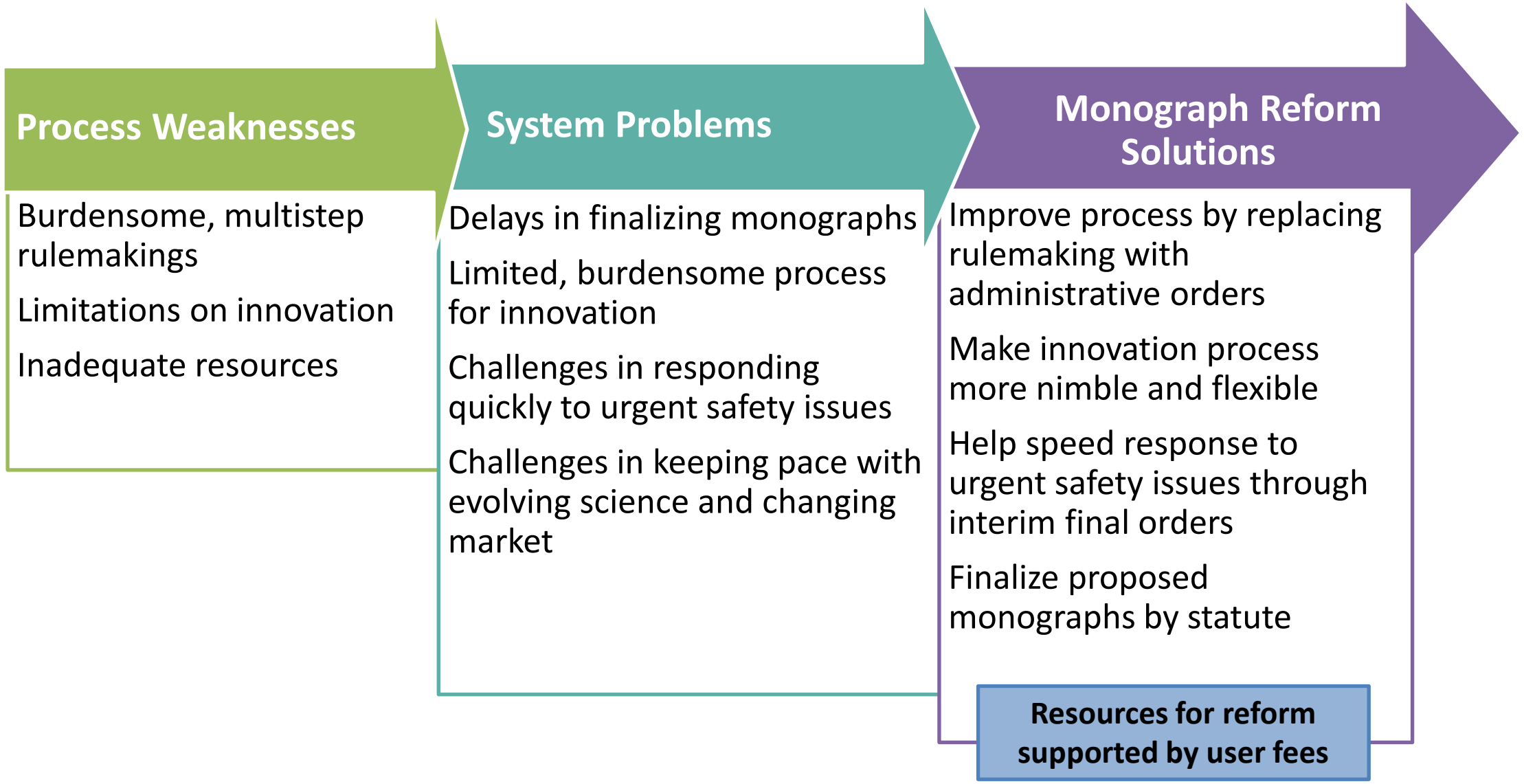
OMUFA REAUTHORIZATION: INTRODUCTORY PUBLIC MEETING

Introduction

- Why OTC Monograph Reform and user fees were needed
- OMUFA I accomplishments
- OMUFA I financial information
- Process for reauthorization
- Questions for public input

OTC Monograph Reform- Why it was Needed



OTC Monograph Reform in the CARES Act

- On March 27, 2020, the “Coronavirus Aid, Relief, and Economic Security Act” (CARES Act) was enacted
- Included important statutory provisions that reform and modernize the way OTC monograph drugs are regulated in the United States
  - Replaces the rulemaking process with an administrative order process to establish, revise, or amend OTC monographs
- Grants FDA the authority to assess and collect fees from regulated industry

OMUFA Goals Years 1-3*

Activity	Date Associated with Specified Activity						
	Year 0	Year 1	Year 2			Year 3	
	Oct 2020	Oct 2021	Feb 2022	Apr 2022	Jul 2022	Oct 2022	Feb 2023
Effective date	X						
Hiring annual goal assessment		X				X	
Monograph forecast annual posting		X				X	
TFM Category I finalization activities complete		X					
Meetings draft guidance issued			X				
Public-facing IT dashboard contract awarded		X					
Public-facing IT dashboard functional						X	
IT platform for electronic submission receipt, archiving, and reporting Request for Proposals			X				
IT platform initial contracts awarded				X			
Content and format draft guidance issued				X			
Dispute resolution draft guidance issued							X
Meeting management goals begin						X	
Pre-OMUFA paper cataloging contract awarded							X

*Adapted from the OMUFA Goals Document

OTC Monograph Reform Accomplishments

- Hiring goals
- Annual Forecast for Planned Monograph Activities
- New IT systems: OTC Monographs @FDA, CDER NextGen Portal, and internal review management system
- Paper Cataloging Project Contract Issued
- Draft Guidances
  - OTC Monograph Meetings
  - Electronic Submissions
  - Dispute Resolution and Administrative Hearings
  - OMOR Format and Content
  - Assessing OMUFA User Fees
- Meeting management timelines and goals
- Deemed Final Orders

OMUFA Hiring Goals

Fiscal Year	Hiring/Onboarding Target	Actual Onboard
2021	30	30 (13 in FY21; 17 in FY22)
2022	24	24 (19 in FY22; 5 in FY23)
2023	23	11*
2024	19	Future Goal
2025	9	Future Goal

*as of Sep 11, 2023

Annual Forecast

Each year FDA will post a nonbinding list of OTC monograph issues FDA intends to address in the coming 3 years

Activities on the forecast guided by public health priorities

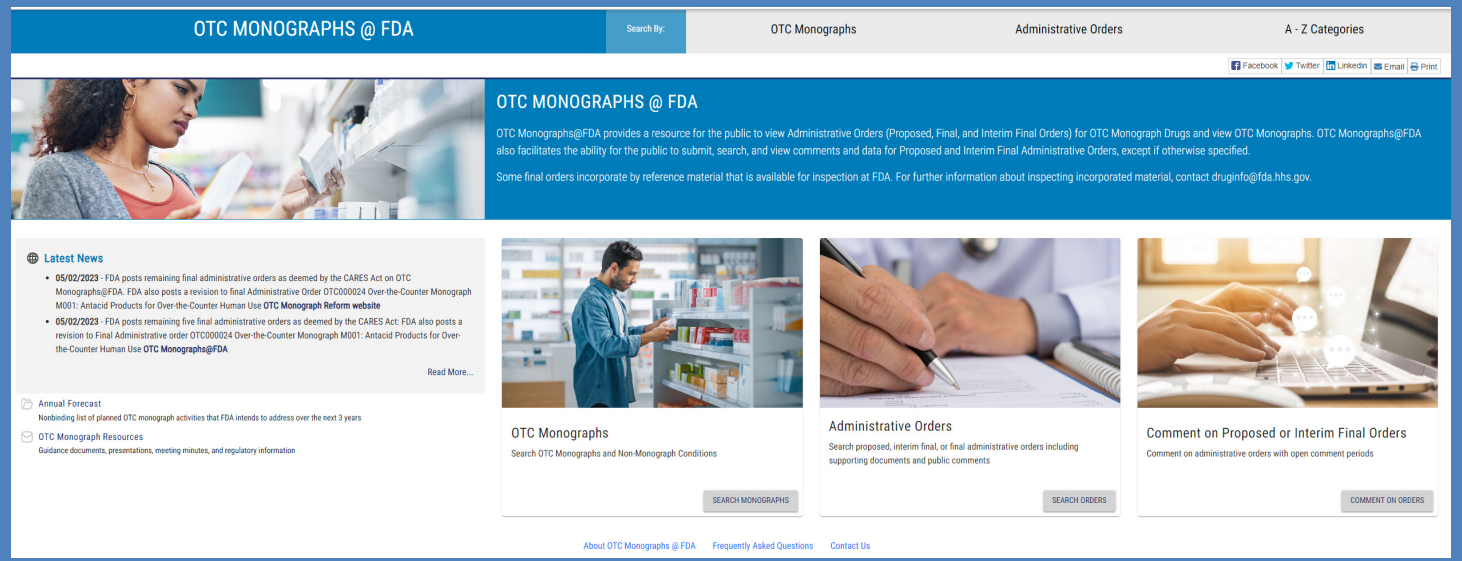
Order of topics does not reflect planned chronological order of FDA actions or order of public health importance

May include planned safety orders, GRASE finalizations, or other monograph issues

New IT Systems

FDA CDER NextGen Portal

OTC MONOGRAPHS @ FDA



Paper Cataloging Project

- Prior to monograph reform, there was no IT system for OTC monograph drugs
- Monograph files available in dockets and in paper files at FDA
- Project organizes and catalogs paper monograph documents at FDA, and makes catalog publicly available

OTC Monograph Formal Meetings Draft Guidance

- Specifies procedures and principles for formal meetings with FDA and sponsors or requestors of OTC monograph drugs
- Describes procedures under which meeting requesters can meet with appropriate FDA officials to obtain advice on:
  - Studies or other information necessary to support a submission under section 505G of the FD&C Act
  - Matters relevant to the regulation of OTC monograph drugs
  - Development of new OTC monograph drugs
- Specifies procedures to facilitate efficient participation by multiple sponsors or requestors and/or organizations nominated by them to represent their interests

OTC Monograph Formal Meetings with FDA

- Monograph meeting goals started October 1, 2022
- Goal to meet 50% of total meeting management goals for the first 12 meetings
- Currently exceeding meeting management goals

OMOR Format and Content Draft Guidance & OTC Submissions in Electronic Format Draft Guidance

- Content and Format guidance provides FDA's recommendations on the format and content of the information requestors should provide in an OTC Monograph Order Request (OMOR)
- All OMORs must be submitted in electronic format
- Electronic Format Guidance describes what documents must be submitted electronically, and provides "how to" recommendations

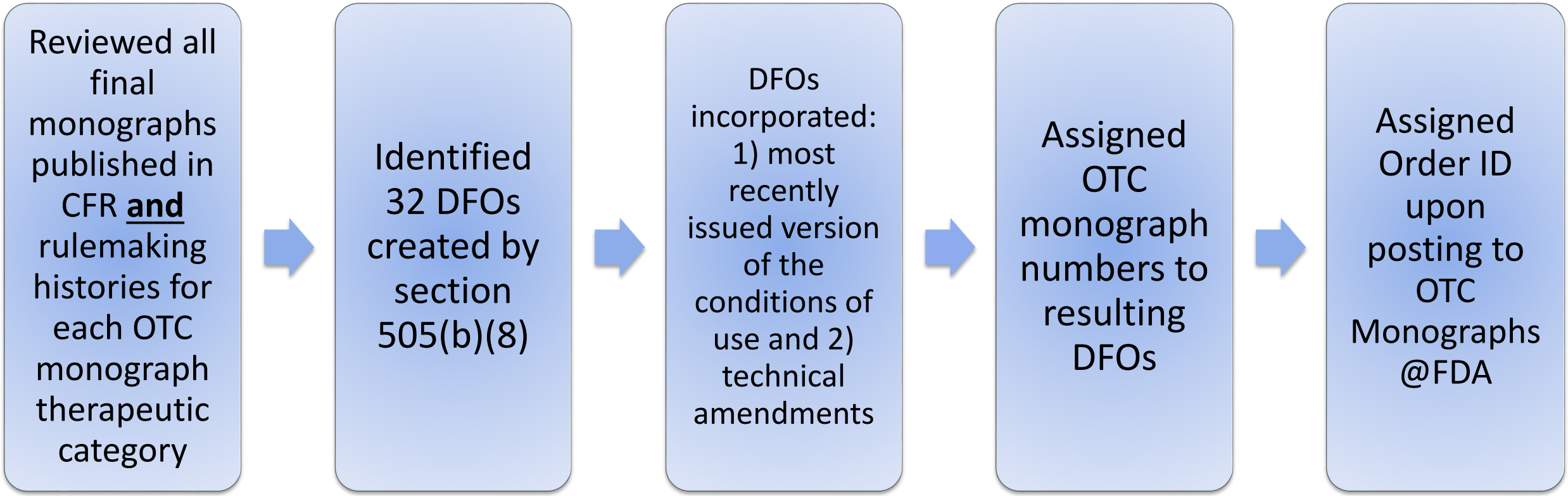
Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Draft Guidance

- Provides recommendations on the formal dispute resolution (FDR) process for resolving scientific disputes regarding final monograph orders
- Also provides guidance on the process for administrative hearings
- Includes consolidated proceedings for FDR

Deemed Final Orders (DFOs)

- Established legislatively by CARES Act
- Effective on March 27, 2020
- Established current monograph requirements for each therapeutic category
- DFOs include 32 different monograph categories
  - Include technical amendments necessary to ensure that the order is appropriately harmonized, in terms of terminology or cross-references, with applicable provisions of the FD&C Act (and regulations)
  - Combine most recently promulgated regulations for a given monograph into one document
- DFOs are posted at OTC Monographs@FDA

DFOs for OTC Monographs Under 505G(b)(8): Process for Making Available



Deemed Final Orders Complete!

- Last 5 DFOs posted May 2
  - M003: First Aid Antiseptics
  - M004: First Aid Antibiotics
  - M007: Laxatives
  - M017: External Analgesics
  - M021: Anticaries
- Completed process of posting 33 DFOs for 32 different monograph therapeutic categories and one for non-monograph conditions
- Important first step for FDA-initiated safety orders and OMORs
- Next step: Issue an FRN to withdraw the corresponding regulations

OTC Monograph Reform: OMOR Format and Content & Electronic Submissions - 08/22/2023 | FDA	Webinar	8/22/2023	Submissions Content/Format
OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2023 User Fees and Registration	Webinar	5/16/2023	OTC Drug Regulation, User Fees
Overview of FDA's Proposed Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use	Webinar	2/1/2023	OTC Drug Regulation
OTC Monograph Reform: Overview of Draft Guidance for Formal Meetings	Webinar	3/29/2022	OTC Drug Regulation, Clinical Trials and Research, Regulatory Submissions, FDA Meetings/Communications
OTC Monograph Reform: Deemed Final Orders	Webinar	12/15/2021	OTC Drug Regulation
OTC Monograph Reform: OTC Sunscreen Drugs	Webinar	12/15/2021	OTC Drug Regulation
OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2021 User Fees Webinar	Webinar	6/3/2021	OTC Drug Regulation
OTC Monograph Reform in the CARES Act: Safety Orders	Webinar	1/27/2021	OTC Drug Regulation
Monograph reform is here! Learn what to expect and how to prepare.	Webinar	5/29/2020	Regulatory Submissions; OTC Drug Regulation

OMUFA Goals Years 3-5*

Activity	Date Associated with Specified Activity						
	Year 3		Year 4		Year 5		
	Apr 2023	Jul 2023	Oct 2023	Apr 2024	Oct 2024	Feb 2025	Apr 2025
Monograph annual forecast			X				
Meetings final guidance		X					
Public facing IT dashboard functional							
Pre-OMUFA paper document cataloging complete						X	
IT platform business requirements/ fully functional	X						X
Meeting management goals annual assessment			X		X		
Electronic submissions final guidance							
Solid oral dosage forms order and draft guidance							X
Innovation and Safety OMOR TPGs begin			X				
Dispute resolution goals begin			X				
Content and format final guidance			X				

*Adapted from the OMUFA Goals Document

Coming Soon to a Monograph Near You

TITLE

SCENE.

DATE.
2023-24

MEMO

- CDER NextGen Portal for OMORs
- FRN withdrawing monograph regs
- OMOR timelines
  - For 50% of OMORs received in Year 4, FDA will issue a final order by the goal date
- Third annual monograph forecast

OMUFA Target Revenue and Fee Amounts (FY23)

Target revenue: $25,421,000

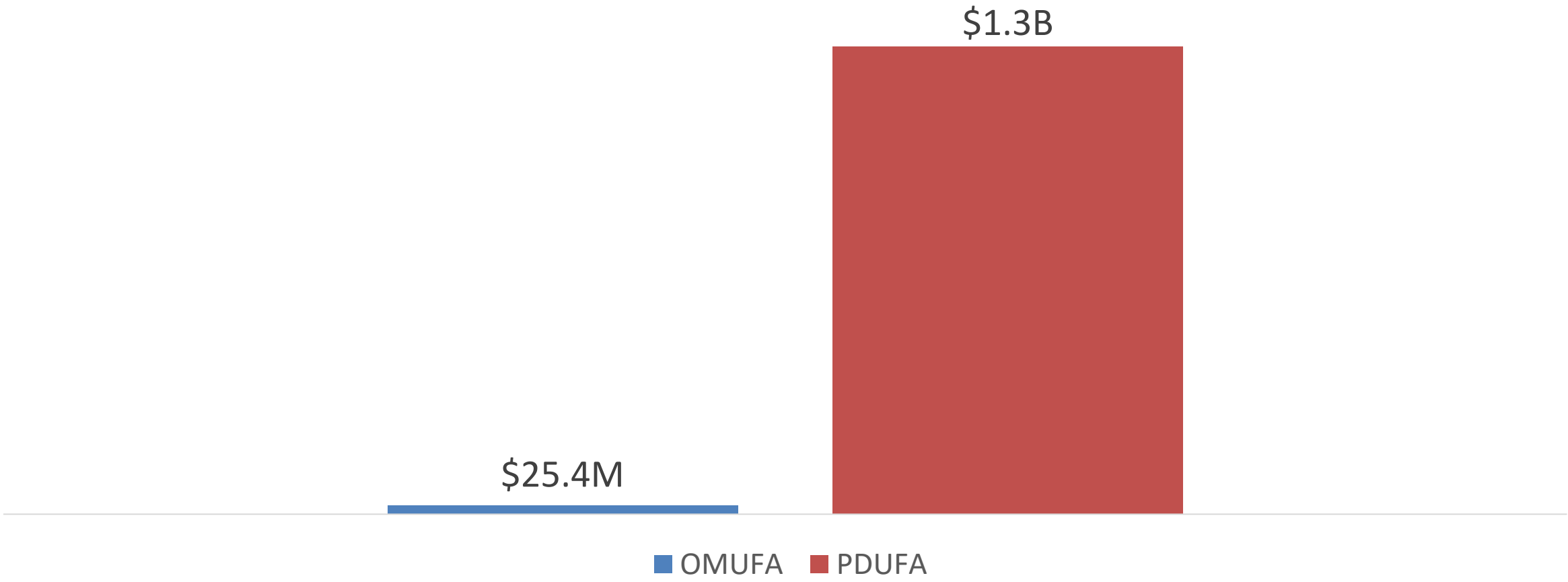
Facility fee:

- MDF: $26,153
- CMO: $17,435

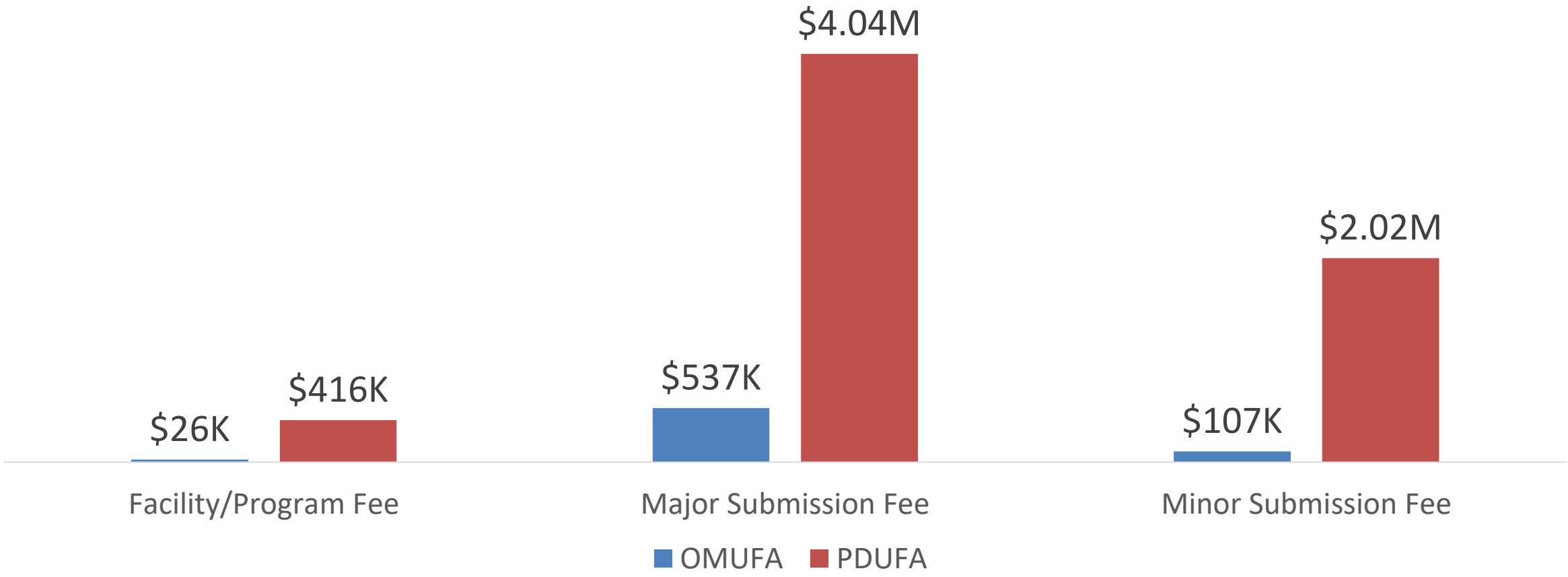
OMOR fee:

- Tier 1: $517,381
- Tier 2: $103,476

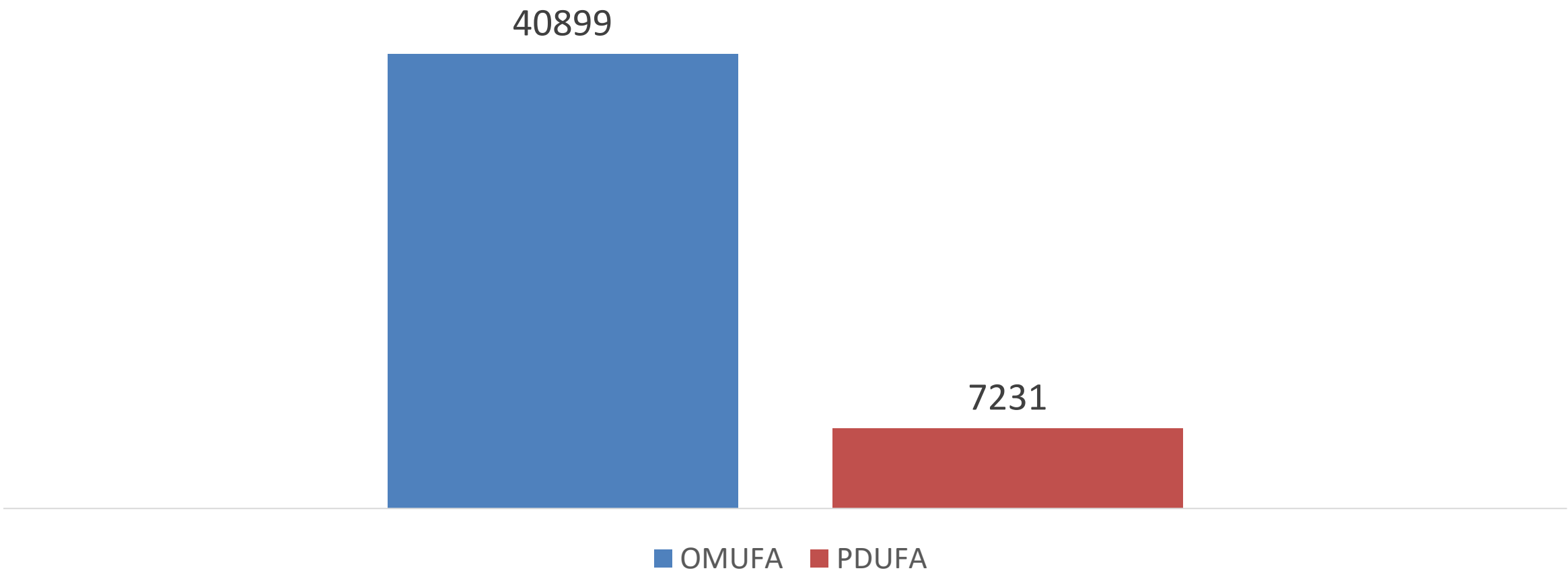
FY23 Program Target Revenue - OMUFA vs PDUFA



FY24 Fees - OMUFA vs PDUFA



Number of Listed Products
OMUFA vs PDUFA



OTC Monograph Drug Reform Benefits Patients, Industry, and our Nation's Health Care System

- Significantly reduces regulatory burden
- Encourages innovation; opens up new markets; expands breadth and depth of OTC product lines
- Enhances self-care, to help reduce need for more costly forms of care, such as emergency room visits and doctor visits
- Increases efficiency, timeliness, and predictability
- Streamlines safety updates

- Reform was guided by input from industry, consumer, patient, and professional groups; OMUFA reauthorization will be also
- FDA meeting its commitments and OMUFA I successful

Process for Reauthorization- the Basics

Consultation

- Includes today's meeting, for input from scientific and academic experts; healthcare professionals; representatives of patient and consumer advocacy groups; and regulated industry
- Includes Congressional committees (Senate HELP and House E&C)

Negotiation between Industry and FDA

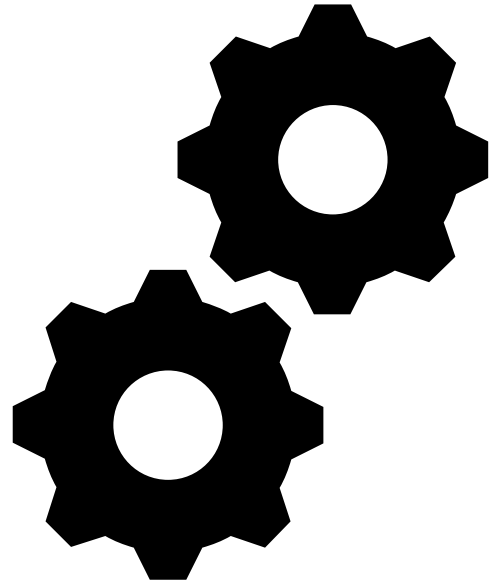
- Begins in the coming months; results in draft Commitment Letter

Public Review of Recommendations

- Draft Commitment Letter to Congress
- Federal Register Notice
- 30-day comment period
- Public meeting

Transmittal of Recommendations to Congress

- Due no later than January 15, 2025



Process for Reauthorization - Statutory Language

744N(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.

Questions for Public Input

- What new elements should FDA consider recommending to be added to the program to enhance the efficiency and effectiveness of the Agency's OTC monograph drug activities?
- What current elements of OMUFA should be modified to ensure the continued efficiency and effectiveness of the Agency's OTC monograph drug activities?

OMUFA Resources

- OTC Monograph Reform in the CARES Act https://www.fda.gov/drugs/over-counter-otc-nonprescriptiondrugs/over-counter-otc-drug-review-otc-monograph-reformcares-act
- OTC Monographs@FDA https://dps.fda.gov/omuf
- Historical Status of OTC Rulemakings https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/historical-status-otc-rulemakings