FDA Records Access Authority for Cosmetics Products: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Food and Drug Administration considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 30 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.

Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2025-D-2243 that is listed in the notice of availability that publishes in the *Federal Register*.

For questions or information regarding this draft guidance, contact the Office of Inspections and Investigations (OII), Office of Field Regulatory Operations, (OFRO), Food and Drug Administration at OIIPolicyStaffs@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations
Office of the Chief Scientist

January 2026

Table of Contents

FDA Records Access Authority for Cosmetic Products: Guidance for Industry

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

I. Introduction

The purpose of this document is to provide guidance to industry on FDA's authority to access and copy records related to cosmetic products under sections 605 (21 U.S.C. 364a), 610 (21 U.S.C. 364f), and 704 (21 U.S.C. 374) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act). The guidance in this document is in the form of Questions and Answers and provides answers to common questions that might arise about the records access provisions and FDA's current thinking regarding their implementation.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

On December 29, 2022, the President signed into law the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), which included the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). Among other provisions, MoCRA added sections 605 and 610 to, and amended section 704(a)(1) of, the FD&C Act, establishing new authorities for the Secretary (by delegation FDA) to access and copy records related to cosmetic products.

Section 605 (21 U.S.C. 364a) specifies that FDA has access to adverse event report records during an inspection under section 704.

Section 610 (21 U.S.C. 364f) authorizes FDA to access and copy certain records if FDA has a reasonable belief that a cosmetic product, including an ingredient in the product, and any other cosmetic product that the FDA reasonably believes is likely to be affected in a similar manner, is likely to be adulterated such that the use or exposure to such product presents a threat of serious adverse health consequences or death to humans (SAHCOD).

Section 704(a)(1) (21 U.S.C. 374(a)(1)) extends FDA's inspectional authority over all records and other information described in sections 605, 606,[1] and 610 from facilities that manufacture and process cosmetic products, when the standard for records inspection under those sections applies.

This guidance focuses on the authorities to access records described in sections 605 (adverse event reports), 610 (SAHCOD), and 704 (inspections) of the FD&C Act.

III. Definitions

We plan to use the following definitions in implementing the records access requirements of sections 605, 610, and 704 of the FD&C Act:

ADVERSE EVENT. — as defined in section 604(1) of the FD&C Act (21 U.S.C. 364(1)), means any health-related event associated with the use of a cosmetic product that is adverse.

COSMETIC PRODUCT. — as defined in section 604(2) of the FD&C Act (21 U.S.C. 364(2)), means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

FACILITY. — as defined in section 604(3) of the FD&C Act (21 U.S.C. 364(3)), includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

This term does not include any of the following:

(i) Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location;

(ii) Cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508(b)(2) of the Internal Revenue Code of 1986 (26 U.S.C 3508(b)(2))), retail distribution facilities, and pharmacies, unless such establishment

[1] Section 606 (21 U.S.C 364b) of the FD&C Act requires FDA to establish by regulation good manufacturing practices (GMPs) for facilities that manufacture or process cosmetic products distributed in the United States. Under section 606, such regulations may allow for the Secretary to inspect records necessary to demonstrate compliance with these GMP practices during an inspection under section 704. FDA intends to establish these regulations through rulemaking. FDA issued a draft guidance, entitled "Draft Guidance for Industry: Cosmetic Good Manufacturing Practices," (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices) in 2013. We intend to withdraw or revise and reissue that draft guidance, as appropriate, based on the GMP rulemaking.

manufactures or processes cosmetic products that are not sold directly to consumers at that location;

(iii) Hospitals, physicians' offices, and health care clinics;

(iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer;

(v) Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services;

(vi) Trade shows and other venues where cosmetic product samples are provided free of charge;

(vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail sale;

(viii) An establishment that solely performs one or more of the following with respect to cosmetic products:

- Labeling,
- Relabeling,
- Packaging,
- Repackaging,
- Holding,
- Distributing.

For purposes of determining whether an establishment solely performs one or more of the activities listed under (viii), the terms 'packaging' and 'repackaging' do not include filling a product container with a cosmetic product.

MANUFACTURING OR PROCESSING OF A COSMETIC PRODUCT. — means engaging in one or more steps in the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.

RESPONSIBLE PERSON. — as defined in section 604(4) (21 U.S.C 364(4)) of the FD&C Act, means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the FD&C Act (21 U.S.C 364e) or section 4(a) of the Fair Packaging and Labeling Act (15 U.S.C 500.5(a)).

SERIOUS ADVERSE EVENT. —as defined in section 604(5) (21 U.S.C 364(5)) of the FD&C Act, means an adverse event that—

(A) Results in—

(i) Death;

(ii) A life-threatening experience;

(iii) Inpatient hospitalization;

(iv) A persistent or significant disability or incapacity;

(v) A congenital anomaly or birth defect;

(vi) An infection; or

(vii) Significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or

(B) Requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

IV. Questions and Answers

The following section provides information and recommendations in a question and answer format about: (1) records access authority under section 605 (adverse events); (2) records access authority under section 610 (SAHCOD); and (3) confidentiality and refusal.

1. Section 605 Adverse Event Reports

1.1. To whom does FDA's records access authority under section 605 of the FD&C Act apply?

FDA's records access authority for records related to adverse event reports applies to the responsible person for a cosmetic product.

1.2. Under what circumstances may FDA access and copy records under section 605 of the FD&C Act?

Within the scope of an inspection under section 704, records related to each report of an adverse event received by a responsible person and associated with the use, in the United States, of a cosmetic product manufactured or distributed by such person must be made available to FDA.

1.3. What records may FDA access and copy under section 605 of the FD&C Act?

FDA may access and copy records related to each report of an adverse event associated with the use, in the United States, of a cosmetic product received by the responsible person that manufactured or distributed it. Such records would include communications and records of communications between the responsible person and any person(s) who provided information related to the adverse event, and records of the responsible person's assessment of the event as serious or non-serious. For serious adverse event reports, such records would also include the responsible person's serious adverse event report to FDA, with attachments; any new and material medical information about the serious adverse event received by the responsible person; and any reports to FDA of new and material medical information related to the serious adverse event.

1.4. What are the general guidelines for how records should be maintained under section 605?

In accordance with section 605(e)(1) of the FD&C Act (21 U.S.C. 364a(e)(1)) records should be retained in either paper or electronic format. All required documents and records should be kept as original documents or true copies (such as photocopies, or accurate reproductions of the original records). Records related to an adverse event must be maintained for a period of six years after the date such record was created. If the responsible person is considered a small business for the purposes of section 612 (21 U.S.C. 364h), who does not engage in the manufacturing or processing of the cosmetic products described in subsection 612(b) (21 U.S.C. 364h(b)), the records must be maintained for a minimum of three years.

2. Section 610 Serious Adverse Health Consequences or Death (SAHCOD)

2.1 To whom does FDA's records access authority under section 610 of the FD&C Act apply?

FDA's records access authority for records under section 610 of the FD&C Act applies to responsible persons and facilities.

2.2. Under what circumstances may FDA access and copy records under section 610 of the FD&C Act?

FDA may access and copy records if FDA has a reasonable belief that a cosmetic product, including an ingredient in the product, and any other cosmetic product that the FDA reasonably believes is likely to be affected in a similar manner, is likely to be adulterated such that the use or exposure to such product presents a threat of SAHCOD. Upon presentation of appropriate credentials and written notice to the responsible person and/or facility, and at reasonable times within reasonable limits and in a reasonable manner, records related to such cosmetic product must be made available to FDA.

2.3. What records may FDA access and copy if the circumstances under section 610 of the FD&C Act are met?

If the required circumstances are met, FDA may access and copy the records that are needed to assist FDA in determining whether the cosmetic product is adulterated and presents a threat of SAHCOD.

This may include records related to the manufacture, processing, packing, distribution, receipt, or importation of the cosmetic product believed to be affected. This applies to records maintained by or on behalf of such person, in any format (including paper and

electronic formats), and at any location. FDA recognizes that some persons store their records at a location other than the establishment where the covered activities take place. Because the circumstances of each particular event vary, the scope of an FDA request for records may vary by situation.

Examples of records that FDA may access and copy include:

- Manufacturing records,
- Raw materials (ingredients and packaging) receipt records,
- Product distribution records,
- Product inventory records,
- Raw ingredient and finished product analytical results,
- Recall records,
- Customer distribution lists,
- Complaint and adverse event records,
- Safety substantiation records.

2.4. When is FDA likely to exercise its authority under section 610 of the FD&C Act to access and copy records?

Upon presentation of appropriate credentials and written notice to the responsible person and/or facility, FDA may request to access and copy records whenever the requirements of section 610 are satisfied, but requests are most likely to occur when FDA becomes aware of:

- Product recalls,
- Adverse event reports,
- Consumer complaints,
- Situations in which specific cosmetic products present a threat of SAHCOD, or
- Inspection or sampling which reveal conditions indicating a cosmetic product presents a threat of SAHCOD.

2.5. What records may FDA not access and copy under section 610 of the FD&C Act?

FDA's authority to access records under section 610 of the FD&C Act does not apply to the following records:

- Recipes or formulas for cosmetics,
- Financial data,
- Pricing data,
- Personnel data (other than data as to qualification of technical and professional personnel performing functions subject to the FD&C Act),
- Research data (other than safety substantiation data for cosmetic products and their ingredients), or
- Sales data (other than shipment data regarding sales).

2.6 When is a cosmetic product, including an ingredient in such product, deemed adulterated under section 601 of the FD&C Act?

There are many reasons a cosmetic product, including an ingredient, may be deemed adulterated under section 601 of the FD&C Act (21 U.S.C 361) including, but not limited to:

- If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling, or under customary or usual conditions of use,
- If it consists in whole or in part of any filthy, putrid, or decomposed substance,
- If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health,
- If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health,
- If it is not a hair dye and it is, or bears or contains, a color additive which is unsafe within the meaning of 721(a) of the FD&C Act (21 U.S.C. 379e(a)),
- If it has been manufactured or processed under conditions that do not meet the good manufacturing practice requirements of section 606 (21 U.S.C 364b),
- If it is a cosmetic product, and the cosmetic product, including each ingredient in the cosmetic product, does not have adequate substantiation for safety, as defined in section 608(c) (21 U.S.C 364d(c)).[2]

2.7 What are some examples of situations in which cosmetic products may cause SAHCOD?

Certain situations increase the potential that a cosmetic may cause SAHCOD. These situations include:

- Microbial contamination – presence and/or growth of pathogenic or opportunistic microorganisms that may cause infection, irritation, or other adverse reactions,
- Chemical or toxicological hazards – presence of unsafe ingredients, impurities, or contaminants that may trigger acute or severe reactions,
- Design-or-use related vulnerabilities – cosmetic forms or applications that cause unintended contact with sensitive areas of the body (such as eyes) or allow systemic exposure to potentially harmful ingredients,
- Improper storage, distribution, or labeling – conditions that compromise the product or result in unsafe use.

The following are some examples of situations in which cosmetic products may cause SAHCOD:

[2] Under section 608(c), "adequate substantiation of safety" means tests of studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.

- Cleansing cloths contaminated with the bacteria *Burkholderia cepacia,* which can cause severe infections in immunocompromised individuals and children,
- Alcohol-free mouthwash contaminated with the bacteria *Burkholderia cepacia*, presenting risk to oral and systemic infection,
- Eye area cosmetic products contaminated with the bacteria *Pseudomonas aeruginosa*, a pathogen linked to sight-threatening ocular infections,
- Products containing Benzimidazole pigments, which may cause allergic reactions in some individuals,
- Disposable, no-rinse, shampoo caps determined to be contaminated with the bacteria *Serratia marcescens*, an opportunistic pathogen associated with bloodstream and urinary tract infections,
- Tattoo ink with microbial contamination, which may result in systemic and localized infections following injection,
- Skin care products contaminated with *Staphylococcus aureus* or other harmful bacteria, which may lead to skin infections or systemic illness,
- Nail products (e.g., gels, adhesives, removers, dehydrators) containing toxic solvents or contaminated applicators that can result in systemic absorption or infections,
- Cosmetic products with unsafe levels of heavy metals (e.g., lead, cadmium), which can be especially harmful to babies and young children.

2.8. What are some examples of situations in which other cosmetic products are "likely to be affected in a similar manner" such that the use or exposure to such product presents a threat of SAHCOD?

The concept of "likely to be affected in a similar manner" recognizes that conditions leading to adulteration often extend beyond a single batch or product. By examining records that document shared manufacturing conditions, equipment, ingredients, or packaging, FDA can more accurately determine the scope of products at risk and work with firms to implement appropriate corrective actions, including recalls if necessary. This process helps ensure timely identification and removal of unsafe products from the market, thereby minimizing the risk of harm to consumers.

The following are some examples of such situations:

- Shared manufacturing or processing conditions: cosmetic products manufactured or processed at the same time, in the same manner, location, or environment, and/or on the same equipment without adequate controls as cosmetic products that are likely to be adulterated such that the use or exposure to such product presents a threat of SAHCOD,
- Common ingredients, containers, or closures: cosmetic products manufactured or processed using the same or similar ingredients, containers and/or closures without adequate controls as cosmetic products that are likely to be adulterated such that the use or exposure to such product presents a threat of SAHCOD,
- Cross contamination potential: when cosmetic products are manufactured or processed in proximity, without proper separation or controls, to or alongside cosmetic products

that are likely to be adulterated such that the use or exposure to such product presents a threat of SAHCOD, raising likelihood of shared exposure to harmful contaminants,

- Systemic process deficiencies: when a failure in a critical process (such as sterilization, preservation, pH adjustment, microbial testing, or labeling controls) affects multiple cosmetic products manufactured or processed under the same process,
- Supplier-related risks: when cosmetic products use or incorporate raw materials, ingredients, or packaging obtained from the same supplier that was the source of contaminated or defective inputs in other cosmetic products that are likely to be adulterated such that the use or exposure to such product presents a threat of SAHCOD.

3. Confidentiality and Refusal

3.1. How will FDA maintain the confidentiality of any protected information in records it obtains?

Information obtained under the records access provisions of sections 605, 610, and 704 of the FD&C Act may include, but is not limited to, personal privacy information or a company's non-public confidential commercial or trade secret information. Several statutes (e.g., Trade Secrets Act (18 U.S.C. 1905), FD&C Act (21 U.S.C. 331(j)), and the Freedom of Information Act (5 U.S.C. 552)) and the agency's information disclosure regulations at 21 CFR Part 20 govern the agency's disclosure of information to the public. For both foreign and domestic firms, FDA personnel will comply with all applicable protections, procedures, and legal requirements against the unauthorized disclosure of non-public information, such as personal privacy information, trade secrets, or confidential commercial information. FDA personnel will only disclose non-public information as permitted by law and FDA's procedures (see e.g., 21 U.S.C. 375(b)). For example, FDA's regulations (set forth in 21 CFR Part 20) permit agency officials to disclose certain non-public information to other federal, state, local, or foreign government officials, or to FDA's contractors, if certain conditions are met.

3.2. What actions may FDA take when a firm refuses to permit access to 605 (adverse event reports) or 610 (SAHCOD) records?

The refusal to permit access to or copying of 605 (adverse events) or records requested in the scope of an inspection under section 704(a)(1) of the FD&C Act, which includes 610 (SAHCOD) records, is a prohibited act under section 301(e)[3] of the FD&C Act (21 U.S.C. 331(e)). Under section 302 of the FD&C Act (21 U.S.C. 332), the United States can bring a civil action in federal court to enjoin a person who commits a prohibited act. Under section 303 of the FD&C Act (21 U.S.C. 333), the United States can bring a criminal action in federal court to prosecute a person who is responsible for the commission of a prohibited act.

[3] It is also a prohibited act under section 301(e) to fail to establish or maintain any adverse event record, or to fail to make any adverse event report, required by section 605.

Additionally, under section 801(a) of the FD&C Act (21 U.S.C. 381(a)), as amended by MoCRA, FDA shall refuse admission of cosmetic products offered for import into U.S. commerce if the Secretary of Health and Human Services has credible evidence or information indicating that the responsible person has not allowed access to records described in section 605.[4]

[4] This provision also applies where FDA has credible information that the responsible person has not complied with a requirement of section 605 with respect to any such article.