U.S. FOOD & DRUG ADMINISTRATION

WELCOME

We'll begin the meeting promptly at 9:00am.

U.S. FOOD & DRUG ADMINISTRATION

Public Meeting on the Recommendations for OMUFA II

Wednesday, November 20, 2024

Note: A video recording and transcription of today's meeting will be published on the FDA website after this meeting.

Nana Adjeiwaa-Manu

Center for Drug Evaluation and Research, FDA

Meeting Moderator, Program Evaluation and Implementation Staff,
Office of Program and Strategic Analysis, Office of Strategic Programs

AGENDA

- Welcome and Introduction
- Opening Remarks
- OMUFA Background and Reauthorization Process
- OMUFA II Agreement Overview
- Break
- Regulated Industry Perspectives
- Academic and Advocacy Perspectives
- Open Public Comment
- Closing Remarks

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Patrizia Cavazzoni

Center for Drug Evaluation and Research, FDA

Center Director

OMUFA
Background and Reauthorization Process

Theresa Michele

Center for Drug Evaluation and Research, FDA

Director, Office of Nonprescription Drugs (ONPD), Office of New Drugs

Basic User Fee Construct

- On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted. The CARES Act included important amendments to the Federal Food, Drug, and Cosmetic (FD&C) Act that reformed and modernized the way OTC monograph drugs are regulated in the United States. It also gave FDA the **authority to assess and collect fees from regulated industry with respect to OTC monograph drugs.**
- The provisions of the FD&C Act enacted in 2020 under the CARES Act also direct FDA, through the OMUFA reauthorization negotiation process, to develop recommendations regarding the OTC monograph drug user fee portions of the FD&C Act and commitment-letter goals.
- FDA negotiates with industry about desired enhancements related to FDA activities supported by the OTC Monograph Drug User Fee Program (OMUFA).
  - What new or enhanced process will the FDA or industry seek to include in the next 5 years?
  - What is technically feasible?
  - What resources are required to implement and sustain these enhancements?
  - What are the user fee mechanics (collection mechanisms, fee types, etc.)?
  - **Note: FDA does not commit t**o future **policy positions** or to a specific policy position (e.g., to be outlined in guidance).
- Medical product user fee programs **have been reauthorized every 5 years.**

OTC Monograph Reform Significantly Modernized OTC Drug Review

- The CARES Act:
  - Replaced the rulemaking process with an administrative order process
  - Gave FDA the authority to **issue an administrative order that adds, removes or changes** Generally Recognized as Safe and Effective (**GRASE) conditions for an OTC drug monograph**
  - Established an expedited process to address safety issues

- These changes benefitted patients, industry and the nation's health care system by:
  - Significantly **reducing regulatory burden**;
  - **Encouraging innovation**; opening new markets; expanding breadth and depth of OTC product lines
  - **Increasing efficiency**, timeliness, and predictability
  - **Streamlining safety** updates

Guided by input from industry, consumer, patient and professional groups,

OMUFA reauthorization helps ensure those continued benefits.

OMUFA I Accomplishments

Under OMUFA I, FDA:

- Issued its first proposed order on sunscreens (September 24, 2021)
- Issued its first FDA-initiated safety order addressing a safety issue related to acetaminophen serious skin reactions (June 14, 2024)
- Received its first OTC Monograph Order Request (OMOR)
- Issued an FDA-initiated order to remove phenylephrine from the OTC monograph (November 7, 2024)

- OMUFA I established **critical infrastructure** for the OTC Monograph Program:
  - Annual Forecast for Planned Monograph Activities
  - New IT systems: OTC Monographs @FDA and CDER NextGen Portal/CDER Nexus
  - Cataloged paper documents (ongoing)
  - Draft guidances (OTC Monograph Meetings, OMOR Format and Content, Electronic Submissions, Assessing OMUFA User Fees, Dispute Resolution and Consolidated Proceedings)
  - Meeting management timelines and goals
  - New hires (As of September 29, 2024, FDA had hired 85 OMUFA positions)
- FDA also **posted all final orders** deemed established by law upon enactment of OTC monograph reform

This public meeting is one of the last steps in the reauthorization process

FD&C Act section 744N(d):

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for OTC monograph drug activities for the first 5 fiscal years after fiscal year 2025, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

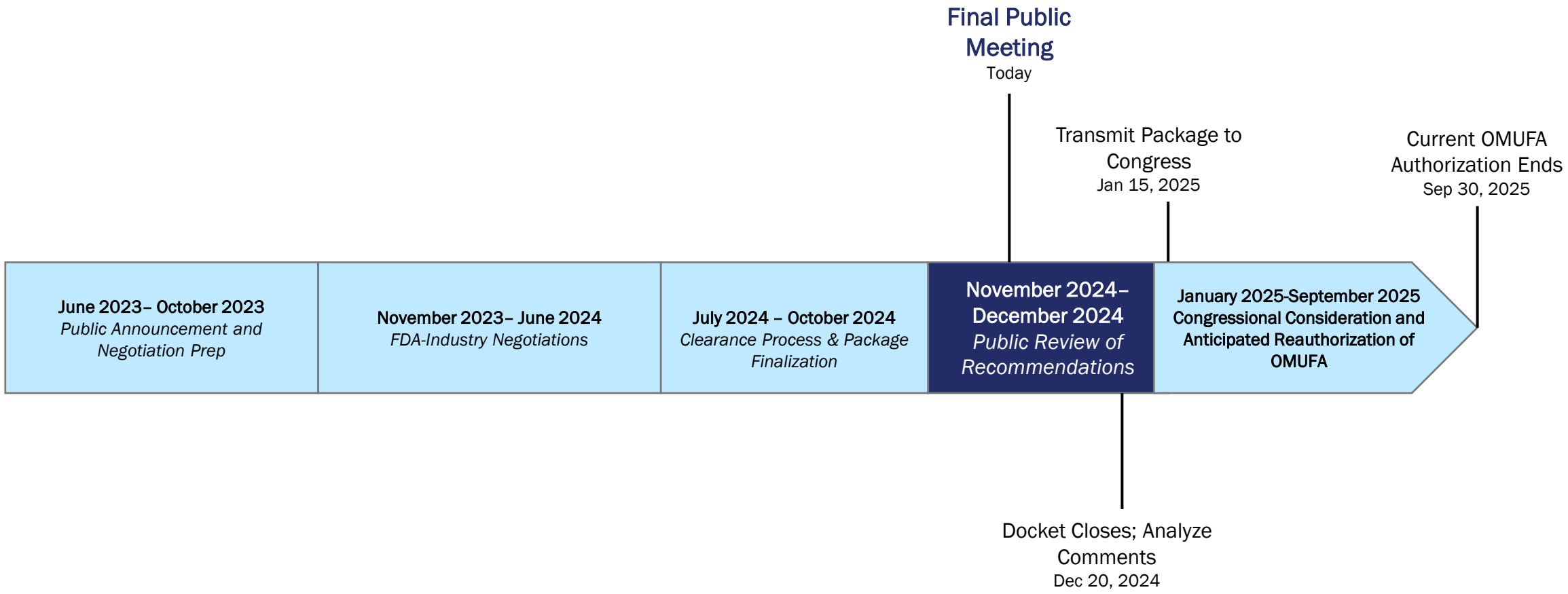
(A) the Committee on Energy and Commerce of the House of Representatives;
(B) the Committee on Health, Education, Labor, and Pensions of the Senate;
(C) scientific and academic experts;
(D) health care professionals;
(E) representatives of patient and consumer advocacy groups; and
(F) the regulated industry.

(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;
(B) publish such recommendations in the Federal Register;
(C) provide for a period of 30 calendar days for the public to provide written comments on such recommendations;
(D) hold a meeting at which the public may present its views on such recommendations; and
(E) after consideration of such public views and comments, revise such recommendations as necessary

(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2025, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

OMUFA II Reauthorization Timeline



OMUFA II
Agreement Overview

Dr. Karen Murry

Center for Drug Evaluation and Research, FDA

Deputy Director, Office of Nonprescription Drugs (ONPD), Office of New Drugs

OMUFA II Enhancement Areas

- **Education|** Improving Industry's understanding of how to navigate OTC monograph regulatory processes
- **Quality|** Enhancing quality surveillance and information transparency
- **Test Methods|** Addressing testing methods in existing monographs
- **Statutory Alignment|** Adjusting continuing commitments to align with Section 505G of the FD&C Act
- **Meetings|** Introducing new approaches to improve efficiency and expand communication
- **Information Transparency|** Investing in mechanisms to support documentation and transparency
- **Finance|** Enhancing financial efficiency and transparency

Improving Industry's understanding of how to navigate OTC monograph regulatory processes

Webinars

- Crowdsourcing to solicit external stakeholder questions related to OMOR submissions and requirements for GRASE finalizations, followed by webinar to answer those questions for which FDA has established policy.
- Webinar to detail steps of how to submit an OMOR using the NextGen Portal.

Confidentiality Guidance

- Draft guidance to assist with understanding confidentiality as it pertains to OTC monograph information submitted to FDA.

Eligibility Guidance

- Draft guidance pertaining to eligibility determination requirements for OMORs proposing new monograph active ingredients and implementation of this part of the filing process.

Enhancing quality surveillance and transparency

Quality Surveillance Enhancement

- Commitment to vet new OTC monograph drug registrants for the OTC monograph drug catalog within 6 months of registration.
- Updates to CDER's risk-based site selection model and related MAPP to include OTC monograph-related risk factors for potential quality problems.

Education

- Workshop to assist industry in improving quality and compliance with current good manufacturing practice (CGMP) requirements.

Transparency

- Annual reporting on records requests issued to OTC drug manufacturers.
- Enhancement of warning letter webpage to improve search capabilities.

Addressing testing methods in existing monographs

Tier 2 OMOR Statutory Definition Change

- Proposed addition of a new type of Tier Two (lower-cost) OMOR, i.e., for OMORs proposing the addition or modification of certain testing conditions in the monograph. These testing methods would need to reflect a voluntary consensus standard for pharmaceutical quality established by a national or international standards development organization and recognized by FDA (via a process described in guidance), with such recognition being made available on the FDA website.*

Crowdsourcing

- Commitment to publish an FR notice soliciting feedback on existing test methods in monographs, followed by a crowdsourcing to further refine the input.

*See FDA's guidance on *CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality Guidance for Industry.*

Alignment of Commitment Letter with Statute

Filing Eligibility Determination Timelines Language

- The OMUFA I CL has filing eligibility determination and associated timelines occurring prior to OMOR submission. However, the (subsequently enacted) statute specifies that filing eligibility determinations required for certain types of OMORs occur after submission of the OMOR. The OMUFA II commitment regarding the filing review period for such Tier One OMORs reflects the post-OMOR submission filing eligibility determinations specified in section 505G (with a commitment for draft guidance on the requirements of this eligibility provision and part of the filing process).
- Additional time (15 or 60 days) incorporated into the filing review period for Tier One OTC Monograph Order Requests (OMORs) proposing new monograph ingredients, based on current US marketing history of the drug involved.

Major Amendment Language

- CL Language stating that FDA does not intend to review major amendments submitted after a proposed order is issued. This helps ensure that the public will have the opportunity to comment on any changes made to the proposed order as a result of a major amendment.

Public Comment Period Language

- Extension of the final order goal date by the same length of any public comment period extension, up to 15 days, given that the statute gives flexibility for the public comment period to be extended.

J. Paul Phillips

Center for Drug Evaluation and Research, FDA

Director, Office of Program Operations (OPO), Office of New Drugs

Meetings: Introducing new approaches to improve efficiency and expand communication

Meeting Efficiency

- Update to definition of face-to-face meetings to include virtual meetings with cameras on, in alignment with other UFAs.
- Clarification that meetings longer than one hour can be requested for complex topics and may be granted in appropriate circumstances.
- Specification that formal OMUFA meeting requests are to be submitted to FDA via the CDER NextGen Portal (or any successor system).

Follow-up Opportunity

- New follow-up opportunity for requestors to ask clarifying questions about information in meeting minutes or written response.

Protocol Synopsis Review

- Clarification that requestors may request feedback on a protocol synopsis as part of other topics that qualify for a Type Y meeting or as a stand-alone topic at a Type Z meeting.

Advisory Committee (AdCom) Meetings

- Commitment to post a website notice announcing a certain subset of OTC-related AdCom meetings 100 business days in advance of the meeting, i.e., those where the AdCom is not intended to address an emerging safety issue and the existing policy on advance notice in FDA's 2008 Advisory Committee Meetings Guidance does not apply.

Enhancing documentation and information transparency

Exclusivity Web Page

- Web page detailing monograph-related exclusivity afforded by final orders to include a table of relevant monograph change(s), requestor(s), the final order date, and date of the relevant eDRLS drug listing update.

Scanned Paper Documents

- Pre-OMUFA paper documents that were catalogued in OMUFA 1 will be scanned, linked to a searchable catalog, and posted to a public docket.

OTC Monograph Historical Website Links

- Commitment to maintain the Historical Status of OTC Rulemakings website and keep links active.

Angela Granum

Center for Drug Evaluation and Research, FDA

Division Director, Division of User Fee Management (DUFM), Office of Management

Enhancing financial efficiency and transparency

Facility Fee Due Date Alignment

- Proposed statutory revision to move the facility fee due date from June of the fiscal year (FY) to October 1, the start of the federal FY, to align with the due date for other UFA annual fees for administrative efficiency.
- Transition in FY 2027, with fees due in two installments that year to help address cash flow concerns industry expressed.
- Transition year has a nine-month fee liability period to avoid facilities potentially being liable for an annual facility fee for two fiscal years based on an overlapping three-month period of fee liability.

One-Time Facility Fee Adjustor

- Proposed statutory addition to make a one-time adjustment in calculating target revenue if the average number of fee-liable facilities exceeds 1625 in certain years of OMUFA II (with the average percent in arrears below 30%). This would help accommodate the additional work required to oversee these facilities. Once (and if) this adjustment is made, it would be part of the base going forward.
- Need for the adjustment is not anticipated but it helps guard against volatility.

Enhancing financial efficiency and transparency (cont.)

Arrears List Visibility

- Commitments to highlight arrears list information:
  - utilizing records request information to focus fee recovery efforts,
  - publishing a list of facilities that have paid their fees per FY,
  - publishing registration and arrears information in the annual OMUFA financial reports.

Base Revenue

- Resets the starting base revenue for OMUFA II to include the $3M additional direct cost adjustment from the final year of OMUFA I.

U.S. FOOD & DRUG ADMINISTRATION

BREAK

We'll return promptly at 10:00am (ET).

Note: A video recording and transcription of today's meeting will be published on the FDA website after this meeting.

Panel 1:
Regulated Industry Perspectives

Mike Bailey

Consumer Healthcare Products Association

Senior Vice President, Regulatory & Scientific Affairs

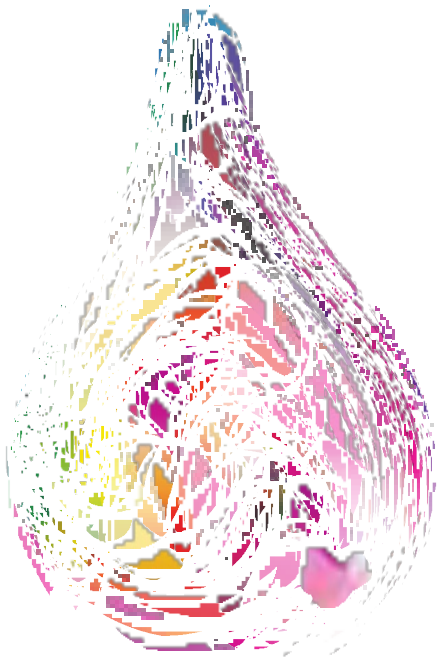
Dan Selechnik

Fragrance Creators Association

Director of Regulatory Science

OMUFA: FRAGRANCE INDUSTRY PERSPECTIVE

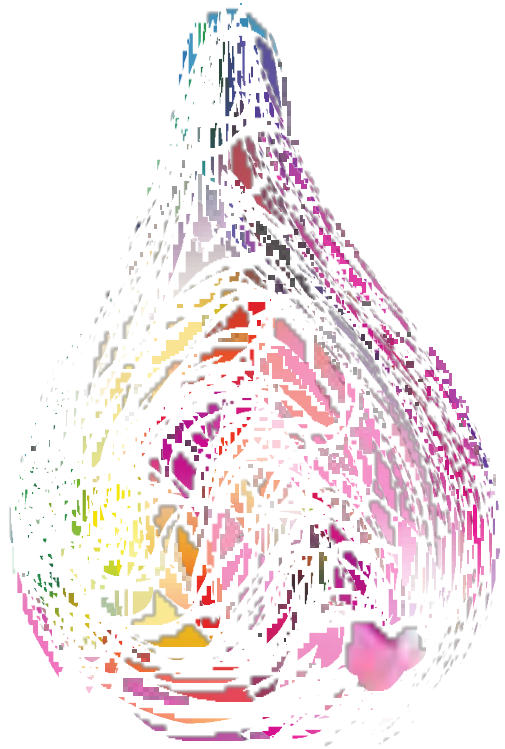
November 20, 2024



FRAGRANCE CREATORS ASSOCIATION®

FRAGRANCE CREATORS ASSOCIATION

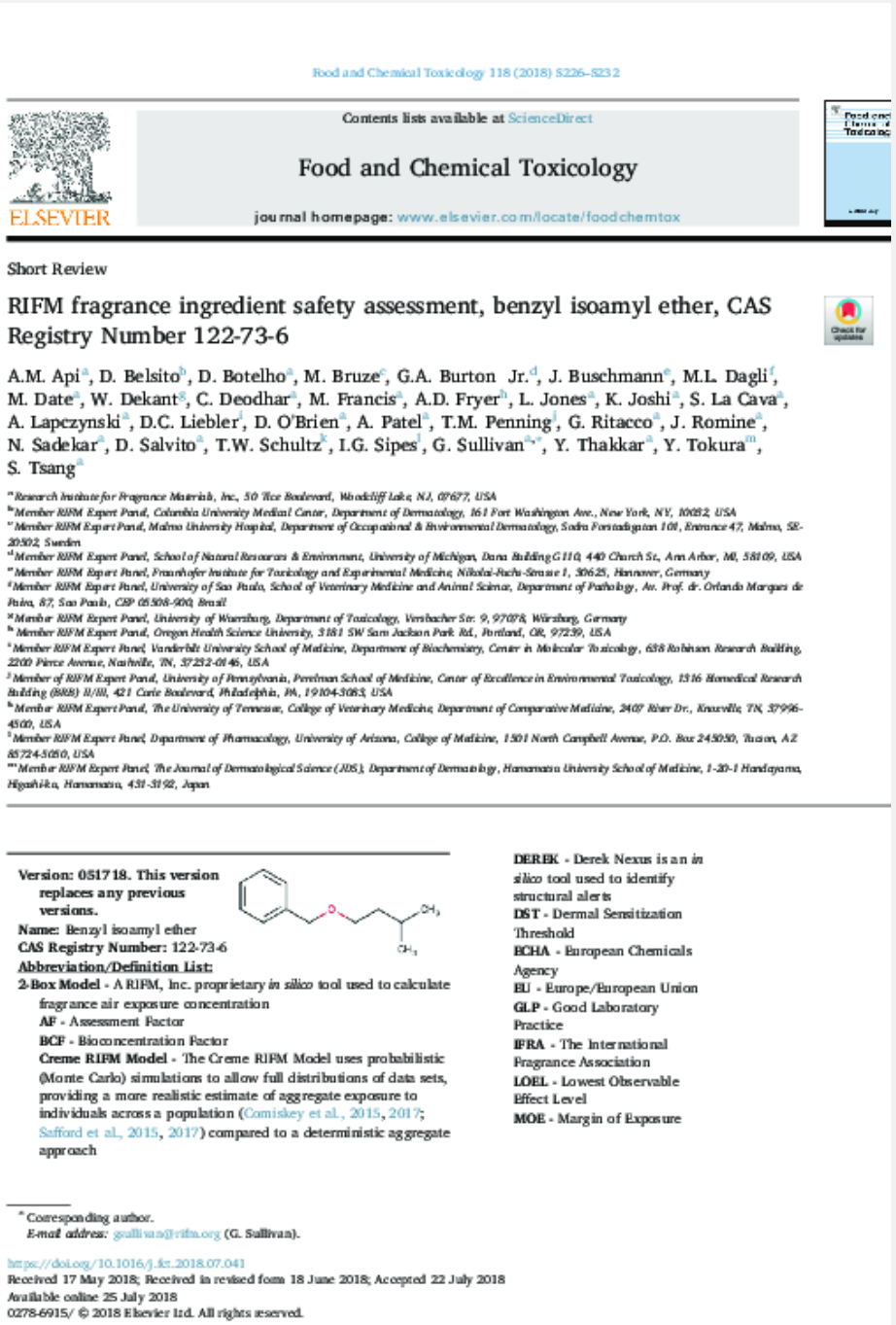
- Trade association representing majority of fragrance manufacturing in North America
- Diverse membership of 60+ companies
- Full value chain
- Proactively and reactively manage matters related to legislative, regulatory, retailer, consumer, and other stakeholders like NGOs
- FCA relies upon independent, industry science from RIFM



FRAGRANCE CREATORS ASSOCIATION®

FRAGRANCE INDUSTRY: HISTORY OF SAFETY

- Established in 1966
- Member-funded non-profit
- Diverse 60+ members
- Staffed by experts in human health and environmental toxicological endpoints



Food and Chemical Toxicology 118 (2018) S226–S232

Contents lists available at ScienceDirect

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

Short Review

RIFM fragrance ingredient safety assessment, benzyl isoamyl ether, CAS Registry Number 122-73-6

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Version: 051718. This version replaces any previous versions.

Name: Benzyl isoamyl ether
CAS Registry Number: 122-73-6
Abbreviation/Definition List:
2-Box Model - A RIFM, Inc. proprietary *in silico* tool used to calculate fragrance air exposure concentration
AF - Assessment Factor
BCF - Bioconcentration Factor
Creme RIFM Model - The Creme RIFM Model uses probabilistic (Monte Carlo) simulations to allow full distributions of data sets, providing a more realistic estimate of aggregate exposure to individuals across a population (Comiskey et al., 2015, 2017; Safford et al., 2015, 2017) compared to a deterministic aggregate approach
DEREK - Derek Nexus is an *in silico* tool used to identify structural alerts
DST - Dermal Sensitization Threshold
ECHA - European Chemicals Agency
EU - Europe/European Union
GLP - Good Laboratory Practice
IFRA - The International Fragrance Association
LOEL - Lowest Observable Effect Level
MOE - Margin of Exposure

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https://doi.org/10.1016/j.fct.2018.07.041
Received 17 May 2018; Received in revised form 18 June 2018; Accepted 22 July 2018
Available online 25 July 2018

FRAGRANCE INDUSTRY: HISTORY OF SAFETY

- Maintain a continuously updated database of safety data
- Generate exposure data using Creme-RIFM Aggregate Exposure Model
- Conduct detailed safety assessments that are peer reviewed and published
- All publications are open-access and available on the Fragrance Material Resource Center
- Research innovative new approach methodologies (NAMs)

FRAGRANCE INDUSTRY: HISTORY OF SAFETY

EXPERT PANEL for FRAGRANCE SAFETY

Independent team of experts (academics, physicians) with no affiliations to industry

Critically review RIFM's safety assessments and research projects

Determines safety of use for fragrance ingredients through consideration of available information and active generation of additional data

FRAGRANCE INDUSTRY: HISTORY OF SAFETY

- Abundance of guidelines for proper safety testing
  - Good Laboratory Practice
  - Organization for Economic Cooperation and Development
  - National Toxicology Program

NTP
National Toxicology Program
U.S. Department of Health and Human Services

GOOD LABORATORY PRACTICE
GLP
GOOD LABORATORY PRACTICE

OECD

ROLE OF FRAGRANCE IN OTC DRUGS

- Excipient ingredients
- Enhance smell
- Mask malodor
- Palatability/appeal to consumers

FRAGRANCE CREATORS' STANCE ON OMUFA

- Value safety and innovation
- Appreciate OMUFA's flexibility
- Support collection of fees for OTC monograph activities
  - Believe in discretion as to where funds are allocated

SUGGESTIONS FOR EFFICIENT APPROACH

- Identify industries with a strong safety record
  - Take advantage of existing safety information/expertise
- Use FDA resources where gaps exist

FRAGRANCE INDUSTRY: FDA REGULATION

- Resource for FDA Office of Cosmetics and Colors in implementing the *Modernization of Cosmetics Regulation Act*

CONCLUSIONS

- OMUFA program can be most efficient if FDA does not have to duplicate work
- Fragrance Creators is the expert source for fragrance related matters
- RIFM is the expert source and scientific authority for Fragrance Safety Information

THANK YOU!

Gil Roth

Pharma and Biopharma Outsourcing Association

President

Emily Manoso

Personal Care Products Council

General Counsel and EVP for Legal and Regulatory Affairs

James Kim

American Cleaning Institute

Senior Vice President, Science & Regulatory Affairs

Meredith Petillo

Independent Beauty Association

VP, Technical and Regulatory Affairs

Panel 2:
Academic and Advocacy Perspectives

Dr. Eric Brass

University of California, Los Angeles

Professor Emeritus of Medicine

OMUFA and improving the public heath: Opportunities and challenges

Eric P. Brass, M.D., Ph.D.

Professor Emeritus of Medicine

David Geffen School of Medicine at UCLA

OMUFA and evolution of the OTC monograph

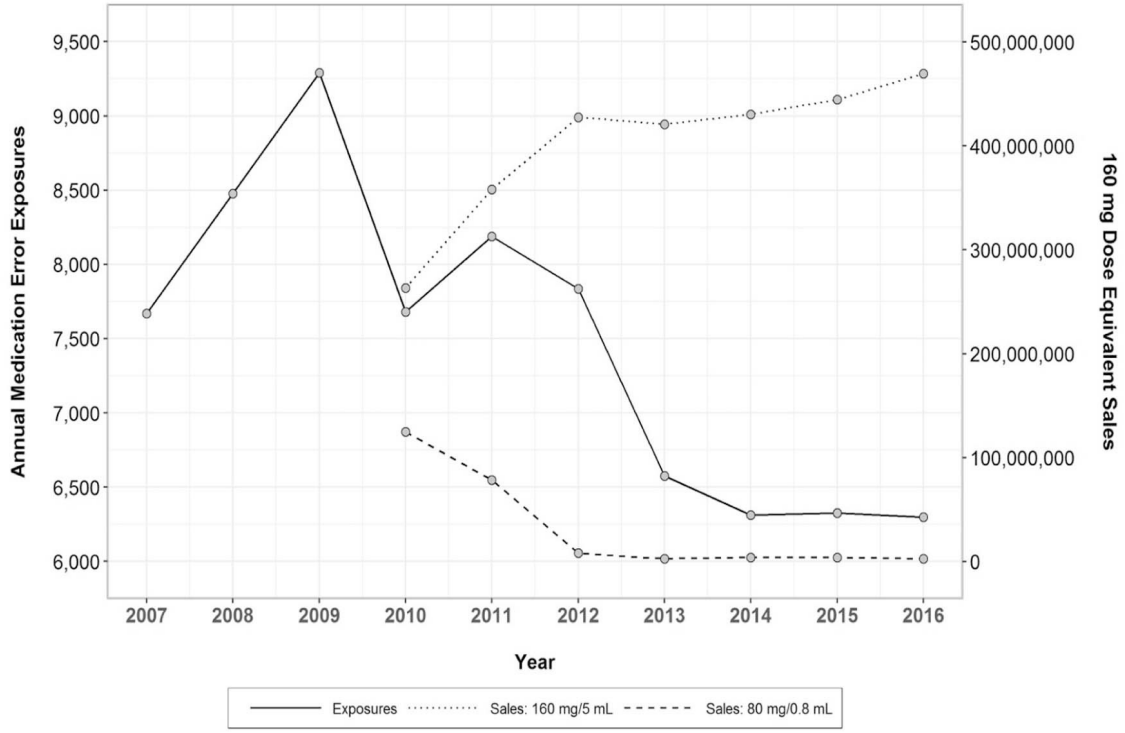
- The OTC monograph has facilitated consumer access to safe and effective ingredients in a broad range of drug products for 50 years
- Born out of necessity, the monograph process has often limited important actions by industry and regulators
- OMUFA I initiated long overdue reforms
- FDA's work to date has focused on developing the infrastructure and tools needed to institute reforms
- Now have the opportunity to implement changes targeted at public health needs
  - Reflected in FDA's latest forecast for planned monograph activities

Key tool: Over-the-counter monograph order request (OMOR)

- OMUFA II Proposed Commitment Letter
    - “Addition of a new ingredient to a monograph that already has one or more ingredients that have been found to be GRASE.”
    - Specified Safety Change OMOR: “An instruction about dosage and administration that is intended to increase the safe use of the monograph drug product”.
        - “…Safety Change OMORs have a shorter timeline for FDA action…”

Medication errors with pediatric acetaminophen products during therapeutic use

- Voluntary actions in 2011:
  - Tabular format for dosing (weight and age)
  - Use only milliliter units
  - Include calibrated dosing device consistent with dosing instructions
  - Standardize concentration 160 mg/5ml (FDA Guidance 2015)
- National Poison Data System exposure data



Brass et al Acad Pediatr 18:253, 2018

Residual medication errors despite voluntary actions

- **Children < 2 yo account for 66% of exposures!**
  - Where was dosing information obtained for children under 2 yo?
    - Packaging: 21%
    - Prior experience/memory 9%
    - Friend/relative 3%
    - Health professional 69%
- Label dosing instruction for children under 2 yo – “ask a doctor”
- Consumers need more information to dose properly!
- FDA Planned Activities:
  - “Addresses dosage strengths of oral, single ingredient pediatric acetaminophen products.”
  - “Proposes addition of weight- and age-based dosing for children under age 12 years”
  - Include dosing information for < 2 yo?
  - Meets criteria for Specified Safety Change OMOR and shorter review timelines?

Adding new ingredients to the monograph

- Existing monograph “Antihistammine active ingredients” include diphenhydramine, chlorpheniramine, others

- Subsequent approval of ‘2nd generation’ antihistamines for OTC marketing, including loratadine, fexofenadine, cetirizine and others

- Should 2nd generation antihistamines be added to the monograph?
  - Potential advantages:
    - More opportunities for innovation in OTC products?
    - Consistent reporting requirements for industry?
    - More facile review and action by FDA?

Challenges and questions for using OMORs to improve public health

- Who has incentive to initiate an OMOR under OMUFA procedures?
  - FDA: Address a safety concern
    - Transparent assessment of benefits and risk in decision making
  - Industry: Potential advantage clear for new ingredient vs NDA?
    - Existing ingredient – all manufacturers will benefit while one manufacturer incurs cost
    - Potential for exclusivity – but how apply to existing ingredients as in the two examples presented?
- Who has incentive to generate/submit data to support an OMOR under OMUFA procedures?
  - Consider acetaminophen dosing for children under 2 yo – clear public health need
    - Pharmacokinetic data
    - Comprehensive review of safety data/exposure relationships
    - Who has that data and does holder of the data have the incentive to initiate/participate in process

Challenges and questions for using OMORs to improve public health

- Are filing requirements for an OMOR too inflexible/onerous?
- Should there be more flexibility/tailoring to need for OMOR submission requirements?
  - Consider second generation antihistamines
    - ‘Obvious’ GRASE satisfied, labeling exists – why need more than simple summary of status/rationale?
- OMOR submission facilitated by early, explicit agreement between FDA-sponsor on data requirements

Summary

- OMUFA and OMOR processes provide mechanisms that can be used for improving consumer access to safe and effective OTC drugs
- Addition of currently marketed OTC drugs to existing monograph categories may help rationalize regulatory structure
- Acetaminophen dosing for children < 2yo is an example where a Specified Safety Change OMOR has the potential to impact public health
- However, unclear if incentives exist for industry to utilize these mechanisms

Thank you for your attention

Dr. Diana Zuckerman

National Center for Health Research

President

Public Comment

Public Commenters

- Marc Scheineson
- Kim Wezik
- Samantha Wigglesworth
- Samantha Sears

FDA Public Meeting: Recommendations for OMUFA Reauthorization

Statement of Marc J. Scheineson, Esq
Partner
Alston & Bird
Representing Client Drug Repackagers

November 20, 2024

ALSTON & BIRD

www.alston.com

Definition of OTC Monograph Drug Facility

- Technical glitch exists in OMUFA Facility Fee (744L(10)(A))
- Definition of "OTC Monograph Drug Facility"
  - Foreign or domestic business or other entity
  - Under one management, direct or indirect
  - At least one geographic location or address engaged in manufacturing or processing finished dosage form of OTC monograph drug
  - **Includes a finished dosage form manuf. facility in contractual relationship with sponsor of one or more OTC monograph drugs to manuf. or process such drugs**; and
  - Does not include business or other entity whose only manuf. or processing activities:
    - Production of clinical research supplies
    - Testing, or
    - Placement of outer packaging on packaging containing multiple products…

Improper Application of Facility Fee to Repackagers

- Many repackagers have no contractual relationship w/ OTC monograph drug sponsors
- They buy larger quantities from primary drug wholesaler-distributors (e.g., repack 1,000 tablet bottles into 100 ct. bottles; or create unit dose packs for physician/patient convenience)
- These downstream entities should not be assessed annual $34,166+ facility user fee
  - No benefit derived from OMUFA (funding streamlined drug monograph system)
  - Definition meant to be read as series (A,B and C)-requiring relationship w/ sponsor
  - Will eliminate downstream handling of OTC drug products
  - Disincentive to orgs. to carry OTC drugs because of cost; making more expensive Rx drugs a formulary preference

Thank you

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ALSTON & BIRD

www.alston.com

Closing Remarks

U.S. FOOD & DRUG ADMINISTRATION

THANK YOU