, or WARNINGS sections, and a link to the revised prescribing information.

Key to Label Section Acronyms:

BW=BOXED WARNING, C=CONTRAINDICATIONS, W=WARNINGS, P=PRECAUTIONS AR=ADVERSE REACTIONS, PPI/MG=PATIENT PACKAGE INSERT/MEDICATION GUIDE

DRUG NAME	SECTIONS MODIFIED					
(Click on drug name to go to detailed view)	BW	C	W	P	AR	PPI/MG
Enjuvia (synthetic conjugated estrogens, B) Tablets	X	X	X	X	X	
Hycamtin (Topotecan) Injection	X					
(Click on drug name to go to detailed view)	BW	C	W	P	AR	PPI/MG
Capoten (captopril) Tablets		X	X			
Jevtana (cabazitaxel) Injection		X	X	X		
Rocephin (ceftriaxone sodium) for Injection		X	X		X	
(Click on drug name to go to detailed view)	BW	C	W	P	AR	PPI/MG
Angeliq (drospirenone and estradiol) Tablets			X	X		

Monthly Safety Labeling Changes

MedWatch Communication OUT

- Distributes important and timely information about safety issues involving medical products via MedWatch safety alerts:
- 149 MedWatch Alerts in 2015
  - 76 drugs and therapeutic biologics
  - 65 medical devices
  - 7 products with undeclared ingredients
  - 1 special nutritional
- 484 safety labeling changes posted for medical products in 2015
  - Update to the prescribing information, package insert, medication guide, and/or product label

Conclusion/Review

- MedWatch is the FDA's safety information and adverse event reporting program.
- Through FDA MedWatch, healthcare professionals should report serious events adverse events.
- Healthcare professionals can submit the completed Form 3500 to the FDA MedWatch system online, by fax, or mail.

Thank You
Questions?

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