

OTC Drug Listing Updates and Validation

Leyla Rahjou-Esfandiary, PharmD
Drug Registration and Listing Branch
Office of Unapproved Drugs and Labeling Compliance
Office of Compliance
CDER | US FDA

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct –
SBIA 2024 Workshop



Learning Objectives



- Describe listing updates for OTC drug marketing authorization
- Name the latest OTC drug marketing categories
- Describe listing updates needed for FY2025 OMUFA determination

OTC Monograph Reform in the CARES Act



- Signed into law in March 2020
- Included provisions on OTC drugs regulations
 - Section 505G

OTC Monograph

- Establishes conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing that are deemed generally safe and effective under a therapeutic category
 - Monograph IDs

Drug Listing Changes



- Went into effect on October 1, 2023
 - New marketing categories:
 - OTC Monograph Drug -- C200263
 - OTC Monograph Drug Manufactured Under Contract -- C132334
 - New Monograph IDs

Drug Listing Changes



- Applied to all new OTC listing submissions after implementation
- FDA listing inventory still includes reference to the old OTC categories and CFR citations in older submissions

2024 Listing Certification Period



- Under 21 CFR 207.57(b)(2):
 - Each listed drug must be certified if no changes have occurred since its last review and update
 - All outdated OTC drug listing submissions must now be updated
 - Old marketing categories and citations won't be available for certification
 - Old marketing categories and citations will fail validation

OMUFA Facility Fees



- The FRN for OTC Monograph Order Request (OMOR) fee rates for fiscal year (FY) 2025 was published in July 2024
 - Effective on October 1, 2024, till September 30, 2025

Hand Sanitizer Manufacturers



- Manufacturers of hand sanitizers registered with FDA during the COVID-19 public health emergency (PHE) were not subject to OMUFA facility fees
- This PHE ended on May 11, 2023
- Hand sanitizer manufacturers will be subject to OMUFA facility fees for FY2025

What to Do



- If you plan to continue manufacturing hand sanitizers:
 - Renew your registration and certify your drug listing
 - Be aware of and pay your OMUFA facility fees for FY2025
- If you plan to discontinue manufacturing hand sanitizers by December 31, 2024:
 - Deregister your facility with FDA
 - Delist all your hand sanitizers
 - Inactivate your FDA-assigned labeler code (recommended)

Challenge Question 1



- Which statement is true?
 - A. All OTC drug listing submissions currently reference the appropriate Monograph ID
 - B. All OTC drug listing submissions should reference the appropriate Monograph ID by September 30th 2024
 - C. All OTC drug listing submissions should reference the appropriate Monograph ID by December 31st 2024
 - D. None of the above

Challenge Question 2



- If you discontinue manufacturing hand sanitizers in November 2024 and continue manufacturing other OTC drugs, you may still be subject to OMUFA facility fees for FY2025:

A. False

B. True

Challenge Question 3



- You won't be subject to OMUFA facility fees if you only manufactured hand sanitizers under PHE, and you stop manufacturing them by:
 - A. September 1, 2024
 - B. September 30, 2024
 - C. December 31, 2024
 - D. September 30, 2025

Closing Thoughts



- By December 31, 2024:
 - Deregister and delist if you no longer manufacture hand sanitizers
- By December 31, 2024:
 - All drug listing submissions for OTC drugs must be updated to reference the latest marketing categories and appropriate marketing authorization

Resources



- <https://dps.fda.gov/omuf>
- <https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources>
- <https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instructions>
- <https://www.federalregister.gov/documents/2024/07/31/2024-16878/over-the-counter-monograph-drug-user-fee-program-otc-monograph-order-request-fee-rates-for-fiscal>



U.S. FOOD & DRUG
ADMINISTRATION

Questions?

Leyla.Rahjou-Esfandiary@fda.hhs.gov
eDRLS@fda.hhs.gov

