



**AIM Global**

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**Dockets Management Staff (HFA-305)**

Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2025-D-2243**

**Draft Guidance for Industry: “FDA Records Access Authority for Cosmetics”**

To Whom It May Concern:

On behalf of [AIM Global](#), we appreciate the opportunity to submit comments in response to the U.S. Food and Drug Administration’s draft guidance, “**FDA Records Access Authority for Cosmetics: Guidance for Industry**,” announced by notice of availability under **Docket No. FDA-2025-D-2243**.

AIM Global strongly supports FDA’s issuance of this draft guidance and the Agency’s efforts to provide clarity to industry regarding the criteria, process, and expectations for FDA access to records related to cosmetic products under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). We believe this guidance is an important and timely step in helping regulated entities better understand FDA’s records access authorities under sections 605, 610, and 704 of the Federal Food, Drug, and Cosmetic Act, while also promoting more effective product safety oversight and response.

AIM’s detailed comments are provided in the accompanying AIM Comment Form, which corresponds to this cover letter and outlines our specific recommendations in the format of the draft guidance. This letter is intended to provide additional context regarding AIM’s support for the guidance, our experience in this area, and the general themes reflected in our submitted comments.

**About AIM Global**

AIM Global is the leading international industry association and global authority for automatic identification and data capture (AIDC) technologies, including barcodes, two-dimensional symbols, RFID, NFC, RTLS, machine-readable identifiers, and related digital traceability technologies. AIM represents stakeholders across the supply chain ecosystem, including technology providers, manufacturers, solution integrators, standards participants, and end users who depend on accurate, available, and identifiable data to support product traceability, safety, quality, and interoperability.

AIM also serves as the ISO/IEC Registration Authority for ISO/IEC 15459, the internationally recognized framework for globally unique identifiers used across supply chains and other ecosystems. Our members and technical experts routinely work on issues involving product identification, serialization, data carriers, event-based traceability, interoperability, and regulatory implementation across healthcare, food, cosmetics, industrial, retail, logistics, and other sectors.

### **AIM's Regulatory and Standards Experience**

AIM's comments are informed by extensive experience supporting traceability, identification, and interoperable data capture across a range of regulatory and policy initiatives, including:

- FDA implementation efforts related to the Drug Supply Chain Security Act (DSCSA), including industry engagement around serialization, interoperable exchange of transaction information, and the role of machine-readable identifiers in enabling efficient product verification and traceability
- FDA and broader industry efforts related to the Food Safety Modernization Act (FSMA), including enhanced food traceability initiatives where structured, interoperable records and event-based traceability play an increasingly important role
- Broader standards and policy work related to product identification, supply chain visibility, serialization, secure data structures, RFID-enabled data capture, packaging and sustainability-related product information, and cross-sector traceability interoperability

Across these initiatives, a consistent lesson has emerged: when regulatory oversight and product safety depend on timely access to accurate records, the most effective systems are increasingly those built upon interoperable, machine-readable, standards-based identification and traceability frameworks.

In addition, AIM and its members are actively engaged in emerging global regulatory and policy discussions involving Digital Product Passport (DPP) concepts and related product transparency frameworks. These efforts similarly depend on globally unique identifiers, machine-readable access to product information, interoperable data exchange, and secure methods for linking physical products to digital records across the product lifecycle. While these frameworks differ from FDA's authorities under MoCRA, they further illustrate the growing importance of standards-based digital traceability across regulated and adjacent markets.

### **General Overview of AIM's Comments**

AIM's attached comments are supportive of the Agency's overall approach and are intended to strengthen the final guidance by helping ensure it clearly reflects how modern records are created, maintained, and used in today's supply chains.

In particular, our comments encourage FDA to recognize that relevant records under sections 605, 610, and 704 may include not only traditional paper or manually created electronic files but also records generated and maintained through modern automated identification and digital traceability systems. These may include:

- Barcode scan records
- RFID event records
- Lot-based and serialized product identifiers
- Shipment, aggregation, and transformation records
- Structured, machine-readable datasets generated by traceability systems

- Cloud-based or third-party traceability platform records
- Supply chain event histories maintained across multiple entities
- Digitally verifiable or integrity-preserving record structures, where applicable

We believe it would be helpful for the final guidance to more explicitly acknowledge the growing role of these types of records in supporting product safety investigations, adverse event follow-up, scope determination, and timely corrective actions.

### **Examples of Relevant Traceability Frameworks and Standards**

AIM's comments do not advocate for any one proprietary approach, nor do they suggest that the cosmetics sector should be subject to the same statutory requirements as other regulated sectors. Rather, we respectfully note that FDA and industry have already seen the value of interoperable, machine-readable traceability in adjacent regulatory environments.

For example, modern records access and traceability environments may involve standards and frameworks such as:

- **ISO/IEC 15459**, which provides a framework for globally unique identification of items and entities
- **GS1 GTIN and SGTIN**, which support product identification and serialization
- **GS1 EPCIS**, which supports the capture and exchange of event-based traceability data such as commissioning, aggregation, shipping, receiving, and transformation events
- **GS1 Digital Link**, which supports web-resolvable product identity and access to structured product information
- **ISO/IEC 18000-63 (RAIN RFID)**, which supports RFID-based item identification and event capture
- **ISO/IEC 20248**, which supports digitally verifiable data structures and trusted data exchange

FDA has also previously recognized the value of interoperable, machine-readable traceability records in other regulatory contexts, including implementation frameworks associated with the Drug Supply Chain Security Act (DSCSA) and food traceability initiatives under the Food Safety Modernization Act (FSMA). While the statutory requirements differ across product categories, these prior efforts illustrate the importance of globally unique identifiers, event-based traceability records, and interoperable digital record systems in supporting product safety investigations, supply chain visibility, and efficient regulatory response.

### **AIM's Position on FDA's Draft Guidance**

AIM supports the FDA's draft guidance and appreciates the Agency's effort to provide clarity to industry on these important records access authorities. Our comments are intended to be constructive and practical. We believe the final guidance can be strengthened by more explicitly acknowledging that modern recordkeeping and traceability often depend on automated identification, machine-readable data carriers, interoperable event records, and cross-enterprise digital traceability systems.

We also believe that doing so would improve the guidance's usefulness to industry by reducing ambiguity around what types of records may be relevant, where such records may reside, and how such records may be used to support timely product safety investigations and regulatory response.

### **Offer to Support Further FDA Engagement**

AIM Global would welcome the opportunity to further support FDA on these issues. Our organization and member experts can provide additional technical input, concrete examples, and cross-sector perspective regarding how modern identification and traceability systems are implemented in practice, including examples from cosmetics-adjacent sectors where interoperable, machine-readable records have improved supply chain visibility and response capabilities.

If helpful, AIM would be pleased to engage with FDA staff in the future to discuss:

- How modern barcode, RFID, and digital traceability systems generate and maintain records relevant to inspections and investigations
- Practical examples of event-based traceability and records access across distributed supply chains
- The role of globally unique identifiers in narrowing affected product scope and supporting more targeted corrective action
- How standards-based approaches can support technology-neutral implementation while improving interoperability and regulatory utility

Thank you again for the opportunity to provide comments on this important draft guidance. AIM appreciates FDA's leadership in this area and supports the Agency's efforts to improve clarity, consistency, and practical implementation under MoCRA.

Respectfully submitted,



**Dan Quagliana**  
**AIM Visibility Technologies Group Chair**



**Chuck Evanhoe**  
**AIM Chairman**



# AIM Public Review Comment Form

(Formerly 13B)

Date:	Document:
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1	2	3	(4)	5	6	(7)	(8)
Org <sup>1</sup>	Comment Number <sup>2</sup>	Clause No./ Subclause No./ Annex (e.g. 3.1)	Paragraph/ Figure/Table/ Note (e.g. Table 1)	Type of comment <sup>3</sup>	Comment (justification for change)	Proposed change	Committee Action/Response
AIM	1	Introductio n	General	ge	The guidance explains FDA authority to access and copy records but does not acknowledge that many relevant records are now generated and maintained through automated identification and data capture (AIDC) systems rather than solely through traditional paper or manually created electronic files. In modern manufacturing and distribution environments, records supporting product traceability are frequently generated through barcode, RFID, and other machine-readable data capture systems that utilize globally unique identifiers.	Add language acknowledging that records subject to FDA access may include records generated through automated identification and data capture technologies, including barcode systems, RFID systems, and digital traceability platforms that use globally unique identifiers and machine-readable data carriers.	

1 **Org.** = Name of entity submitting comments      2. **Comment Number:** itemize each comment      3. **Type of comment:**    **ge** = general            **te** = technical            **ed** = editorial

**NOTE**      Columns 1, 2, 3, 5, and 6 are compulsory.

**NOTE:**    If you have a concern about or objection to a particular section, you must suggest a proposed change for your concern to be addressed by the Review Committee.

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AIM	2	Background	Section 704 Authority	te	<p>Many companies maintain required regulatory and traceability records in cloud-based or third-party digital traceability systems rather than solely within facility-based systems. These platforms may capture product movement, aggregation, transformation, shipping, and receiving events across multiple entities in the supply chain. Without clarification, it may be unclear to industry whether such records fall within the scope of FDA's records access authority when they contain information relevant to product safety investigations.</p>	<p>Clarify that records maintained in third-party electronic systems, cloud-based traceability platforms, or event-based supply chain record systems may be subject to FDA access when they contain required regulatory information relevant to records access under sections 605, 610, or 704.</p>	
AIM	3	Definitions	Facility	ge	<p>The definition of "facility" excludes certain entities that solely perform activities such as holding or distributing cosmetic products. However, traceability records relevant to product investigations are often generated and maintained by distribution centers, third-party logistics providers, and other supply chain partners through barcode scanning, RFID reads, or other automated event capture. Clarification would help ensure industry understands that the location of a record does not necessarily limit its relevance to an FDA investigation.</p>	<p>Clarify, either in this section or in the Questions and Answers section, that records relevant to FDA's records access authorities may include traceability records maintained by supply chain partners when such records are necessary to determine product movement, affected lots, or the scope of a product safety investigation.</p>	

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AIM	4	Questions and Answers	1.3 What records may FDA access and copy under section 605 of the FD&C Act?	te	The examples of records FDA may access under section 605 appropriately include communications and adverse event documentation, but they do not expressly acknowledge that traceability records may also be relevant in evaluating the scope and impact of an adverse event. In practice, firms may rely on lot-level, serial-level, or shipment-level traceability data generated through barcode scanning, RFID event capture, or digital product tracking systems to determine affected products and distribution pathways.	Expand the examples of records that may be relevant under section 605 to include traceability records such as lot tracking data, shipment records, serialized product identifiers, barcode scan logs, RFID event records, and other machine-generated product movement records that may assist in determining the scope or impact of an adverse event.	
AIM	5	Questions and Answers	1.4 What are the general guidelines for how records should be maintained under section 605?	ge	The guidance states that records may be maintained in paper or electronic format, but additional clarification would be helpful to recognize that modern electronic records may consist of structured, machine-readable datasets generated automatically by traceability and identification systems. In some cases, such records may also include secure or digitally verifiable data structures used to preserve data integrity and provenance.	Clarify that electronic records may include structured, machine-readable datasets generated by automated identification and traceability systems, and may include digitally verifiable data structures or metadata used to support data integrity and provenance, where applicable.	
AIM	6		1.4 What are the general guidelines for how records should be maintained under section 605?	ge	How long records should be maintained section is not fully fleshed out.	How is small or large size companies defined? FDA should put the actual criteria in the document: FDA Section 612 (21 U.S.C. 364h), enacted under MoCRA 2022, provides small business exemptions from certain cosmetic regulations. Specifically, it exempts businesses with <\$1 million average annual US sales (previous 3 years) from facility registration and product listing, unless they manufacture specific high-risk products (eye contact, injections, internal use, or -hour appearance change).	

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AIM	7	Questions and Answers	2.3 What records may FDA access and copy if the circumstances under section 610 of the FD&C Act are met?	te	<p>The examples of records FDA may access under section 610 appropriately include manufacturing, distribution, inventory, recall, and complaint records, but the guidance would be strengthened by expressly recognizing digital traceability records that are increasingly central to determining whether a cosmetic product is adulterated and identifying the scope of potentially affected products. Modern supply chain traceability often relies on globally unique identifiers encoded in barcodes or RFID tags, including identifiers structured under recognized frameworks such as ISO/IEC 15459, GS1 GTIN/SGTIN, and associated event records captured through systems such as GS1 EPCIS or RAIN RFID (ISO/IEC 18000-63) deployments.</p>	<p>Add examples of records that may be accessed under section 610 to include digital traceability records such as serialized or lot-based product identifiers, barcode and RFID identification records, event-based product movement records, and other machine-generated traceability data that may assist FDA in determining the scope, origin, distribution, or relatedness of affected products.</p> <p>Similar concepts have been reflected in other FDA-regulated traceability environments, such as DSCSA serialization and transaction data exchange models, and FSMA food traceability initiatives that emphasize more structured and interoperable recordkeeping.</p>	
AIM	8	Questions and Answers	2.8 What are some examples of situations in which other cosmetic products are “likely to be affected in a similar manner”?	te	<p>This section appropriately discusses shared manufacturing conditions, common ingredients, and systemic process deficiencies. Additional clarification would be valuable to recognize that, in practice, firms often determine which products are “likely to be affected in a similar manner” by analyzing traceability records tied to shared identifiers, event histories, common raw materials, packaging components, production lines, aggregation relationships, or distribution events. Standards-based event traceability approaches, including systems that capture commissioning, aggregation, shipping, receiving, and transformation events, can materially improve the speed and accuracy of determining the scope of potentially affected products.</p>	<p>Add clarification that firms may use digital traceability systems and event-based product records, including records associated with shared identifiers, common components, aggregation relationships, or distribution events, to determine which products may be affected in a similar manner and to support timely corrective actions or recalls.</p>	

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AIM	9	Questions and Answers	3.1 How will FDA maintain the confidentiality of any protected information in records it obtains? (or General, if preferred)	ge	<p>Because the guidance increasingly implicates digital records that may be maintained across shared supply chain ecosystems, FDA may wish to recognize that modern traceability records are often generated and exchanged using interoperable standards and protocols. Examples include globally unique identification frameworks such as ISO/IEC 15459 and GS1 GTIN/SGTIN; web-resolvable product identity frameworks such as GS1 Digital Link; event-based traceability frameworks such as GS1 EPCIS; RFID data capture systems such as ISO/IEC 18000-63 (RAIN RFID); and digitally verifiable data structures such as ISO/IEC 20248. Recognizing these frameworks would help clarify that records access under the guidance can apply to modern, interoperable, machine-readable traceability records while remaining technology-neutral.</p>	<p>Add a general statement in the guidance encouraging the use of interoperable, machine-readable identification and traceability frameworks and clarifying that records generated and maintained through such systems may constitute relevant records for purposes of FDA access and review, where applicable.</p> <p>The FDA has previously recognized the value of interoperable, machine-readable traceability records in other regulatory contexts, including implementation frameworks related to the Drug Supply Chain Security Act (DSCSA) and food traceability initiatives under the Food Safety Modernization Act (FSMA). While the statutory authorities and sector-specific requirements differ, these prior efforts demonstrate the practical importance of globally unique identifiers, event-based traceability records, and interoperable digital record systems in supporting product safety, supply chain visibility, and efficient regulatory response.</p>	
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