OTC REFORM LEGISLATION

PCPC Member Webinar
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PRESENTERS

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Tom Myers is the EVP-Legal & General Counsel for the Personal Care Products Council (PCPC) and is responsible for managing legal and regulatory issues facing the industry. Myers provides legal and strategic advice to the organization, and assess potential risks and liabilities for the organization. Tom manages an extensive litigation portfolio; develops domestic regulatory strategy; and serves as key adviser on issues of governance, risk management and policy implementation for the organization. Before coming to PCPC, he spent more than two decades in private practice.

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Emily Manoso is the Assistant General Counsel at PCPC. Her primary areas of focus include litigation, Over-the-Counter drug regulations, claims, and other related topics that impact the industry. Emily also serves as the primary PCPC liaison for the PCPC Sunscreen Committee. In this capacity, she is familiar with many of the regulatory policies and challenges facing sunscreen manufacturers and suppliers. Prior to joining PCPC in 2016, Emily was an Assistant District Attorney in Charlotte, North Carolina where she conducted numerous bench and jury trials.

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Wade Ackerman is a partner in Covington's FDA Regulatory group and is based in Los Angeles. Wade provides clients with strategic FDA regulatory and policy advice to companies and trade associations marketing products regulated by the Agency. He previously served as Senior FDA Counsel to the Senate Health Education, Labor & Pensions (HELP) Committee where he handled all FD&C Act legislation. Prior to his Senate role, Wade worked in FDA's Office of Chief Counsel (OCC) for over five years. He is currently working on behalf of PCPC and its members on various regulatory and policy issues.

WHAT HAPPENED

- On March 27, 2020, Congress enacted the "Coronavirus Aid, Relief, and Economic Security Act" ("CARES Act"), which *included* OTC monograph reform provisions.

- The OTC provisions fundamentally change how FDA regulates drugs marketed under a monograph.

OVERVIEW OF OTC MONOGRAPH DRUG REVIEW

As conceived in 1972, the OTC Monograph Drug Review process consisted of a three-step process

Advisory Review Panels review and categorize classes of OTC drugs:

- Category I: GRASE
- Category II: not GRASE
- Category III: Insufficient data available to determine if safe and effective

FDA publishes the panel's recommendations in an Advance Notice of Proposed Rulemaking (ANPR)

After reviewing the panel's findings, FDA publishes its conclusions in a tentative final monograph (TFM)

FDA reviews submissions to the TFM and publishes the final monograph

REFORM: REGULATORY STATUS OF OTC PRODUCTS

Final Monographs

- Final Monographs are deemed final administrative orders and drugs marketed in conformity with a final monograph will not be considered a new drug requiring premarket approval.
- Special provisions for Sunscreens Stayed Final Monograph (1999).

Tentative Final Monographs (TFM)/Advanced Notice of Proposed Rulemaking (ANPR)

- Product status post OTC Reform depends on what Category (I, II, III) the product or ingredient was placed into in prior rulemaking—see next slide.

REFORM: REGULATORY STATUS OF TFMS AND ANPRS

Category I

- If Category I for safety and effectiveness and adheres to requirements of monograph, not considered a new drug.
- Treated as if TFM were a final rule; but Cat I in ANPRs treated same as Cat III in TFMs (see below).

Category II

- Not GRASE for either safety or effectiveness, and must be removed from the market within 180 days.
- Note if Cat I for efficacy, but Cat II for safety, the Cat II for safety controls and product must be removed absent further action from FDA.

Category III

- May remain on the market without approved NDAs unless FDA issues a final administrative order determining they are not GRASE.
- Same applies to Cat I in ANPRs.

REGULATORY STATUS OF OTC MONOGRAPH PRODUCTS

- How do you determine what is governing?

  - Look for "***the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal 2 Regulations.***"

  - We will use three product types to illustrate these concepts- Hand Sanitizers, Skin Bleaching, & Sunscreens

ANTISEPTIC HAND WASHES, CATEGORY III-TFM

Final Rule issued in April 2019 finalized 1994 TFM

FDA did not make a GRASE determination for three active ingredients, Category III

May continue to be marketed pending final administrative order from FDA

SKIN-BLEACHING-PROPOSED RULE, CATEGORY II

1982 Tentative Final Monograph

In a 2006 proposed rule, proposed to withdraw 1982 TFM and FDA tentatively conclude[d] that skin bleaching products, including but not limited to those that contain hydroquinone . . . should not be considered GRASE", i.e. Category II

Products would be new drugs 180 days after Mar. 27, 2020.

STATUS OF THE SUNSCREEN MONOGRAPH

Stayed 1999 Final Monograph

- GRASE if complies with stayed 1999 Final Monograph.
- **No longer operating under 2019 TFM, but see Next Steps.

Labeling

- GRASE if it conforms with the 1999 final monograph, and the testing and labeling requirements in 21 C.F.R. § 201.327.
- **No longer operating under 2019 TFM, but see Next Steps.

Next Steps

- No later than 18 months after enactment (September 2021), FDA must issue a proposed admin. order.
- This could include all or a portion of what FDA outlined in the 2019 TFM-we just don't know right now.
- No date for final administrative order but final order must have an effective date of at least one year after the publication of the revised order.

ADMINISTRATIVE ORDER: TYPES

FDA Initiated

- Public notice and comment; dispute resolution; opportunity for administrative hearing*; judicial review

Industry Initiated

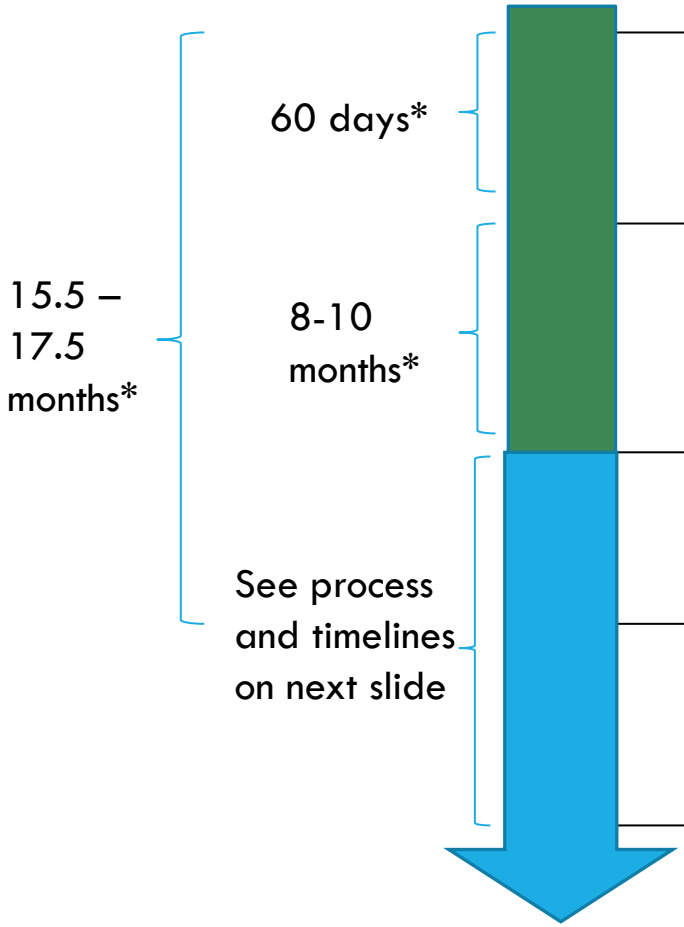
- Public notice and comment; dispute resolution; opportunity for administrative hearing*; judicial review

Expedited Orders

- Issued in *final form* before opportunities for notice and comment, dispute resolution, etc.
- Issued when drugs are deemed "imminent hazard"
- Public notice, etc. available *after* order takes effect

* FDA can deny if no new safety data has been submitted to docket or if no genuine and substantial question of material fact

PROCESS FOR INDUSTRY-INITIATED ADMINISTRATIVE ORDERS (E.G. ADD SUNSCREEN ACTIVE INGREDIENT)



Sponsor submits a request for an industry-initiated administrative order. Request may be related to whether a drug is GRASE or whether a change to a condition of use of a drug is GRASE.

FDA makes filing determination. If request is sufficiently complete, FDA files the request and initiates proceedings.

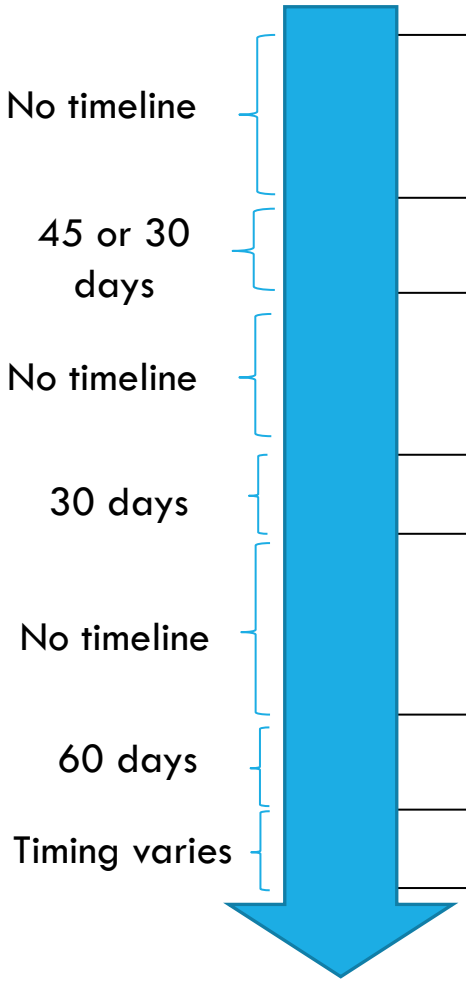
FDA issues a proposed administrative order.

FDA issues a final administrative order.

Final order becomes effective.

* Based on OTC monograph user fee goals negotiated in 2017.

PROCESS AND TIMELINES FOR ADMINISTRATIVE ORDERS



FDA issues proposed administrative order. Before issuing an FDA-initiated proposed order, FDA must notify sponsors of affected drugs at least 2 business days before the issuance of the order. FDA must provide at least 45 days of comment (or 180 days if not GRASE for Cat III TFM, Cat I ANPR).

FDA issues final administrative order.

Sponsors initiate formal dispute resolution (FDR). Manufacturers have opportunity to FDR up to the CDER Director. There could be two or three rounds of dispute resolution depending on the initial FDR.

CDER Director issues final decision under FDR.

Sponsors submit a request for a hearing. Hearing procedures are outlined in legislation and incorporate elements of FDA's Part 15 and Part 16 hearings (e.g. cross-examination).

FDA issues final decision after a hearing.

Sponsors seek judicial review.

Final order becomes effective unless stayed by court or FDA.

OTC MONOGRAPH USER FEES

Facility Registration Fees

- Entities that manufacture or process finished OTC drugs
- FDA to publish facility fees by 5/11/2020
- FY 2021 fees due the later of 7/1/2020 or 45 days after FDA publishes fee list in Fed Reg

Order Request Fees

- Persons who submit an OTC monograph order request
- Tier 1: $500,000 (any request that is not Tier 2)
- Tier 2: $100,000 (minor monograph modifications)

NOTE: A drug is "misbranded" if made in a facility that did not pay user fees

IMPACT TO SUNSCREEN INNOVATION ACT?

"Sunsets" the SIA

on 9/20/2022

UNTIL THEN:

- Sponsor of sunscreen active subject to proposed sunscreen order may choose to continue under SIA provisions or the new admin order process.
- Final sunscreen orders no longer incorporated into final monograph; rather automatically deemed final admin order.
- Sponsors can request confidential meetings.
- Final order will provide requestor 18 months exclusivity from date sunscreen ingredient can be *lawfully marketed*.

OTHER SIGNIFICANT ISSUES: EXCLUSIVITY

18 Month Exclusivity

Available for the requestor of an industry-initiated administrative order for:

- Drug containing an active ingredient (including any ester or salt of the active ingredient) not previously in an OTC monograph drug;
- Drug with a change in the conditions of use of a drug for which "new human data studies conducted or sponsored by the requestor" were essential to issuance of order.

Exclusivity begins on the date the requestor "may lawfully market such drugs pursuant to the order."

OTHER SIGNIFICANT ISSUES: MINOR DOSAGE FORM CHANGES

- Manufacturer may make certain dosage form changes to a GRASE drug without approval from FDA.
  - **BUT:** FDA must first issue an administrative order specifying which dosage form changes are acceptable. Manufacturer must maintain information demonstrating that dosage form change will not affect safety or effectiveness.
  - **NOTE:** Manufacturer can continue to make changes that fall within the administrative order.

OTHER SIGNIFICANT ISSUES: CONFIDENTIALITY

- Trade secret and confidential commercial information submitted by a manufacturer in connection with administrative order proceedings (including in meetings with FDA) are confidential.
  - **BUT:** Information will become public when FDA issues a proposed administrative order related to the request.
  - **EXCEPTIONS:** Certain information will remain confidential:
    - Pharmaceutical quality information (e.g. testing methods) unless necessary to establish GRASE standards.
    - Information submitted to an administrative order request withdrawn before FDA issues proposed order.
    - Information submitted in response to FDA request under minor changes provision.
    - Information contained in raw datasets.

OTHER SIGNIFICANT ISSUES: ORDERS FOR NEW ACTIVES?

- YES, BUT:
  - **YES:** FDA could feasibly accept requests for orders permitting active ingredients not previously used in the U.S.
  - **BUT:** *Only if* those ingredients were used under conditions comparable to those in the U.S. and subject to adverse event monitoring by agency.

Note: FDA has broad discretion to determine if requirements are met.

FDA GOALS LETTER:

Infrastructure	• Hiring, Training, Implementation of new IT system platform, guidance documents
Industry Innovation	• Tier I, II Innovation OMORs, timelines, performance goals, assumption about OMORs
Communication and Transparency	• Meetings, Planned monograph activities, safety determinations, dispute resolution, guidance and performance goals

FDA GOALS: INFRASTRUCTURE

- **Hiring**
  - New FTEs hired over 5 years
  - FY1-30, FY2-24, FY3-23, FY4-19, FY5-9**
  - FDA does not anticipate to see significant growth in effective review capacity until FY3
- **Implementation**
  - Performance goals for implementation activities such as development of guidances and hiring in the first three years.
  - By Year 3, limited performance goals can begin for meetings.
  - In Years 4 and 5, FDA expects to be able to implement timelines and limited performance goals for OMOR submission
- **Technology Platform**
  - FDA will develop specifications for a public-facing IT dashboard and award a contract, estimated some time in FY1
  - Implement dashboard by FY2
  - Request for Proposal for IT platform for receiving electronic submissions, archiving review work, and generating reports, for (OTC) drug monograph review in FY3
  - Anticipates a fully functioning IT platform for OTC drug monograph review in FY 5
- **Guidance Documents**
  - Anticipates issuing guidance documents on content and form for monograph submissions by Year 3.

**FIGURES BASED OFF GOALS LETTER DEVELOPED IN 2017. ASSUMES SIMILAR FIGURES FOR PRESENT

FDA GOALS: INDUSTRY INNOVATION

- OTC Monograph Order Requests
  - Eligibility determination for a new ingredients.
    - If currently marketed for the same Use in OTC NDA and has documented sales of over 1 million units, the requestor will submit the eligibility determination request at least 60 calendar days in advance of the OMOR submission.
      - FDA responds in 30 calendar days after receipt.
    - For other eligibility requests, requestor to submit 120 days before OMOR submission. FDA responds in 90 calendar days after receipt.

	Tier One Innovation: Eligible1 New Ingredient	Tier One Innovation: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other Monograph Change	Tier Two Innovation
Filing Determination	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR
Issuance of Proposed Order	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 10 months after receipt of OMOR
Public Comment Period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assess Comments	Begins one calendar day after the end of the comment period, and lasts 60 calendar days.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issue Final Order	17.5 months after receipt of OMOR	17.5 months after receipt of OMOR	15.5 months after receipt of OMOR

FDA ASSUMPTIONS ABOUT INNOVATION OMORs

- The first year in which Innovation OMORs will be associated with timelines and performance goals will be Year 4.
- For Innovation OMOR submissions, the following performance goals will apply:
  - Year 4: For 50% of OMOR submissions received in Year 4, FDA will issue a final order by the specified goal date.
  - Year 5: For 75% of OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date.
- Can still file OMORs in Years 1-3, but there will not be timelines or performance goals.
- FDA assumes that there would be no Innovation OMORs submitted by Industry over the first 3 years of OMUFA, that 5 Innovation OMORs would be submitted in Year 4, and that 10 Innovation OMORs would be submitted in Year 5.

FDA GOALS: COMMUNICATION AND TRANSPARENCY

Meeting Goals

FY 1: 6 meetings (not under timelines or performance goals).

FY 2: 9 meetings (not under timelines or performance goals).

FY 3: 12 meetings (with performance goal below).

FY 4: 24 meeting requests (with performance goal).

FY 5 40 meeting requests (with performance goal below).

FDA will develop guidance regarding formal meetings between FDA and sponsors or requestors for OMUFA ingredients and drug products within about two years and likely would issue final guidance by sometime in Year 3.

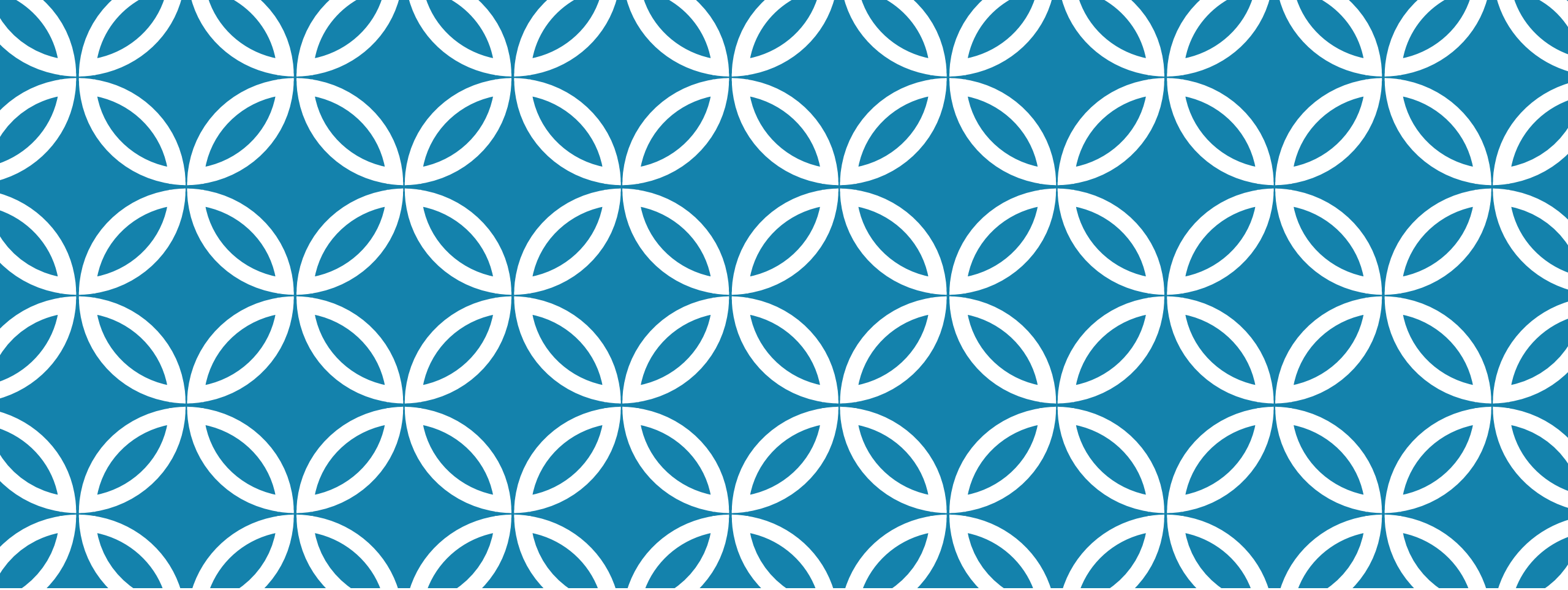
Dispute Resolution Goals

Performance goal: For dispute resolution requests received in Year 4, FDA will meet 50% of the timeline dates.

For dispute resolution requests received in Year 5, FDA will meet 75% of the timeline.

INTERSECTION WITH COSMETICS REFORM

- **Requirements for OTC Drug / Cosmetic Products**
- **User Fees**



THANK YOU!