Cosmetic Adverse Event Reporting

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What Are Our Learning Objectives?

- FDA's authority over cosmetics
- Methods to monitor the safety of cosmetics
- Simple ways to reduce consumer risks
- Cosmetic adverse event reporting & process
- Regulatory enforcement actions for cosmetics
- Key actions for cosmetic safety

What Is a Cosmetic?

- Articles intended for
  - Cleansing (except some soap)
  - Beautifying
  - Promoting Attractiveness
  - Altering appearance

What Are Some Examples of Cosmetics?

What Is FDA Authority Over Cosmetics?

- Cosmetic products and ingredients are NOT subject to FDA premarket approval authority, with the exception of color additives.

- Companies and individuals who market cosmetics have the legal responsibility to ensure the safety of their products prior to marketing.

How Does FDA Monitor the Safety of Cosmetics?

- Voluntary Cosmetic Registration Program
- Inspections
- Surveys of products
- Cosmetic Ingredient Review (CIR) expert panel
- Consumer complaints (Adverse events reports)
- FDA's own research
- Research by other organizations

What Can Consumers Do to Reduce Risks?

- Observe the product for unusual odors and discolorations
- Read and follow instructions
- Be aware of ingredients
- Stay informed by visiting the FDA Web site

How to Use Cosmetics Safely

- If any cosmetic causes irritation, stop using it immediately; if irritation persists, see a doctor
- Wash your hands before applying cosmetics
- Keep containers clean
- Discard old products
- Use cosmetics for their intended use
- Store cosmetics at room temperature

What Is MedWatch?

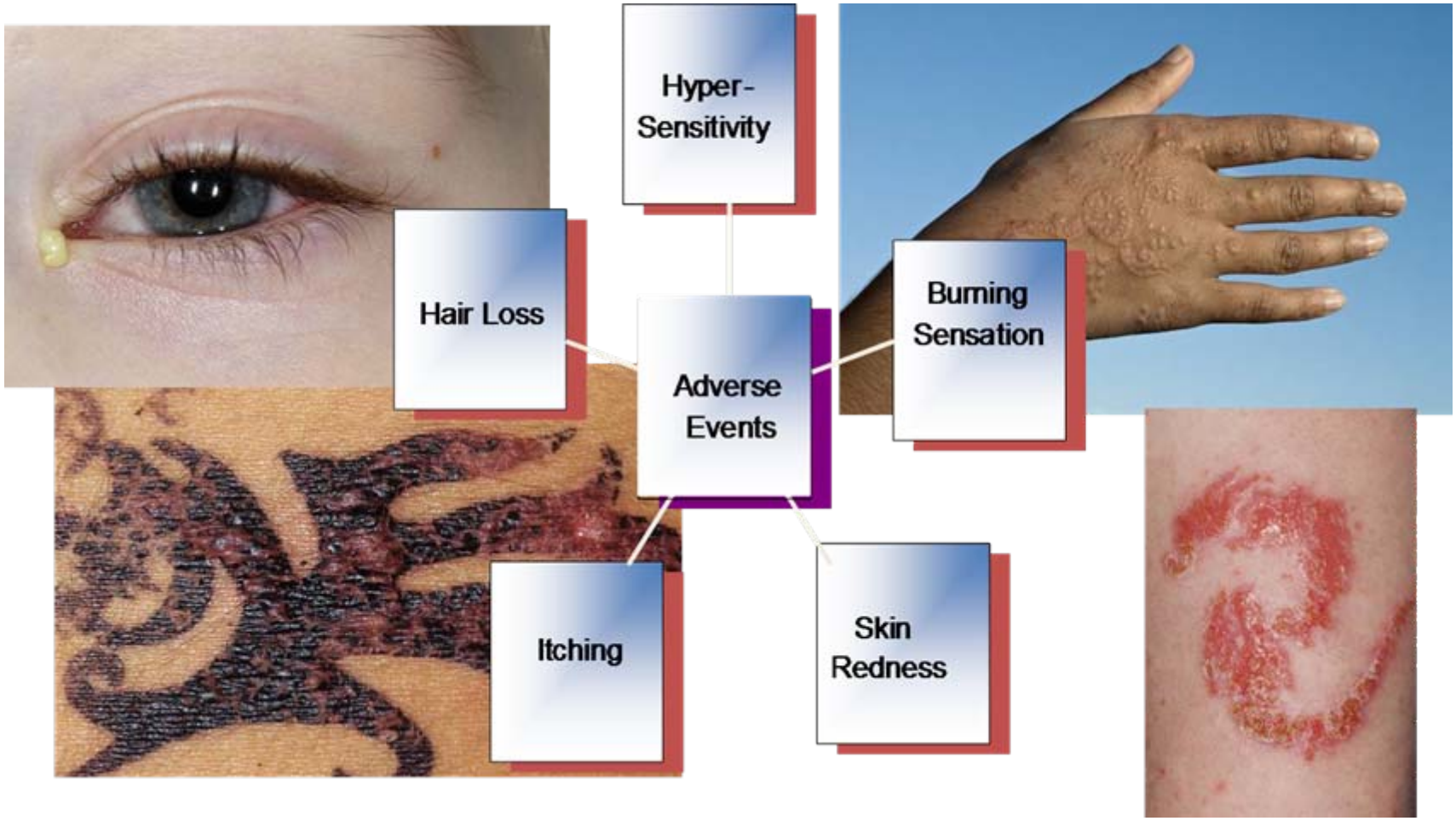
A system for consumers, medical professionals, and manufacturers to report bad experiences associated with FDA-regulated products including cosmetics

How Are MedWatch Reports Filed?

- By Online:
  - https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
- By Mail or Fax:
  - http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
  - Fax 1-800-332-0178
- By Phone:
  - 1-800-332-1088
  - FDA Consumer Complaint Coordinator in your state: http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm

What Are the Elements for an Adverse Event Report?

What Are Commonly Reported Adverse Events?



How Does Your Adverse Event Report Help FDA?

- Detect problem products, manufacturers, and ingredients
- Identify common injuries among product types
- Determine if warning statements are needed to prevent injuries or other action
- Discover common misuses of products

MedWatch Online Voluntary Submission Form 3500

A. PATIENT INFORMATION

1. **Patient Identifier** Unspecified
2. **Age** (at Time of Event): _____ _____
   or
   Date of Birth: _____ (MM/DD/YYYY)
3. **Sex** ☐ Female ☐ Male
4. **Weight** _____ lbs or _____ kgs

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B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ **Adverse Event**
   ☐ **Product Use Error**
   ☐ **Product Problem** (e.g., defects/malfunctions)
   ☐ **Problem with Different Manufacturer of Same Medicine**
2. **Outcomes Attributed to Adverse Event** (Check all that apply)
   - ☐ **Death** _____ (MM/DD/YYYY)
   - ☐ **Life-threatening**
   - ☐ **Hospitalization - initial or prolonged**
   - ☐ **Disability or Permanent Damage**
   - ☐ **Congenital Anomaly/Birth Defect**
   - ☐ **Required Intervention to Prevent Permanent Impairment/damage (Devices)**
   - ☐ **Other Serious (Important Medical Events)**
3. **Date of Event** _____ (MM/DD/YYYY)
4. **Date of This Report** 09/27/2011 (MM/DD/YYYY)
5. **Describe Event, Problem or Product Use Error** *up to a total of 6400 characters allowed*
6. **Relevant Tests/Laboratory Data,** Including Dates
   up to a total of 2000 characters allowed
7. **Other Relevant History, Including Preexisting Medical Conditions** (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems,etc.) *up to a total of 2000 characters allowed*

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E. SUSPECT MEDICAL DEVICE

1. **Brand Name****
2. **Common Device Name****
3. **Manufacturer Name, City and State****
   Please use no more than 3 lines.
4.
   - **Model #**
   - **Catalog #**
   - **Serial #**
   - **Lot # ****
   - **Expiration Date** (MM/DD/YYYY)
   - **Other #**
5. **Operator of Device** ☐ Health Professional ☐ Lay User/Patient ☐ Other Describe 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**
   Please use no more than 4 lines.

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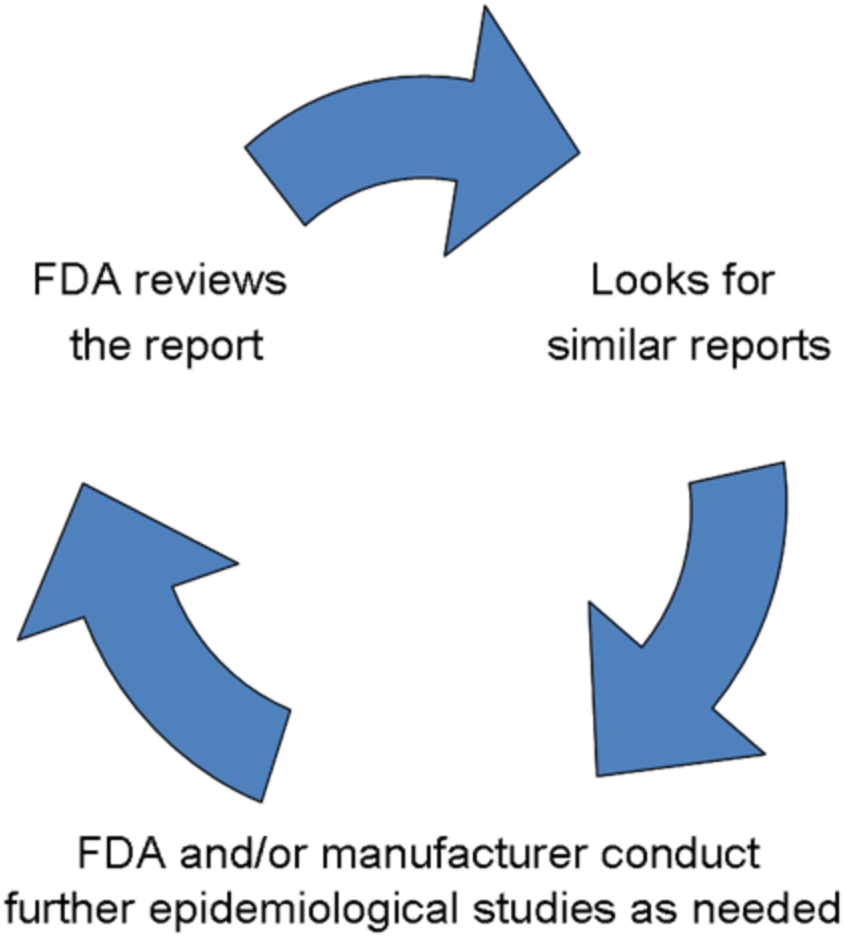
F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
up to a total of 2000 characters allowed

Data Search, Retrieval & Analysis



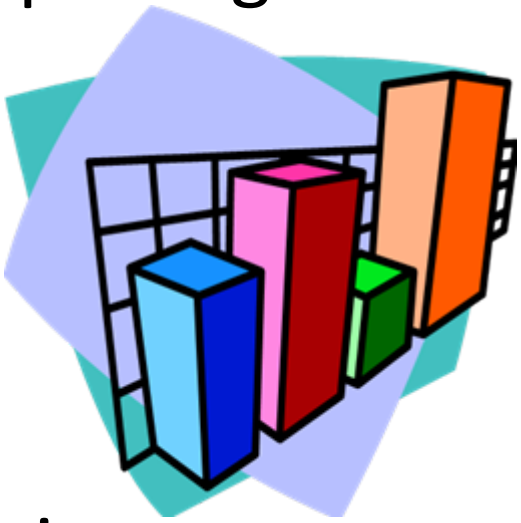
What Can FDA Do if a Cosmetic Is Not Safe?

- FDA can issue a public warning in the form of a Consumer Alert
- Work with State authorities to embargo product
- Product seizure by U.S. Marshals
- Refuse importation into the U.S.
- Request that the firm recall product
- Inspect a firm for violative practices

What Are Some Examples of FDA Actions on Unsafe Cosmetics?

- Warning letters
  - safety and labeling violations
    - Brazilian Blowout
- Seizures
  - 12,682 eye lash product applicator tubes containing an drug ingredient

What Are Some of the Limitations of Adverse Event Reporting?



- Under-reporting
- Erroneous reporting
- Duplicate reports
- Missing data
- Inconsistencies and changes over time (product name change or coded differently)
- No linkable measures of exposure

Where Can You Go for Additional Resources?

- Bad Reaction to Cosmetics? Tell FDA
  - http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm241820.htm

- FDA MedWatch Webinar
  - http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM275939.pdf

Questions?

Outreach and Information Center
1-888-SAFEFOOD
1-888-723-3366
Consumers: consumer@fda.gov
Industry: industry@fda.gov

Center for Food Safety and Applied Nutrition
Food and Drug Administration
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