

COSMETICS FACTS

From the U.S. Food and Drug Administration

How to Report a Cosmetic-Related Problem to FDA



If you've had a reaction to a cosmetic product, the U.S. Food and Drug Administration (FDA) wants to know about it.

The law does not require cosmetic companies to report problems to FDA. Therefore, **the information you report is very important** in order to help FDA monitor the safety of cosmetics on the market. You should also remember that FDA does *not* provide medical advice.

In the case of a reaction or problem with a cosmetic product, the **first step is to stop using the product** and contact your healthcare provider. Then, report the problem to FDA.

What Kinds of Problems to Report

You are urged to notify FDA if you experience any of these situations:

- **A reaction after using a cosmetic**, such as a rash, redness, burn, hair loss, headache, infection, illness or any other unexpected reaction, whether or not it required medical treatment.
- **A problem with a cosmetic product**, such as a bad smell, color change, other sign of contamination, or foreign material in the product.

Types of Products that are “Cosmetics”

Cosmetics products are not the same as drug products, and they are regulated differently by FDA. Here are some examples of cosmetic products:

- Face and body cleansers
- Deodorants
- Moisturizers and other skin lotions and creams
- Baby lotions and oils
- Makeup
- Hair care products, dyes, conditioners, straighteners/relaxers, perms
- Hair removal creams
- Nail polishes
- Shaving products
- Perfumes and colognes
- Face paints and temporary tattoos
- Permanent tattoos and permanent makeup

See How to Report a Problem



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Report a Problem

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| How to Report a Problem | <p>You can report a problem with a cosmetic to FDA in either of these ways:</p> <ol style="list-style-type: none">Contact MedWatch, FDA's Safety Information and Adverse Event Reporting Program:<ul style="list-style-type: none">By Phone: 1-800-FDA-1088Online: File a voluntary report at http://www.fda.gov/medwatchContact a Consumer Complaint Coordinator in your area. Locate one here: http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators |
| Who Should Report a Problem | <p>A consumer, a healthcare provider, or a salon professional can report a problem.</p> |
| What Information to Provide in Your Report | <p>When you contact FDA, you are asked to include the following information in your report, if known:</p> <ul style="list-style-type: none">About the Person Affected<ul style="list-style-type: none">Name and contact information (address, phone, and e-mail address)Age, gender, and ethnicityAbout the Product<ul style="list-style-type: none">Name of the product and the manufacturerProduct codes or identifying marks on the label or container <i>[Note: do not discard the product packaging and labeling. They provide information that will help FDA investigate the problem]</i>When and where the product was purchasedAbout the Problem<ul style="list-style-type: none">Description of the reaction or problemDescription of medical treatment provided, if any |
| What FDA Will Do with Your Report | <p>Once a report is received:</p> <ul style="list-style-type: none">FDA will keep your report confidential.FDA will add the report to our database so that we can see if other people are reporting the same problem.FDA will use the information to determine if the product or similar products have a history of problems and represent a public health concern that needs to be addressed. <p>FDA may not <i>take action</i> on every report received, but the Agency <i>does</i> check all reports to determine if action is necessary to protect the public health.</p> |



To learn more about cosmetics and using them safely, visit:

- <http://www.fda.gov/Cosmetics>
- <http://www.fda.gov/Cosmetics/ResourcesForYou/Consumers>



www.fda.gov/educationresourcelibrary

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For more information, contact the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition's Food and Cosmetic Information Center at **1-888-SAFEFOOD** (toll free), Monday through Friday 10 AM to 4 PM ET (except Thursdays from 12 PM to 1 PM ET and Federal Holidays). Or, visit the FDA website at <http://www.fda.gov/educationresourcelibrary>