Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022

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Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022

I. Introduction and Background

This draft document contains the performance goals and procedures for the Over-the-Counter Monograph Drug User Fee Act initial program. If the program is enacted by Congress, the program will likely subsequently be abbreviated OMUFA. For simplicity, the program will generally be abbreviated as OMUFA in the remainder of this document. The over-the-counter drug monograph will generally be referred to simply as the monograph. The document assumes that the effective date of the OMUFA program will be October 1, 2017, and that it will cover fiscal years (FYs) 2018-2022. If the program has a different effective date, goal dates in this document will need to be adjusted accordingly.

For user fee programs, this type of document is commonly referred to as the "goals letter" or "commitment letter." This goals document represents the product of FDA's discussions with the regulated Industry, and consideration of input by public stakeholders.

OMUFA discussions ensued from prior discussions of the need for extensive policy reforms in order to preserve and modernize the over-the-counter drug monograph regulatory system. These reforms, if enacted by Congress, will result in numerous positive benefits to the public health, and to regulated Industry. The United States Food and Drug Administration (hereafter generally referred to as FDA) and regulated Industry have also come to agreement on the principles of a system of monograph user fees through which regulated Industry will provide resources to enable the range of review activities necessary to meet the goals of the monograph reform.

The performance and procedural goals and other commitments specified in this letter apply to aspects of the over-the-counter monograph drug review program that are important for facilitating timely access to safe and effective medicines regulated under the over-the-counter drug monograph, and to implementing the aforementioned policy reforms. While much of FDA's work is associated with formal tracked performance goals, FDA and Industry mutually agree that it is appropriate to manage some areas of the human drug review program with internally tracked timeframes. This provides FDA the flexibility needed to respond to a highly diverse workload, including unanticipated public health needs. FDA is committed to meeting the performance goals specified in this goals document and to continuous improvement of its performance. FDA and the regulated Industry will periodically assess the progress of the over-the-counter drug monograph review program. This will allow FDA and the regulated Industry to identify emerging challenges and develop strategies to address these challenges to ensure the efficiency and effectiveness of the over-the-counter monograph drug review program.

Many aspects of this goals document will be addressed in statutory language. If differences are noted between the OMUFA goals document and statutory language, statutory language will supersede this goals document.

II. Goals for the First Cycle of an Over-the-Counter Monograph User Fee Program

It should be noted that, when there are very few instances of a given activity, adherence to performance goals should be interpreted accordingly. For example, if there are so few occurrences of an activity that missing only one or two goal dates would make it appear that the performance goal was not met, a qualitative description of performance may provide more useful data to be used in improving future performance.

A. Building the Basic Infrastructure to Enable the Goals of Monograph Reform to be Met

1. Hiring

The FDA will target onboarding of the following numbers of new fulltime employee equivalents (FTEs) in each of the fiscal years (FYs) specified below.

Hiring Onboarding Targets:

FY 2018: 30
FY 2019: 24
FY 2020: 23
FY 2021: 19
FY 2022: 9

2. Training and Growth of Effective Review Capacity

FDA will work toward the above hiring goals, but it is important to note that, although new scientific reviewers begin review work immediately, new reviewers will not be fully effective immediately as scientific reviewers, and that effective review capacity will grow slowly at first. FDA scientific review work is highly technical and specialized, requiring knowledge and skills that must be taught after onboarding. Typically, two years are required for a scientific reviewer to take all the necessary training, and acquire all the knowledge and experience needed to be fully effective. This training process occurs simultaneously with assigned review work, with increasing review workload as a new reviewer gains experience and training.

Immediately prior to OMUFA, FDA expects to have approximately 35 FTE working on monograph issues, only 18 of whom work fulltime in the relevant review division. A total of 29 of these 35 FTE are expected be fully trained at the time OMUFA becomes effective, and 6 are expected to be recent hires who are still training. Given this fact, and the time required for

training of additional hires under OMUFA, and the above hiring numbers, effective review capacity is expected to grow as follows:

Mean Effective Monograph Review Capacity, FYs 2018-22:

FY 2018: 31 FTE
FY 2019: 42 FTE
FY 2020: 64 FTE
FY 2021: 88 FTE
FY 2022: 110 FTE

This concept is important, because it illustrates that during the early years of OMUFA, although FDA will be striving to meet onboarding targets, FDA will actually not begin to see significant growth in effective review capacity until FY 2020. Also of note is the fact that although hiring is to be complete by the end of FY 2022, growth in review capacity will continue beyond the end of FY 2022 as employees hired in FYs 2021 and 2022 continue and complete their training in the ensuing years.

During FYs 2015, 2016, and 2017 (which began October 1, 2016), essentially all of FDA's current monograph review capacity has been consumed by the following three activities:

- Statutory requirements of the Sunscreen Innovation Act
- Court-mandated requirements of the antiseptic consent decree
- Pressing safety activities

During FYs 2018 and 2019, FDA will continue to have mandated obligations under the antiseptic consent decree. As of the writing of this goals document, mandated obligations also continue under the Sunscreen Innovation Act during those years (and perhaps subsequent years as well), unless Congress chooses to change that law. Safety activities, for both pressing issues and routine pharmacovigilance, are continuous at FDA.

In addition, during the first three years of OMUFA, numerous activities will need to occur to put the necessary infrastructure into place, and to begin to implement the various aspects of the proposed monograph reforms. Examples of these activities include:

- Leadership development (particularly important when beginning from such a small initial staff knowledgeable in the monograph)
- Information technology (IT) platform development and implementation (no IT platform exists for the monograph prior to OMUFA)
- Development and posting of a nonbinding list of forecasted monograph activities (see Section II.C.2)
- Activities to reflect finalization of Category I ingredients from Tentative Final Monograph (TFM) status to Generally Recognized as Safe and Effective (GRASE)

- For TFM Category II ingredients, which will be deemed not GRASE (not Generally Recognized as Safe and Effective) at time of enactment, Industry requestors may elect to submit requests to submit data packages supporting the safety and/or efficacy of these ingredients. FDA resources will be required to consider these requests.
- User fee collection system implementation and collection activities

Resource estimates indicate that, in order to implement all these activities and continue externally mandated activities, FDA will be substantially "net-negative" in terms of effective review capacity for the first 3 years of OMUFA. There will be performance goals for implementation activities such as development of guidances and hiring in the first three years. By Year 3, review resources will grow to the point where 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 submissions, and will continue progressive performance goals for meeting management, guidance development, and other activities, although FDA's effective monograph review capacity will still not be expected to be at the steady state required to handle the eventual anticipated full workload of OMUFA activities. Training will continue, with expected continued growth of review capacity beyond the first five years of OMUFA as all hirees finish their training and reach full review capability.

After establishment of the necessary infrastructure, and based on estimates of review activity expected numbers provided by Industry, FDA expects that the FTE need for monograph activities at steady state will be the equivalent of approximately 140 FTE. The steady state estimate includes those activities that are expected to be part of a continuing program over time, and does not include activities that are only part of start-up and implementation. Some examples of activities expected to occur at steady state include:

- Industry-requested Over-the-Counter Monograph Order Requests (OMORs) for innovations and other changes to the monograph
- Industry-requested guidances for innovations (and administrative orders that will accompany these guidances)
- Industry-requested meetings with FDA
- Industry-requested dispute resolution, up to the Center for Drug Evaluation and Research (CDER) level, and above CDER under a new administrative hearing procedure
- Industry-requested finalizations of GRASE determinations for nonfinal monograph ingredients and other monograph conditions of use
- Industry-requested safety changes to monograph drug labeling
- Industry resubmissions of OMORs for which a previous final order did not result in the requested change to the monograph
- FDA-requested safety changes to monograph drug labeling
- FDA-requested packages for GRASE determinations
- Other monograph review activities

- Other guidance and policy development
- Information technology support
- Reporting
- User fee management
- Other activities specified in the OMUFA statute

In summary, during the first three years of OMUFA, essentially all effective review capacity is expected to be consumed by current external mandates, safety activities, and OMUFA implementation and infrastructure development activities. Beginning in Years 4 and 5 (and to a limited extent in Year 3), FDA expects to have built sufficient effective review capacity to begin to have timelines and performance goals for review activities expected to be part of the steady state of a monograph review program.

3. Development and Implementation of an Information Technology Platform

Prior to OMUFA, no IT platform exists for the monograph, a lack which greatly hampers review efficiency.

a. Development of the Information Technology Platform

FDA will develop specifications for a public-facing IT dashboard and award a contract by October 1, 2018.

FDA will implement the above public-facing IT dashboard by October 1, 2019.

FDA will issue a Request for Proposals for an information technology (IT) platform for receiving electronic submissions, archiving review work, and generating reports, for over-the-counter (OTC) drug monograph review, by February 1, 2019.

FDA will award the initial contracts for the above IT platform by April 1, 2019.

FDA will establish business requirements for the above IT platform by April 1, 2020.

FDA will establish a fully functioning IT platform for OTC drug monograph review by April 1, 2022.

b. Electronic Submissions

In order to maximize the efficiency of the monograph review process, all monograph submissions from industry are to be electronic rather than paper. Industry may submit monograph electronic submissions to FDA starting on October 1, 2017.

FDA will provide additional information regarding electronic submissions for the monograph in draft guidance to be issued by October 1, 2019. FDA will issue final guidance for electronic submissions for the monograph by April 1, 2021.

c. Content and Format of Monograph Submissions

Initially (beginning October 1, 2017), Over-the-Counter Monograph Order Requests (OMORs) are to be submitted using content and format recommendations described in the guidance for Industry *Nonprescription Sunscreen Drug Products – Content and Format of Data Submissions.* The format recommendations of this guidance, although developed for sunscreen drug products, are generally applicable to all monograph submissions.

FDA will modify the above content and format guidance to clarify its applicability across monograph drug products. FDA will issue updated draft guidance by April 1, 2019. FDA will issue final guidance by October 1, 2020.

OMORs are expected to be complete at the time of submission, and are expected to include all information, both positive and negative, relevant to the determination of general recognition of safety and effectiveness for the ingredient or other condition(s) of use under consideration. OMOR requestors are required to submit a certification that the requestor has submitted all evidence created, obtained, or received by that requestor that is relevant to whether the ingredient or other condition of use is generally recognized as safe and effective (GRASE).

d. Cataloging of Pre-OMUFA Paper Documents

Some paper documents that reside with FDA contain information of importance relating to monograph ingredients and their review. Prior to OMUFA, FDA has not had the resources to catalog and archive these documents. Many of these documents are old and fragile. It is important to catalog the content of these documents, and FDA must retain paper documents as required by established records retention policies. Because of the large volume of these documents, and the fragility of many of them, the process of sorting, scanning, and archiving them would be costly and time-consuming. Industry does not support provision of user fee funds to permit electronic archiving of these documents during the first five years of OMUFA, but agrees that cataloging them could have value to Industry, because some of the documents may contain data that Industry requestors could use to support order requests or other activities of interest to Industry. FDA and Industry have agreed that, among IT-related goals, the

priority of creating the IT platform is higher than that of cataloging these paper documents, and therefore IT platform development would be pursued first. Cataloging will have a limited goal of identifying the monograph ingredient(s) discussed in each document, and creation of a searchable electronic catalog. Cataloged paper documents will be stored per records retention policies, but the paper documents themselves will not be scanned and electronically archived. By February 3, 2020, FDA will award a contract for the cataloging project. By Feb 3, 2022, the cataloging project will be complete. FDA will be able to initiate GRASE determinations prior to completion of the cataloging project.

B. Enabling Industry-Initiated Innovation

1. Over-the-Counter Monograph Order Requests (OMORs) for Innovations

Prior to the proposed monograph reforms, innovation under the monograph has been difficult. Under monograph reform, sponsors (hereafter referred to as requestors when referencing submission of OMORs) will be able to submit data packages (Over-the-Counter Monograph Order Requests, or OMORs) to FDA, with requests that FDA issue an administrative order for a change to a monograph. Hereafter, these packages requesting changes to monographs will be referred to as "Innovation OMORs."

a. Tier One and Tier Two Innovation OMORs

There will be two types of Innovation OMORs, referred to as Tier One Innovation OMORs and Tier Two Innovation OMORs.

Most Innovation OMORs will be Tier One OMORs. Examples include, but are not limited to, requests for the following:

- Addition of a new ingredient to a monograph that already has one or more ingredients that have been found to be GRASE
- Addition of a new indication to a monograph that already has one or more ingredients that have been found to be GRASE, and the new indication applies to one or more of the GRASE ingredients
- Addition of a new fixed-dose combination of ingredients to a monograph that already has one or more ingredients that have been found to be GRASE
- Addition of a new test method for a monograph that already has one or more ingredients that have been found to be GRASE, and the new test method applies to one or more of the GRASE ingredients
- Addition of a new route of administration for a monograph that already has one or more ingredients that have been found to be GRASE, and the new route of administration applies to one or more of the GRASE ingredients

- Addition of a new dose or concentration for a GRASE ingredient for a particular monograph
- Addition of a new monograph therapeutic category (each ingredient proposed for the new therapeutic category will be a separate OMOR)
- All other Innovation OMORs not covered in Tier Two

Tier Two Innovation OMORs will be limited to requests for the following:

- Reordering of existing information in the Drug Facts label (DFL)
- Standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph
- An ingredient nomenclature change to align with nomenclature of a standards-setting organization
- Addition of an interchangeable term under 21 CFR 330.1(i)
- Modification to existing DFL Directions for Use, in order to be consistent with a final order/guidance pair on minor dosage form changes (see Section II.B.2)
- Addition of information (either required or optional) to be included under the "Other Information" section of Drug Facts labeling, as limited by 21 CFR 201.66(c)(7)
- Other specific items may be added by FDA later as FDA gains experience with Tier Two OMORs

The decision regarding whether a proposed Innovation OMOR meets one of the above criteria for a Tier Two OMOR will be made by the review division after receipt of the OMOR.

b. Innovations May Only be Made to Ingredients that have had a Final Determination of "Generally Recognized as Safe and Effective"

Innovations may only be made to ingredients that have had a final determination of "Generally Recognized as Safe and Effective", or GRASE. Under monograph reform, ingredients that are GRASE are limited to the following:

- Ingredients that were GRASE in a Final Monograph at the time of enactment of monograph reform
- Ingredients that, immediately prior to monograph reform, were proposed as Category I in a Tentative Final Monograph
- Ingredients that have been found GRASE in a final order after enactment of monograph reform

All other ingredients will require a final GRASE determination, with finalization of all relevant monograph conditions of use for that ingredient for a particular therapeutic use, in order for FDA to consider an Innovation OMOR relevant to that ingredient. Examples of these types of ingredients that would require GRASE finalization include, but are not limited to:

- Ingredients that, immediately prior to monograph reform, were Category III in a Tentative Final Monograph
- Ingredients that, immediately prior to monograph reform, were proposed Category I in an Advance Notice of Proposed Rulemaking
- Other ingredients that have not had a final GRASE determination

Ideally, if a requestor wants to request a change for an ingredient for which a final GRASE determination has not been made, the requestor would submit an OMOR for the final GRASE determination for the ingredient and all of the relevant monograph conditions of use first, and would submit the Innovation OMOR after FDA issues its final order regarding the GRASE determination for the ingredient. However, a requestor may submit a single OMOR package that contains both the complete data necessary for final GRASE determination for that ingredient and all its relevant conditions of use (referred to as a GRASE Finalization OMOR), and the complete data to support the proposed innovation. Cosubmission of a GRASE Finalization OMOR with an Innovation OMOR will extend the GRASE Finalization OMOR timeline from receipt to issuance of the proposed order by six months, with a consequent extension of the total GRASE Finalization OMOR timeline to final order by six months. If a requestor submits a GRASE finalization OMOR, and later submits an Innovation OMOR before the final order for the relevant GRASE finalization OMOR, the timeline of the subsequently submitted Innovation OMOR will be extended by six months.

c. OMOR Packages Expected to be Complete at Time of Submission

OMOR packages are expected to be complete at the time of submission, and FDA will make a determination of whether each package is acceptable for filing. As described in Section II.A.3.c, FDA will issue guidance regarding the content and format of OMOR packages. OMOR requestors are strongly encouraged to request and attend a presubmission meeting (as described in Section II.C.1) for their proposed OMOR, to discuss the expected content, format, and tier for a particular OMOR.

d. Timelines

The following table outlines the timelines for Innovation OMOR review, i.e. review of Industry-requested changes to finalized monographs, other than Drug Facts label (DFL) specified safety changes as outlined in Section II.D.

Currently, prior to enactment of proposed monograph reforms, it takes many years to make a change to a monograph, and the goal under monograph reform is to shorten that timeframe substantially, while still maintaining public comment between proposed and final orders, and maintaining FDA's standards for safety and efficacy. These substantially shortened timeframes are reflected in Table II.B.1.d.

Eligibility determination for a new ingredient (a pre-OMOR activity):

Innovation OMORs for new ingredients will require an eligibility determination. Industry may submit a request for ingredient eligibility determination well in advance of submission of the OMOR. Minimum advance submission periods for eligibility determination requests are specified in the following paragraphs.

If the ingredient is currently marketed for the same Use in a drug product under a US OTC NDA, and the US OTC NDA drug product 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. For US OTC NDA products that meet these specific requirements, FDA will issue an eligibility determination by 30 calendar days after receipt of the ingredient eligibility determination request.

For any ingredient eligibility determination request that does not meet the specific requirements in the immediately preceding paragraph, but that the requestor believes meets eligibility requirements as stated in the applicable statute, the requestor will submit the eligibility determination request at least 120 calendar days in advance of the OMOR submission. For these other types of ingredient eligibility determination requests, FDA will issue an eligibility determination by 90 calendar days after receipt of the eligibility determination request.

Table II.B.1.d: Timelines for Innovation OMORs (Industry-Initiated Over-the-Counter Monograph Order Requests OMORs for Monograph Changes)

	Tier One Innovation: Eligible[1] New Ingredient	Tier One Innovation: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other[2] 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
Assessment of volume and substantiveness[3] of 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
Issuance[4] of final order	17.5 months after receipt of OMOR	17.5 months after receipt of OMOR	15.5 months after receipt of OMOR

Abbreviations: OMOR = Over-the-Counter Monograph Order Request
1 Eligibility determinations will be required for proposals for the addition of new ingredients to a monograph, but not for changes to other monograph conditions of use for a finalized monograph. See paragraphs immediately preceding this table.
2 This includes all proposed changes to the monograph, except for safety changes described in Section II.D, the addition of new ingredients, Tier Two Innovation OMORs, and specific changes for which FDA has issued a final guidance stating that an OMOR is not required (see Section II.B.2).
3 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review.
4 If comments received are numerous or substantive, there will be a Comment Review Extension of the final order goal date. For Tier One Innovations, the extension will be 5 months; and for Tier Two Innovations, the extension will be 3 months.

e. Comment Review Extension

If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date. For Tier One Innovations, the extension will be 5 months; and for Tier Two Innovations, the extension will be 3 months. This extension will be additive to those generated by any major amendment(s).

f. Performance Goals

The first year in which Innovation OMORs will be associated with timelines and performance goals will be Year 4 of OMUFA (Innovation OMORs received on or after October 1, 2020.)

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

Although there will not be timelines and performance goals associated with Innovation OMORs submitted in Years 1-3, requestors may still submit Innovation OMORs in Years 1-3. If resources permit, FDA intends to review these early OMORs in order of receipt, but timelines and performance goals will not apply.

g. Assumptions Regarding Expected Numbers of Innovation OMORs in First Five Years of OMUFA

The assumptions for the first OMUFA cycle were 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.

h. Major Amendments

OMORs are expected to be complete at the time of submission, and therefore, unsolicited amendments are expected to be rare. (Unsolicited amendments are amendments other than those submitted in response to a specific FDA information request.) Major amendments (whether solicited or unsolicited) submitted by the original requestor prior to issuance of the proposed order may extend the time to issuance of the proposed order by three months, and consequently may extend the final goal date by three months. Major amendments submitted by the original requestor after the end of the comment period and prior to issuance of a final order may also extend the final goal date by three months. Major amendments may apply to Innovation OMORs, Industry-initiated requests for GRASE finalizations (as discussed in Section II.F), and Industry-initiated requests for certain safety changes to the monograph (as described in Section II.D).

A major amendment may include, for example:

- a major clinical safety or efficacy study that was not previously submitted to the current OMOR
- a major reanalysis of a study or studies previously submitted to the current OMOR

i. In-Review Meeting

For filed Innovation OMORs and for filed Industry-requested GRASE Finalization OMORs, FDA will schedule an in-review meeting to be held between the requestor of the OMOR and FDA. This meeting will generally be held between 8 and 9 months after receipt of the OMOR. The OMOR requestor may request that the meeting be held either face-to-face or via teleconference.

FDA representatives at the in-review meeting are expected to include:

- The signatory authority for the OMOR review
- Discipline review team representatives from discipline areas for which substantive issues in the OMOR have been noted to date

Not less than 12 calendar days prior to the scheduled in-review meeting, FDA will send a premeeting document to the requestor. The premeeting document will include an agenda, a brief list of substantive issues noted to date, and a brief description of information requests that FDA will ask of the requestor. The total length of the premeeting document generally will not exceed three pages.

Potential topics for discussion at the in-review meeting include:

- Substantive issues identified to date
- Information requests from the review team to the requestor
- Additional data or analyses the requestor may wish to submit

Review of the OMOR will not be complete at the time of the in-review meeting, and thus definitive information regarding the content of the future proposed order will not be discussed.

j. Resubmitted Original OMORs

A resubmitted original OMOR is an OMOR resubmitted after FDA has issued a Final Order declining to make the requested change to the monograph. The resubmitted OMOR must address all of the deficiencies noted in the final order. A resubmitted OMOR pertains only to the monograph changes requested in the original OMOR; if new changes are requested, a new OMOR is required.

There will be two classes of resubmitted original OMORs: Class One and Class Two.

Class One resubmitted original OMORs are limited to the following items, or combinations of these specified items:

- Draft or final labeling
- Safety updates submitted in the same format, including tabulations, as the original safety submission, with new data and changes highlighted. (However, resubmissions with large amounts of new information including important new adverse experiences not previously reported for the ingredient(s) will be Class Two resubmissions.)
- Assay validation data
- A minor reanalysis of data previously submitted to the OMOR
- Other minor clarifying information (determined by the FDA as fitting the Class One category)
- Other specific items may be added by the FDA later as the FDA gains experience with resubmitted OMORs

Class Two resubmitted original OMORs are resubmissions that include any other items, including any items that the FDA decides would need presentation to an Advisory Committee.

The FDA and Industry do not expect any resubmitted original OMORs during the first five years of a user fee agreement.

If any resubmissions of original OMORs occur, the following timelines will apply:

Table II.B.1.j: Timelines for Resubmitted Original OMORs

	Class One Resubmission	Class Two Resubmission
Issuance of proposed order	FDA issues proposed order 4 months after receipt of resubmitted original OMOR	FDA issues proposed order 6 months after receipt of resubmitted original 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
Assessment of volume and substantiveness[1] of 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
Issuance of final order[2]	FDA issues final order 9.5 months after receipt of Class I resubmitted original OMOR	FDA issues final order 11.5 months after receipt of Class I resubmitted original OMOR

Abbreviation: OMOR = Over-the-Counter Monograph Order Request
1 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review.
2 If comments received are numerous or substantive, there will be a Comment Review Extension of the final order goal date by 5 months, for both Class I and Class II resubmitted original OMORs

Comment Review Extension: If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 5 months, for both Class One and Class Two resubmitted original OMORs.

Performance Goal:

Year 5: For 50% of resubmitted original OMORs received in Year 5, FDA will issue a final order by the specified goal date

2. Guidance Development for Innovation

Under the proposed policy reforms for the monograph, most innovations would occur through submission of an OMOR by an Industry requestor. However, it is possible that a few types of changes to the monograph could be accomplished through a process that would not require an OMOR for each change. One area where such changes might occur is for minor dosage form changes.

In order to clarify which types of minor changes to solid oral dosage forms might be possible without an OMOR (when the monograph does not already provide for these types of changes), FDA will issue a proposed administrative order outlining key requirements, and draft guidance providing details of what sponsors will need to do in order to comply with the proposed administrative order. This order and guidance are referred to together as an "order/guidance pair". FDA will issue the proposed administrative order and draft guidance by April 1, 2022.

C. Enhancing Communication and Transparency for the Public and Regulated Industry

1. Meeting Management Goals

Formal OMUFA meetings between monograph sponsors/requestors and FDA will consist of Type X, Y, and Z meetings. These meetings are further described below.

Type X meetings are those meetings that are necessary for an otherwise stalled monograph drug development program to proceed, or meetings that are necessary to address an important safety issue. A meeting requested by an Industry requestor within 3 months after FDA has taken a refusal-to-file action on an OMOR submitted by that requestor would be a Type X meeting. A meeting requested by an Industry requestor within 3 months after FDA has declined to issue an administrative order requested by that requestor would be a Type X meeting.

Type Y meetings are intended for milestone discussions during the lifecycle of Industry development programs for monograph ingredients and monograph conditions of use. Examples of appropriate circumstances for Type Y meetings include:

- Overall Data Requirements Meetings: After FDA has stated its intent to make a final GRASE determination for a particular monograph ingredient or monograph condition of use, an Industry sponsor may request a meeting to discuss the overall data requirements to support that GRASE determination. Similarly, an Industry sponsor interested in initiating an OMOR for an FDA action on a monograph ingredient or monograph condition of use may request a meeting to discuss the overall data requirements to support that OMOR.
- Presubmission Meetings: When an Industry sponsor is nearing completion of its development program for an OMOR package, the sponsor may request a meeting to present a summary of the data supporting the proposed OMOR, and of the proposed format for the OMOR package, to obtain FDA feedback on the adequacy of the proposed package. For an Innovation OMOR, the proposed Tier (One or Two) may also be discussed at the presubmission meeting. The presubmission meeting should be held sufficiently in advance of the planned submission of the order request to allow for meaningful response to FDA feedback and should generally occur not less than 3 months prior to the planned submission of the order request.

A Type Z meeting is any other type of meeting.

a. Responses to Meeting Requests

Procedure: FDA will notify the requestor in writing of the date, time, and place for the meeting, as well as expected FDA participants, following receipt of a formal meeting request. Table II.C.1.a below indicates the timeframes for FDA's response to a meeting request.

Table II.C.1.a: Meeting Request Response Time Goals

Meeting Type	Response Time (calendar days)
X	14
Y	14
Z	21

- For any type of meeting, the requestor may request a written response to its questions rather than a face-to-face meeting or teleconference. FDA will review the request and make a determination regarding whether a written response is appropriate or whether

679 a face-to-face meeting or teleconference is necessary. If FDA deems a written response
680 appropriate, when FDA responds to the meeting request, FDA will notify the requestor
681 of the date FDA intends to send the written response. This date will be consistent with
682 the timeframes specified in Table II.C.1.b below for the specific meeting type.
683 • For Type Z meetings, while the requestor may request a face-to-face meeting, FDA may
684 determine that a written response to the requestor's questions would be the most
685 appropriate means for providing feedback and advice to the requestor. When it is
686 determined that the meeting request can be appropriately addressed through a written
687 response, FDA will, in FDA's response to the meeting request, notify the requestor of
688 the date FDA intends to send the written response. This date will be consistent with the
689 timeframes specified in II.C.1.b below for the specific meeting type.
690
691 b. Meeting Scheduling
692
693 Procedure: FDA will schedule the meeting on the next available date at which all applicable FDA
694 personnel are available to attend, consistent with the FDA's other business; however, the
695 meeting should be scheduled consistent with the type of meeting requested. Table II.C.1.b
696 below indicates the timeframes for the scheduled meeting date following receipt of a formal
697 meeting request, or in the case of a written response, the timeframes for FDA to send the
698 written response. If the date requested by the requestor for any meeting type is greater than
699 the specified timeframe, the meeting date should be within 14 calendar days of the requested
700 date.
701

Table II.C.1.b: Meeting Scheduling or Written Response Times

Meeting Type	Meeting Scheduling or Written Response Time
X	30 calendar days from receipt of meeting request
Y	70 calendar days from receipt of meeting request
Z	75 calendar days from receipt of meeting request

702
703 See Section II.C.1.h for meeting performance goals.
704
705 c. Meeting Background Packages
706
707 The requestor of the requested meeting will submit the background package for each meeting
708 type no later than the date specified in Table II.C.1.c below.
709

Table II.C.1.c: Timelines for Submission of Meeting Background Packages	
Meeting Type	**Receipt of Background Package**
X	At the time of the meeting request
Y	50 calendar days before the date of the meeting or expected written response
Z	47 calendar days before the date of the meeting or expected written response

d. Preliminary Responses to Requestor Questions

Procedure: FDA will send preliminary responses to the requestor's questions contained in the background package no later than five calendar days before the meeting date for Type Y and Z meetings. FDA will generally not send preliminary responses for Type X meetings.

See Section II.C.1.h for meeting performance goals.

e. Requestor Notification to FDA Regarding Whether Meeting is Still Needed, and Anticipated Agenda

Not later than three calendar days following the requestor's receipt of FDA's preliminary responses for a Type Y or Z meeting, the requestor will notify FDA of whether the meeting is still needed, and if it is, the anticipated agenda of the meeting given the requestor's review of the preliminary responses.

f. Meeting Minutes

Procedure: FDA will prepare minutes that will be available to the requestor 30 calendar days after the meeting. The minutes will clearly outline the important agreements, disagreements, issues for further discussion, and action items from the meeting, in bulleted form, and need not be in great detail. Meeting minutes are not required if FDA transmits a written response for any meeting type.

See Section II.C.1.h for meeting performance goals.

g. Assumptions Regarding Number of Meetings Industry Expects to Request per Year

Industry has estimated that approximately the following numbers of meetings will be requested per year:

FY 2018: 6 meetings (not under timelines or performance goals)
FY 2019: 9 meetings (not under timelines or performance goals)
FY 2020: 12 meetings (see performance goal below)
FY 2021: 24 meeting requests (see performance goal below)
FY 2022: 40 meeting requests (see performance goal below)

h. Performance Goals

Requestors may submit meeting requests beginning in FY 2018. However, performance goals regarding meeting management will become effective October 1, 2019. These goals are:

- Year 3: For the first 12 meeting requests received in Year 3, FDA will meet 50% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes). If more than 12 meeting requests are submitted in Year 3, the remainder will not be under timelines.
- Year 4: For meeting requests received in Year 4, FDA will meet 60% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes)
- Year 5: For meeting requests received in Year 5, FDA will meet 80% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes)

Performance goals apply to the aggregate of all types of meeting management goals. However, in FDA's OMUFA performance report, FDA will include information on the various subsets of meeting management goals.

i. Conditions for Performance Goals for Meetings

For a meeting to qualify for OMUFA performance goals, all of the following conditions must be met:

- The meeting must concern issues related to the issuance of an administrative order for the monograph, issues related to a potential request for a monograph order, or issues related to FDA-initiated data requests for the monograph.
- The requestor of the meeting must be subject to, or potentially subject to, OMUFA fees. For example, the requestor may be a monograph establishment owner, a requestor of an OMOR, or a requestor who intends to submit an OMOR. Other entities may request

meetings to discuss monograph issues, but meetings with these other entities will not qualify for OMUFA performance goals.

- A written request must be submitted to the review division.
- The written request must provide:
  - A brief statement of the purpose of the meeting and the requestor's proposal for either a face-to-face meeting or a written response from FDA
  - A listing of the specific objectives/outcomes the requestor expects from the meeting
  - A proposed agenda, including estimated times needed for each agenda item
  - A statement of whether the requestor intends to discuss trade secret or confidential commercial information at the meeting
  - A listing of planned external attendees
  - A listing of requested participants or discipline representatives from the Center with an explanation for the request as appropriate
  - The date that the meeting background package will be sent to the Center. Refer to Table II.C.1.c for timeframes for FDA's receipt of background packages.
- FDA must concur that the meeting will serve a useful purpose (i.e., the meeting is not premature or clearly unnecessary). However, requests for Type Y meetings will be honored except in the most unusual circumstances.
- The requestor of the meeting and any of its affiliates must have no overdue unpaid OMUFA fee.

j. Meetings Guidance Development

FDA will develop guidance regarding formal meetings between FDA and sponsors or requestors for OMUFA ingredients and drug products. FDA will issue draft guidance by February 1, 2019. FDA will issue final guidance by July 1, 2020.

2. FDA Forecasting of Planned Monograph Activities

Procedure: Each year, FDA will publish a nonbinding listing of monograph issues FDA intends to address in the coming three years. For issues for which FDA anticipates that submission of data to FDA will likely be needed, FDA will include a date by which it will expect these data to be submitted. FDA will publish the first list by October 1, 2018; and will publish subsequent lists no less frequently than annually (by October 1 in each of the years 2019, 2020 and 2021.)

Performance goal: FDA will publish each annual forecasting list within 30 days of the goal date.

D. Enhancing Industry's and FDA's Core Mission Efforts to Ensure and Improve the Safety of OTC Monograph Drugs

Prior to the proposed monograph reforms, it has been very difficult and time-consuming to effect changes to monographs, with changes often requiring many years. The significance of this difficulty in changing monographs in a timely manner has been especially problematic when the desired changes have been intended to change the labeling of monograph products to enhance the likelihood of safe use of the product. As noted in sections on timelines for Industry-initiated Innovation OMORs and Industry-requested GRASE Finalization OMORs, FDA intends to reduce the time needed for action on monograph issues, going from the current reality of many years for each change, to a timeframe of less than two years in most circumstances, while still maintaining public comment between proposed and final orders, and maintaining FDA's standards for safety and efficacy.

For certain Industry-requested safety changes to the Drug Facts labeling of monograph drug products, FDA intends an even shorter timeline, as described below.

The following types of proposed changes to the Drug Facts label of monograph drug products qualify for the shorter timeline:

Changes to the Drug Facts labeling of a monograph drug that are intended to add or strengthen any of the following:

- a contraindication, warning, precaution, or adverse reaction
- a statement about risk associated with misuse or abuse
- an instruction about dosage and administration that is intended to increase the safe use of the monograph drug product

OMORs for these types of changes will hereafter be referred to as "Specified Safety Change OMORs." These industry-requested Specified Safety Change OMORs will be made through the ordinary administrative order process proposed under monograph reform (and not through the interim final order expedited procedure for administrative orders proposed under monograph reform.)

In order to qualify for the shortened timelines, OMORs for these types of safety changes are to be submitted as stand-alone packages, and are not to include requests for other types of changes to a monograph. A filing determination will be made, and if an OMOR that is represented by the requestor as fitting into one of the above DFL safety change categories is determined to contain a request for another type of change to the monograph, the applicable timeline will be consistent with that for the other type of request found in the OMOR.

1. Timelines for Industry-Requested Specified Safety Change OMORs

Table II.D.1: Timeline for Industry-Initiated Request for Certain[2] Safety-Related Changes to the Drug Facts Labeling of Monograph Drug Products ("Specified Safety Change OMORs")

Filing determination	FDA makes fileability determination 60 calendar days after receipt of OMOR
Issuance of proposed order	If OMOR is filed, FDA issues proposed order 6 months after receipt of OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness[1] of comments	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order[3]	11.5 months after receipt of OMOR

Abbreviation: OMOR = Over-the-Counter Monograph Order Request

1 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review.

2 Changes to the Drug Facts labeling of a monograph drug that are intended to add or strengthen any of the following:

- **a contraindication, warning, precaution, or adverse reaction**
- **a statement about risk associated with misuse or abuse**
- **an instruction about dosage and administration that is intended to increase the safe use of the monograph drug product**

3 If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 3 months.

2. Assumptions Regarding the Number of Specified Safety Change OMORs Industry Expects to Submit During the First Five Years of OMUFA

Across the first five years of OMUFA, Industry estimates that it will submit a total of two OMORs for the above types of safety-related changes.

3. Performance Goals

Timelines and performance goals will begin on October 1, 2020.

Requestors may submit OMORs for the above types of safety-related changes in Years 1-3, but timelines and performance goals will not apply in those years. However, FDA always strives to review safety data and make appropriate changes in a timely manner.

Performance Goals:

- Year 4: For 60% of OMOR submissions that request the above types of safety changes, and that are received in Year 4, FDA will issue a final order by the specified goal date
- Year 5: For 80% of OMOR submissions that request the above types of safety changes, and that are received in Year 5, FDA will issue a final order by the specified goal date

4. Timelines for FDA-Requested Safety Changes

The above timelines and performance goals apply to Industry-requested specified safety changes. Other Industry-requested changes to the monograph, even if possibly related to safety, will be subject to the same timelines for other OMORs as outlined in Section II.B.1.d.

Under the proposed monograph reforms, two types of FDA-requested safety changes to the monograph are included. One type will include a proposed order, followed by a comment period, followed by a final order. Another type, to be used for certain serious safety concerns defined in the policy reform statutory language, will include an interim final order (that will go into effect immediately), followed by a comment period, followed by a final order. Once FDA has issued an FDA-initiated proposed safety order, or an FDA-initiated interim final order for a safety issue, FDA intends to follow the same timelines outlined in Table II.D.1 above regarding the length of the comment period and lengths of time from the end of the comment period to issuance of a final order.

5. Major Amendments

Major Amendments will be possible; see Section II.B.1.h for further information.

6. Comment Review Extension

Comment Review Extension: If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 3 months. This extension will be additive to those generated by any major amendment(s).

7. Resubmitted Original OMORs

See Section II.B.1.j.

E. Enhancing Efficiency in Continuing FDA's Core Mission Work of Completion of Final GRASE Determinations of Monograph Ingredients

FDA will continue work on finalization of GRASE determinations for ingredients that were Category III in a TFM prior to monograph reform, and for ingredients that were proposed as Category I in an ANPR prior to monograph reform. FDA will request that Industry submit data packages to support these GRASE finalizations.

When an FDA-requested complete package for a final GRASE determination (referred to as a GRASE Finalization Package) is submitted, FDA intends to follow the same timelines as outlined for Industry-submitted OMORs for GRASE finalizations (see below).

Due to the resource requirements for the many implementation activities for other aspects of monograph reform, FDA does not expect to begin to request packages until OMUFA Year 4 or later, and even in Year 4 and the ensuing few years, will likely only have sufficient resources to review one or two packages per FY while still meeting other OMUFA commitments. Once FDA begins to request these packages, FDA plans to request packages for up to 6 ingredients per year.

F. Enabling Efficient Completion of Final GRASE Determinations Requested by Industry

As discussed above, some GRASE finalization packages will be requested by FDA. Industry can also initiate a GRASE finalization process by submitting a GRASE Finalization OMOR. All OMOR packages are expected to be complete at the time of submission. The content and format of a complete OMOR package are to be discussed at a presubmission meeting as discussed in Section II.C.1.

1. Timelines

Table II.F.1: Timeline for Review of Industry-Initiated Over-the-Counter Monograph Order Requests for Final GRASE Determinations (GRASE Finalization OMORs)

Filing determination	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
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness[1] of comments.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order[2]	17.5 months after receipt of OMOR

Abbreviations: GRASE = General Recognition of Safety and Effectiveness; OMOR = Over-the-Counter Monograph Order Request
1 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review.
2 If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 6 months.

2. Assumptions Regarding the Number of GRASE Finalization OMORs Industry Expects to Submit in the First Five Years of OMUFA

Based on discussions between Industry and FDA, an assumption was made that no Industry-initiated requests for GRASE finalizations for existing nonfinal ingredients are likely during the first cycle of OMUFA, as Industry is expected to be more likely to submit Innovation OMORs and Specified Safety Change OMORs in the first cycle.

3. Performance Goal

Timelines and performance goals for Industry-requested GRASE Finalization OMORs will begin in Year 5.

Although there will not be timelines and performance goals associated with GRASE Finalization OMORs submitted in years 1-4, requestors may still submit them.

Performance Goal:
FY 2022: For 50% of GRASE Finalization OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date

4. Major Amendments

Major Amendments will be possible; see Section II.B.1.h for further information.

5. In-Review Meeting

An in-review meeting will be scheduled for Industry-submitted GRASE Finalization OMORs. See Section II.B.1.i.

6. Comment Review Extension

If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 6 months. This extension will be additive to those generated by any major amendment(s).

7. Resubmitted Original OMORs

See Section II.B.1.j.

G. Implementing a New Dispute Resolution System Agreed Upon as Part of Monograph Policy Reform

Under the proposed monograph policy reforms, two (sequential) dispute resolution processes are specified. The first is the current CDER formal dispute resolution request path, referred to here as the CDER FDRR path. If a requestor proceeds through the entire CDER FDRR path, but still wishes to dispute CDER's action, the requestor may request to proceed to a second path, referred to here as the administrative hearing path.

The first path is described in the draft guidance for Industry and review staff entitled *Formal Dispute Resolution: Appeals above the Division Level*, hereafter referred to as the FDRR guidance. This guidance will need some modification of its language to encompass actions covered under OMUFA. If dispute resolution is requested prior to modification of the draft guidance, FDA and Industry intend to follow applicable general procedures in the above existing FDRR draft guidance.

Procedure (for FDRR draft guidance development): FDA will revise the draft guidance for Industry and review staff *Formal Dispute Resolution: Appeals above the Division Level*, to state the circumstances and procedures under which requestors of OMUFA may use the CDER FDRR process. The draft guidance will be revised by February 3, 2020.

Performance goal (for timelines described in the FDRR draft guidance):

FY 2021: For dispute resolution requests received in Year 4, FDA will meet 50% of the timeline dates described in the FDRR draft guidance

FY 2022: For dispute resolution requests received in Year 5, FDA will meet 75% of the timeline dates described in the FDRR draft guidance

After a requestor has proceeded through the entire CDER FDRR path, the sponsor may request to proceed to an administrative hearing path. The above performance goals will not apply to the administrative hearing path.

H. Carrying Out Other Aspects of Monograph Reforms

1. Consolidated Proceedings Guidance

For monograph drugs products, it is common for there to be multiple manufacturers or sponsors of a given drug product with the same active ingredient and other monograph conditions of use.

For Industry-initiated OMORs, it is highly desirable that all Industry sponsors that are relevant for a given OMOR consolidate their data into a single well-organized and complete submission package.

For Industry-initiated appeals of FDA decisions regarding the monograph, FDA intends to conduct a single consolidated appeals process for a given appealed FDA decision, with all relevant sponsors represented as a group.

It will be the responsibility of Industry to organize itself for these consolidated processes. However, FDA will issue guidance on its views regarding best practices for consolidated proceedings for appeals. FDA will issue draft guidance by July 1, 2019, and will issue final guidance by February 1, 2021.

2. Administrative Activities for Category I Ingredients and Other Monograph Conditions of Use from Tentative Final Monographs

Under the proposed monograph reforms, TFM Category I ingredients will be treated as GRASE under the monograph conditions of use specified in the TFM as it was immediately prior to enactment of monograph reform. There will be administrative activities associated with these finalizations and the associated public postings. FDA will complete these administrative activities by October 1, 2018.

3. Conditions that Apply to Over-the-Counter Monograph Order Requests Filed Over Protest

Under proposed monograph reforms, FDA may refuse to file certain OMORs.

FDA will make a filing determination within 60 calendar days after receipt of an OMOR. FDA will issue a letter (a "Day 74 Letter") to requestors within 74 calendar days after receipt of an OMOR. The Day 74 Letter will communicate FDA's filing decision and any filing issues that were identified.

OMOR requestors may choose to file an OMOR over protest after a refusal-to-file decision by FDA. The following conditions will apply to OMORs filed over protest:

- OMORs filed over protest will be subject to the same timelines and performance goals outlined in Sections II.J.1 and II.J.2.
- OMORs filed over protest will not be eligible for in-review meetings with FDA
- FDA generally will not review amendments to OMORs filed over protest
- FDA generally will not issue information requests to requestors of OMORs filed over protest
- The timelines for resubmitted original OMOR reviews will not apply to resubmission of an OMOR that was filed over protest. Any such resubmission will be reviewed as available resources permit.

I. Routine Inspections

For routine FDA inspections of monograph drug manufacturing facilities, FDA intends to continue to follow a risk-based model for prioritization of inspections.

J. Creating a System to Measure the Success of Goals Laid Out in the User Fee Agreement

1. Summary of Performance Goals for OMUFA

As noted earlier, when there are very few instances of a given activity, adherence to performance goals should be interpreted accordingly. For example, if there are so few occurrences of an activity that missing only one or two goal dates would make it appear that the performance goal was not met, qualitative description of performance may provide more useful data to be used in improving future performance.

As discussed in Section II.A.2, the growth of effective review capacity will be limited in the first three years of OMUFA due to the necessary training of newly onboarded hires, and during those first three years, much of the effective review capacity will be consumed by current mandates such as the Sunscreen Innovation Act and an antiseptic consent decree, and by ongoing safety activities. There are also numerous OMUFA implementation and infrastructure establishment activities to be accomplished in those years, resulting in a likely "net-negative" effective review capacity in Years 1-3. Beginning in Year 4 (and to a very limited extent in Year 3), FDA expects to have built sufficient effective review capacity to begin to implement timelines and limited performance goals.

The following table summarizes performance goals for OMUFA activities for the first 5 years of OMUFA:

Table II.J.1: Summary of Performance Goals for OMUFA

Activity	Performance Goal
Industry-Submitted Innovation OMORs	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
Industry-Submitted Specified Safety Change OMORs	Year 4: For 60% of OMOR submissions received in Year 4, FDA will issue a final order by the specified goal date Year 5: For 80% of OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date
Industry-Submitted GRASE Finalization OMORs	Year 5: For 50% of OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date
Resubmitted Original OMORs	Year 5: For 50% of resubmitted original OMORs received in Year 5, FDA will issue a final order by the specified goal date
Meetings between FDA and regulated monograph Industry	Year 3: For the first 12 meeting requests received in Year 3, FDA will meet 50% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes). If more than 12 meeting requests are submitted in Year 3, the remainder will not be under timelines. Year 4: For meeting requests received in Year 4, FDA will meet 60% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes) Year 5: For meeting requests received in Year 4, FDA will meet 80% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes)
Issuance of nonbinding annual forecasting list of planned monograph actions over ensuing 3 years	FDA will publish the forecasting list within 30 days of each goal date (goal dates are Oct 1 of 2018, 2019, 2020, and 2021).
Dispute resolution	Year 4: For dispute resolution requests received in Year 4, FDA will meet 50% of the timeline dates described in the FDRR draft guidance Year 5: For dispute resolution requests received in Year 5, FDA will meet 75% of the timeline dates described in the FDRR draft guidance

Abbreviations: DFL = Drug Facts label; FY = fiscal year; FDRR = Formal Dispute Resolution Request; OMOR = Over-the-Counter Monograph Order Request

2. Summary of Timelines for Industry-Initiated Over-the-Counter Monograph Order Requests

The following table summarizes the timelines for Industry-initiated OMORs.

Table II.J.2: Summary of Timelines for Industry-Initiated Requests for Monograph Actions

	Tier One Innovation OMOR: Eligible[1] New Ingredient	Tier One Innovation OMOR: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other[2] Monograph Change	Tier Two Innovation OMOR	GRASE Finalization OMOR	Specified Safety Change OMOR	Class One Resubmitted[5] Original OMOR	Class Two Resubmitted[5] Original OMOR
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	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	n/a	n/a
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	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 6 months after receipt of OMOR	FDA issues[5] proposed order 4 months after receipt of resubmitted OMOR	FDA issues[5] proposed order 6 months after receipt of resubmitted 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	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	Begins on the date of issuance of the proposed order, and lasts 45 calendar days

Table II.J.2: Summary of Timelines for Industry-Initiated Requests for Monograph Actions

	Tier One Innovation OMOR: Eligible[1] New Ingredient	Tier One Innovation OMOR: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other[2] Monograph Change	Tier Two Innovation OMOR	GRASE Finalization OMOR	Specified Safety Change OMOR	Class One Resubmitted[5] Original OMOR	Class Two Resubmitted[5] Original OMOR
Assessment of volume and substantiveness[3] of 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	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	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order[4]	17.5 months after receipt of OMOR	17.5 months after receipt of OMOR	15.5 months after receipt of OMOR	17.5 months after receipt of OMOR	11.5 months after receipt of OMOR	9.5 months after receipt of resubmitted OMOR	11.5 months after receipt of resubmitted OMOR

Abbreviations: GRASE = generally recognized as safe and effective; OMOR = over-the-counter monograph order request
1 See Section II.B.1.d regarding eligibility determination
2 This includes all proposed changes to the monograph, except for safety changes described in Section II.D, the addition of new ingredients, Tier Two Innovation OMORs, and specific changes for which FDA has issued a final guidance stating that an OMOR is not required (see Section II.B.2).
3 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or full review.
4 If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date. See Sections II.B.1.e, II.B.1.j, II.D.6, and II.F.6.
5 Assumes resubmitter addressed all deficiencies identified in the previous final order

3. Summary of Dates of Specified Activities under OMUFA

Table II.J.3: Summary of Dates of Specified[1] Activities under OMUFA

Activity	Date Associated with Specified Activity														
	1 Oct 2017	1 Oct 2018	1 Feb 2019	1 Apr 2019	1 Jul 2019	1 Oct 2019	3 Feb 2020	1 Apr 2020	1 Jul 2020	1 Oct 2020	1 Feb 2021	1 Apr 2021	1 Oct 2021	1 Feb 2022	1 Apr 2022
Assumed effective date	x														
Hiring annual goal assessment		x				x				x			x		
Monograph forecast annual posting		x				x				x			x		
TFM Cat I finalization activities complete		x													
Meetings draft guidance issued			x												
Meetings final 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: RFP			x												
IT platform: initial contracts awarded				x											
IT platform: business requirements established								x							
IT platform fully functional															x
Content and format draft guidance issued				x											
Content and format final guidance issued										x					
Consolidated proceedings draft guidance issued					x										
Consolidated proceedings final guidance issued											x				

Table II.J.3: Summary of Dates of Specified[1] Activities under OMUFA

Activity	Date Associated with Specified Activity														
	1 Oct 2017	1 Oct 2018	1 Feb 2019	1 Apr 2019	1 Jul 2019	1 Oct 2019	3 Feb 2020	1 Apr 2020	1 Jul 2020	1 Oct 2020	1 Feb 2021	1 Apr 2021	1 Oct 2021	1 Feb 2022	1 Apr 2022
Meeting management TPGs begin						x									
Meeting management TPGs annual goal assessment										x			x		
Electronic submission draft guidance issued						x									
Electronic submission final guidance issued												x			
CDER-level dispute resolution updated draft guidance issued							x								
Pre-OMUFA paper document cataloging contract award							x								
Pre-OMUFA paper document cataloging complete														x	
Innovation OMOR TPGs begin										x					
Industry-initiated Specified Safety Change OMORs TPGs begin										x					
Industry-initiated GRASE Finalization OMOR TPGs begin													x		
CDER-level dispute resolution TPGs begin										x					
Solid oral dosage forms proposed administrative order and draft guidance issued															x

Table II.J.3: Summary of Dates of Specified[1] Activities under OMUFA

Activity	Date Associated with Specified Activity														
	1 Oct 2017	1 Oct 2018	1 Feb 2019	1 Apr 2019	1 Jul 2019	1 Oct 2019	3 Feb 2020	1 Apr 2020	1 Jul 2020	1 Oct 2020	1 Feb 2021	1 Apr 2021	1 Oct 2021	1 Feb 2022	1 Apr 2022

Abbreviations: ANPR = Advance Notice of Proposed Rulemaking; CAT = category; CDER = Center for Drug Evaluation and Research; COU = monograph conditions of use; GRASE = generally recognized as safe and effective; IT = information technology; OMOR = Over-the-Counter Monograph Order Request; OMUFA = Over-the-Counter Monograph User Fee Act; TFM = Tentative Final Monograph; TPGs = timelines and performance goals

1: These are not all the activities that the FDA monograph review staff will be engaged in, but only those for which goal dates are specified under OMUFA. FDA will continue its many baseline monograph activities, such as: addressing ongoing and emerging safety issues; carrying out mandated activities under the Sunscreen Innovation Act and an antiseptic consent decree; training; and numerous other activities described elsewhere in this goals document

4. Annual Performance Reporting

FDA will include in the public annual performance report to Congress an assessment of the activities listed in Table II.J.3 “Summary of Dates of Specified Activities under OMUFA.”

III. Definitions and Explanations of Terms

(If needed, will be added later to be consistent with statutory language)