Office of Inspections and Investigations / OII

INFORMATION FOR SUCCESSFULLY FILING ENTRIES OF COSMETICS

*The data elements below are not all inclusive for successful entry transmission of cosmetics in ACE.

PURPOSE

Products offered for import into the U.S. that meet the definition of a cosmetic are regulated by the U.S. Food and Drug Administration (FDA). To avoid delay in the FDA's import admissibility process, **provide complete and accurate information for each cosmetic as part of the electronic entry**. Your customs broker should be knowledgeable in transmitting FDA-regulated products to the FDA.

DATA ELEMENTS NEEDED FOR FDA REVIEW

(THE FDA SUPPLEMENTAL GUIDE CONTAINS ALL FILING INFORMATION FOR FDA)

GOVERNMENT AGENCY PROGRAM CODE: COS

- Product Code: Application - Product Code Builder (industry code 50 and 53 only)
- Product Description: Include common/usual/market name of the product, include colors, special ingredients, etc.
- Quantity and units of measure (e.g. 10 pallets/40 cases/100 pieces)
- Manufacturer name and address*
- Shipper name and address*
- FDA Importer (Importer of Record) name and address*
- Deliver-to-Party (Consignee) name and address*

*Firm Establishment Identifier (FEI) Number and/or Dun & Bradstreet (DUNS) numbers are optional but encouraged. Utilize the FEI Search Portal to search for the FEI associated with the firm.

THE MODERNIZATION OF COSMETICS REGULATION ACT OF 2022 (MOCRA)

FACILITY REGISTRATION AND PRODUCT LISTING REQUIREMENTS

Manufacturers and processors must register their facilities, and responsible persons must list each marketed cosmetic product with the FDA through Cosmetics Direct. Cosmetics Direct is an electronic submission portal for the registration and listing of cosmetic product facilities and products respectively.

However, there have been no recent changes to the FDA message set to collect cosmetic firm registration and product listing information when the articles are offered for import into the U.S. Continue to monitor the publicly available materials at Modernization of Cosmetics Regulation Act of 2022 (MoCRA) | FDA and additional messaging in support of future enhancements.

FDA CONTACTS AND RESOURCES

- FDA Supplemental Guide for ACE for all cosmetics and cosmetic products requirements: FDA Supplemental Guide,
- For information on registration and listing requirements: Registration & Listing of Cosmetic Product Facilities and Products | FDA.
- For questions related to MoCRA requirements and implementation: QuestionsAboutMoCRA@fda.hhs.gov.
- For general import operations and policy questions: Imports@fda.hhs.gov..
- For questions related to individual shipments, including:
  - entries under initial FDA review (pending review, documents requested, etc.), please contact NERInquiry.
  - entries pending additional FDA field review (pending examination/ sampling, detention, refusal, etc.), please contact the FDA Import Office covering the port of entry.

OTHER CONTACTS AND RESOURCES

- For tariff classification inquiries, consult the CROSS Custom Rulings Online Search System (cbp.gov).
- For information on how to obtain a prospective ruling on the classification of imported goods, consult the CBP website.
- The most recent version of the Harmonized Tariff Schedule of the United States is available on the U.S. International Trade Commission's website.

***** Please share this resource with your customs broker.*****

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