# OTC Drug Listing Updates and Validation

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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    - All outdated OTC drug listing submissions must now be updated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

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# Questions?

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