# OVER-THE-COUNTER MONOGRAPH DRUG USER FEE PROGRAM PERFORMANCE GOALS AND PROCEDURES—FISCAL YEARS 2026-2030

# OVER-THE-COUNTER MONOGRAPH DRUG USER FEE PROGRAM (OMUFA) PERFORMANCE GOALS AND PROCEDURES—FISCAL YEARS 2026-2030

This document contains the performance goals and procedures for the Over-the-Counter (OTC) Monograph Drug User Fee program (referred to as OMUFA) for fiscal years 2026-2030 ("OMUFA II").

This document is commonly referred to as the "goals letter" or "commitment letter." The goals letter represents the product of the U.S. Food and Drug Administration's (FDA's) discussions with regulated industry, and consideration of input by public stakeholders, as mandated by Congress.

The performance and procedural goals and other commitments specified in this letter apply to aspects of OTC monograph drug activities described in section 744L(6) of the Federal Food, Drug, and Cosmetic (FD&C) Act and authorized under section 505G of that Act, and build on commitments made in the goals letter applicable for fiscal years 2021-2025 under OMUFA I. These activities are important for facilitating timely access to safe and effective medicines regulated as OTC monograph drugs under section 505G. FDA is committed to meeting the performance goals specified in this commitment letter and to continuous improvement of FDA's performance.

FDA and the regulated Industry will periodically and regularly assess the progress of program enhancements and commitments outlined in the letter. This will allow FDA and the regulated Industry to identify emerging challenges in implementation of OMUFA II commitments and develop strategies to address these challenges to ensure the efficiency and effectiveness of OTC monograph drug activities addressed in this letter.

It should be noted that, when there are very few instances of a given activity, adherence to performance goals is to 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.

# I. OTC MONOGRAPH DRUG ACTIVITIES

## A. REVIEW PERFORMANCE GOALS

### 1. Over-the-Counter Monograph Order Request (OMOR) Submissions

a. Review and issue a final order for 75 percent of Tier One "Innovation" OMOR submissions within the timelines indicated in Table 1.

b. Review and issue a final order for 75 percent of Tier Two OMOR submissions within 472 calendar days (15.5 months) of receipt.

c. Review and issue a final order for 80 percent of Safety OMOR submissions within 350 calendar days (11.5 months) of receipt.

d. Review and issue a final order for 50 percent of Generally Recognized as Safe and Effective (GRASE) Finalization OMOR submissions within 532 calendar days (17.5 months) of receipt.

### 2. Review Performance Goal Extensions

a. Major Amendment

i. If a major amendment is submitted to a filed OMOR prior to the public comment period for a proposed order related to the OMOR, FDA may extend the proposed order goal date by three months and final order goal date by 3 months. FDA does not intend to review major amendments submitted after the proposed order is issued. This extension will be additive to those generated by any public comment period extension and any numerous/substantive public comments extension.

ii. A major amendment may include, for example, a major clinical safety or efficacy study that was not previously submitted to the filed OMOR, or a major reanalysis of a study or studies previously submitted to the current OMOR.

iii. Major amendments may apply to Tier One Innovation OMORs, OMORs for GRASE finalizations (as discussed in Section I.B.2), and OMORs for certain safety changes to an applicable monograph (as described in Section I.B.3).

iv. 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).

b. Extending Public Comment Period for a Proposed Order

i. If FDA extends the public comment period for a proposed order, the final order goal date will be extended by the same length of time, up to 15 calendar days. This extension will be additive to those generated by any major amendment and any numerous/substantive public comments extension.

c. Numerous or Substantive Public Comments on Proposed Orders

i. If comments received during the comment period on a proposed order are numerous or substantive, there will be an extension of the final order goal date. For proposed orders related to Tier One Innovation OMORs, the extension will be 5 months; for proposed orders related to Tier Two and Safety OMORs, the extension will be 3 months; and for proposed orders related to GRASE finalization OMORs, the extension will be 6 months. This extension will be additive to those generated by any major amendment and any public comment period extension.

## B. OMOR TYPES

### 1. Innovation OMORs

There are 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.

a. Tier One OMORs

Under section 744L(8) of the FD&C Act, a Tier One OMOR is any OMOR not determined to be a Tier Two OMOR (as defined in section 744L(9) of the FD&C Act). Examples of Tier One OMORs include, but are not limited to, requests for the following:

i. Addition of a new ingredient to a monograph that already has one or more ingredients that have been found to be GRASE.

ii. 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.

iii. 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.

iv. 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.

v. 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.

vi. Addition of a new dose or concentration for a GRASE ingredient for a particular monograph.

vii. Addition of a new monograph therapeutic category (each ingredient proposed for the new therapeutic category will be a separate OMOR).

viii. All other OMORs not determined to be a Tier Two OMOR.

b. Tier Two OMORs

Tier Two OMORs are limited to requests described in section 744L(9) of the FD&C Act.

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

**2. GRASE Finalization OMORs**

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 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.

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 described in Section I.E.1.

### 3. Specified Safety Change OMORs

Specified Safety Change OMORs are changes to the Drug Facts Labeling (DFL) of a monograph drug that are intended to add or strengthen any of the following:

a. A contraindication, warning, precaution, or adverse reaction.

b. A statement about risk associated with misuse or abuse.

c. An instruction about dosage and administration that is intended to increase the safe use of the monograph drug product.

Specified Safety Change OMORs have a shorter timeline for FDA action than the timeline for other OMOR types. Industry-requested Specified Safety Change OMORs, as with other OMORs, should be made in accordance with the process specified under section 505G(b) of the FD&C Act, informed by content and format recommendations described in the guidance for industry *Over-the-Counter Monograph Order Requests: Format and Content*. In order to qualify for the shortened performance goal timelines for FDA action, as described below, 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 in accordance with the statute, 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 performance goal timeline will be consistent with that for the other type of request found in the OMOR.

## C. OMOR PROCEDURES

### 1. Content and Format of Monograph Submissions

a. OMORs submitted under section 505G of the FD&C Act generally should use content and format recommendations described in the guidance for industry Over-the-Counter Monograph Order Requests: Format and Content.

b. OMOR requestors should submit a certification that the requestor has submitted in support of the OMOR all evidence created, obtained, or received by that requestor that is relevant to whether the ingredient or other condition of use is GRASE.

c. OMORs are expected to be complete at the time of submission, and 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. FDA will make a determination of whether each OMOR is acceptable for filing in accordance with section 505G of the FD&C Act.

d. OMOR requestors are strongly encouraged to request and attend a presubmission meeting (as described in Section I.E.1.b.ii) for their proposed OMOR, to discuss the expected content, format, and tier for a particular OMOR. Likewise, requestors are encouraged to request and use the overall data requirements meetings to discuss eligibility (as described in Section I.C.2.a.).

**2. OMOR Filing Review**

Innovation OMORs for proposed new monograph active ingredients are subject to a two-step filing assessment process. All other OMORs are subject to a single step filing assessment process.

a. Filing for OMORs proposing new monograph active ingredients

i. In step one of the filing assessment (OMOR eligibility; only for OMORs proposing new monograph active ingredients), the Agency will assess whether, in FDA's view, the OMOR contains sufficient information regarding prior marketing for a prima facie demonstration, as described in section 505G(b)(6) of the FD&C Act, that the subject drug containing the proposed active ingredient(s) can be safely marketed and used as a nonprescription drug. FDA will assess the submitted information that is relevant to section 505G(b)(6) and determine whether such information meets the statutory criteria for the required prima facie demonstration . If the information submitted with respect to the drug does meet the requirements of section 505G(b)(6), FDA will move to step two of the filing assessment. In step two (OMOR content/format), the Agency will assess whether the content of the OMOR is sufficiently complete and formatted to permit a substantive review, in accordance with section 505G(b)(5)(A) of the FD&C Act. If the Agency determines that the statutory conditions applicable to either step one or step two of the filing assessment are not met, the Agency will refuse to file the OMOR, in accordance with sections 505G(b)(6) or 505G(b)(5)(A), as applicable (subject to certain exceptions under those statutory provisions).

1. If the proposed new monograph active ingredient is currently marketed for the same use (i.e., the Indication on Drug Facts label) in a drug product under a US OTC NDA or OTC ANDA, and the total documented sales of such drug products exceeds 1 million retail packages, FDA will issue a written determination for purposes of step one of the filing assessment for the OMOR, under section

505G(b)(6), by 15 calendar days after receipt of the OMOR. FDA will subsequently issue a written determination for purposes of step two of the filing assessment for the OMOR, under section 505G(b)(5)(A), by 75 calendar days after receipt of the OMOR.

2. For any OMOR proposing a new monograph active ingredient that does not meet the specific conditions in the immediately preceding paragraph for FDA to issue a written filing assessment determination within 15 days after receipt of the OMOR, FDA will issue a written determination for purposes of step one of the filing assessment for the OMOR by 60 calendar days after receipt of the OMOR. If FDA determines that the OMOR satisfies step one of the filing assessment, FDA will subsequently issue a written determination for purposes of step two of the filing assessment for the OMOR by 120 calendar days after receipt of the OMOR.

b. Filing for all other OMORs

i. The Agency will conduct only the filing assessment for OMOR content/format described above, i.e., assessing whether the content of the OMOR is sufficiently complete and formatted to permit a substantive review, in accordance with section 505G(b)(5)(A) of the FD&C Act. If the Agency finds that the OMOR is not sufficiently complete and formatted to permit a substantive review, the Agency will refuse to file the OMOR (unless the requestor demands that the OMOR be filed over protest, per section 505G(b)(5)(A)(iii) of the FD&C Act).

ii. FDA will issue a written determination for the single step filing assessment (i.e., OMOR content/format assessment described above) within 60 calendar days after receipt of the OMOR.

**3. Conditions that Apply to OMORs Filed Over Protest**

OMOR requestors may choose to file an OMOR over protest after a refusal-to-file decision by FDA, as described in section 505G(b)(5)(A)(iii) of the FD&C Act. Note that OMORs proposing new monograph ingredients that fail step one of the filing review process (Sections I.C.2.a.i.1 and I.C.2.a.i.2) cannot be filed over protest (except in the narrow instance described in section 505G(b)(6)(E) of the FD&C Act with respect to certain sunscreen drugs). The following conditions will apply to OMORs filed over protest:

a. OMORs filed over protest will be subject to the same timelines and performance goals outlined in Sections I.A.1 and I.A.2 and Tables 1-3.

b. OMORs filed over protest will not be eligible for in-review meetings with FDA.

c. FDA generally will not review amendments to OMORs filed over protest.

d. FDA generally will not issue information requests to requestors of OMORs filed over protest.

**4. In-Review Meeting**

For filed Tier One 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:

a. The signatory authority for the OMOR review.

b. Discipline review team representatives from discipline areas for which substantive issues in the OMOR have been noted to date.

No fewer 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:

a. Substantive issues identified to date.

b. Information requests from the review team to the requestor.

c. 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.

**5. Timelines for FDA Action on OMORs**

**Table 1: Tier One Innovation OMOR Timelines**

| | **Tier One Innovation OMOR (new ingredient previously marketed under US OTC NDA/ANDA[1])** | **Tier One Innovation OMOR (new ingredient <u>not</u> previously marketed under US OTC NDA/ANDA)** | **Tier One Innovation OMOR (change to monograph conditions of use not involving a new ingredient; or request for other[2] monograph change)** |
|---|---|---|---|
| **Filing Determination- Step 1 (eligibility)** | FDA will issue a written determination 15 calendar days after receipt of OMOR | FDA will issue a written determination 60 calendar days after receipt of OMOR | N/A |
| **Filing Determination- Step 2 (content/format)** | FDA will issue a written determination 75 calendar days after receipt of OMOR | FDA will issue a written determination 120 calendar days after receipt of OMOR | FDA will issue a written determination 60 calendar days after receipt of OMOR |
| **Issuance of Proposed Order** | If the OMOR is filed, FDA will issue a proposed order 380 calendar days (~12.5 months) after receipt of OMOR | If the OMOR is filed, FDA will issue a proposed order 426 calendar days (~14 months) after receipt of OMOR | If the OMOR is filed, FDA will issue a proposed order 365 calendar days (12 months) after receipt of OMOR |
| **Public Comment Period** | Begins on the date of issuance of the proposed order and lasts 45 calendar days. FDA may choose to extend the period by up to 15 calendar days if needed. | | |
| **Assessment of volume and substantiveness[3] of comments** | Begins 1 calendar day after public comment period ends and lasts 60 calendar days. | | |

[1] See Section I.C.2 for more detailed description of additional conditions which must be met to fall within this category.
[2] This includes all OMORs, except for safety change OMORs described in Section I.B.3, the addition of new ingredients, Tier Two Innovation OMORs, and specific changes for which FDA has issued a final guidance explaining that under section 505G of the FD&C Act an OMOR is not required.
[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.

| | | | |
|---|---|---|---|
| **Issuance[4] of Final Order** | If the OMOR is filed, FDA will issue a final order 548 calendar days (~18 months) after receipt of OMOR | If the OMOR is filed, FDA will issue a final order 593 calendar days (~19.5 months) after receipt of OMOR | If the OMOR is filed, FDA will issue a final order 532 calendar days (~17.5 months) after receipt of OMOR |

**Table 2: Tier Two Innovation OMOR Timelines**

| | **Tier Two Innovation OMOR** |
|---|---|
| **Filing Determination (content/format)** | FDA will make a determination 60 calendar days after receipt of OMOR |
| **Issuance of Proposed Order** | If the OMOR is filed, FDA will issue a proposed order 304 calendar days (~10 months) after receipt of OMOR |
| **Public Comment Period** | Begins on the date of issuance of the proposed order and lasts 45 calendar days. FDA may choose to extend the period by up to 15 calendar days if needed. |
| **Assessment of volume and substantiveness[5] of comments** | Begins 1 calendar day after public comment period ends and lasts 60 calendar days. |
| **Issuance[6] of Final Order** | If the OMOR is filed, FDA will issue a final order 472 calendar days (~15.5 months) after receipt of OMOR |

[4] See Section I.A.2 for a description of various circumstances that may extend the final order goal date.
[5] 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.
[6] See Section I.A.2 for a description of various circumstances that may extend the final order goal date.

**Table 3: Industry-Requested GRASE Finalization OMOR Timeline**

| | **GRASE Finalization OMORs** |
|---|---|
| **Filing Determination (content/format)** | FDA will make a determination 60 calendar days after receipt of OMOR |
| **Issuance of Proposed Order** | If the OMOR is filed, FDA will issue a proposed order 365 calendar days (~12 months) after receipt of OMOR |
| **Public Comment Period** | Begins on the date of issuance of the proposed order and lasts 45 calendar days. FDA may choose to extend the period by up to 15 calendar days if needed. |
| **Assessment of volume and substantiveness[7] of comments** | Begins 1 calendar day after public comment period ends and lasts 60 calendar days. |
| **Issuance[8] of Final Order** | If the OMOR is filed, FDA will issue a final order 532 calendar days (~17.5 months) after receipt of OMOR |

[7] 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.
[8] See Section I.A.2 for a description of various circumstances that may extend the final order goal date.

**Table 4: Industry-Requested Specified Safety Change OMOR Timelines**

| | **Specified Safety Change OMORs** |
|---|---|
| **Filing Determination (content/format)** | FDA will make a determination 60 calendar days after receipt of OMOR |
| **Issuance of Proposed Order** | If the OMOR is filed, FDA will issue a proposed order 183 calendar days (~6 months) after receipt of OMOR |
| **Public Comment Period** | Begins on the date of issuance of the proposed order and lasts 45 calendar days. FDA may choose to extend the period by up to 15 calendar days if needed. |
| **Assessment of volume and substantiveness[9] of comments** | Begins 1 calendar day after public comment period ends and lasts 60 calendar days. |
| **Issuance[10] of Final Order** | If the OMOR is filed, FDA will issue a final order 350 calendar days (~11.5 months) after receipt of OMOR |

## D. FORMAL DISPUTE RESOLUTION

1. **Procedure:** With respect to formal dispute resolution (FDR) described under section 505G(b)(2)(A)(iv)(III) of the FD&C Act in connection with a final order issued under such section, the substantive response to appeals of decisions will occur within 30 calendar days of the Center's receipt of the written appeal.

   The process that will be followed with respect to FDR (and any subsequent administrative hearing), is described in *Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Food, Drug, and Cosmetic Act*.

2. **Performance Goal:** 75 percent of responses to FDRs are provided within 30 calendar days of the Center's receipt of the written appeal. This performance goal will not apply to the administrative hearing process described in section 505G(b)(3) of the FD&C Act.

[9] 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.
[10] See Section I.A.2 for a description of various circumstances that may extend the final order goal date.

## E. MEETING MANAGEMENT

### 1. Meeting Types

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

a. Type X meetings are those meetings that are necessary for an otherwise stalled OMOR 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.

b. Type Y meetings are intended for milestone discussions during the lifecycle of Industry OMORs for proposed new monograph active ingredients and for new monograph conditions of use. Examples of appropriate circumstances for Type Y meetings include:

    i. Overall Data Requirements Meetings: After FDA has stated its intent to make a final GRASE determination for a particular proposed monograph active ingredient or monograph condition of use, an Industry requestor may request a meeting to discuss the overall data needed to support that GRASE determination. Similarly, an Industry requestor 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 needed to support that OMOR. A requestor may also raise questions about requirements for filing eligibility determination.

ii. Presubmission Meetings: When an Industry requestor is nearing completion of its development program for an OMOR package, the requestor 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.

iii. Protocol Synopsis Review and Feedback: An Industry requestor may solicit feedback from FDA on a protocol synopsis as part of a Type Y meeting request for another purpose (i.e., i and ii above)

c. A Type Z meeting is any other type of meeting including a request for feedback on a protocol synopsis as a stand-alone topic.

d. Follow-Up Opportunity: For all meeting types, to facilitate the requester's understanding of FDA feedback from meeting discussions or a WRO, requesters may submit clarifying questions to the Agency within 30 calendar days following receipt of the meetings minutes or a WRO. Only questions of a clarifying nature will be considered, i.e., to confirm something in minutes or a WRO issued by FDA, rather than raising new questions or new proposals. FDA will determine whether questions are clarifying. For questions that go beyond clarifying, FDA intends to notify the requester and they may submit a new meeting request.

Clarifying questions are to be sent as part of a formal submission via the CDER NextGen Portal (or any successor system) as a "Request for Clarification to Meeting Minutes or WRO." The request is to be submitted to the FDA within 30 calendar days following receipt of meeting minutes or a WRO. For questions that meet the conditions described above, FDA will generally issue a response in writing within 60 calendar days of receipt of the clarifying questions. FDA's response will reference the original meeting minutes or WRO.

**2. Responses to Meeting Requests**

a. 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 2 below indicates the Meeting Request Response Time Goals for FDA's response to a meeting request.

**Table 5. Meeting Request Response Time Goals**

| Meeting Type | Response Time (Calendar Days) |
|---|---|
| X | 14 |
| Y | 14 |
| Z | 21 |

i. For any type of meeting, the requestor may request a written response to its questions rather than a face-to-face[11] meeting or teleconference. FDA will review the request and make a determination regarding whether a written response is appropriate or whether a face-to-face meeting or teleconference is necessary. If FDA deems a written response to be appropriate, when FDA responds to the meeting request, FDA will notify the requestor of the date FDA intends to send the written response. This date will be consistent with the timeframes specified in Table 3 below for the specific meeting type.

ii. For Type Z meetings, while the requestor may request a face-to-face meeting, FDA may determine that a written response to the requestor's questions would be the most appropriate means for providing feedback and advice to the requestor. When it is determined that the meeting request can be appropriately addressed through a written response, FDA will, in FDA's response to the meeting request, notify the requestor of the date FDA intends to send the written response. This date will be consistent with the timeframes specified in Table 3 below for the specific meeting type.

iii. FDA acknowledges that complexity of meeting topics will be a factor when determining meeting format (e.g., WRO vs. teleconference or Face-to-Face), and when considering requests for meetings longer than the standard 1-hour duration. Meetings longer than an hour may be granted in appropriate circumstances.

b. Performance goal: See Section I.E.8 for meeting performance goals.

**3. Meeting Scheduling**

a. Procedure: FDA will schedule the meeting on the next available date at which all applicable FDA personnel are available to attend, consistent with the FDA's other business; however, the meeting is to be scheduled consistent with the type of meeting requested. Table 3 below indicates the timeframes for the scheduled meeting date following receipt of a formal meeting request, or in the case of a written response, the timeframes for FDA to send the written response. If the date

[11] A "face-to-face" meeting includes both in-person meetings and virtual meetings on IT platforms that allow for both audio and visual communications.

requested by the requestor for any meeting type is greater than the specified timeframe, the meeting date is to be within 14 calendar days of the requested date.

**Table 6. 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 |

b. Performance goal: See Section I.E.8 for meeting performance goals.

**4. Meeting Background Packages**

a. The requestor of the requested meeting will submit the background package for each meeting type no later than the date specified in Table 7.

**Table 7. 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 |

**5. Preliminary Responses to Requestor Questions**

a. Procedure: FDA will send preliminary responses to the requestor's questions contained in the background package no later than 5 calendar days before the meeting date for Type Y and Z meetings. FDA will generally not send preliminary responses for Type X meetings.

b. Performance goal: See Section I.E.8 for meeting performance goals.

**6. Requestor Notification to FDA**

a. Not later than 3 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.

**7. Meeting Minutes**

a. 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.

b. Performance goal: See Section I.E.8 for meeting performance goals.

**8. Performance Goals**

a. For the aggregate of Types X, Y, and Z meetings, FDA will meet 80% of the combined total of meeting management goal dates for response, scheduling, preliminary responses (Type Y only), and minutes.

b. As noted above, preliminary responses will not generally be sent for Type X meetings. For Type Z meetings, there is no performance goal for preliminary responses.

c. 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.

**9. Conditions for Performance Goals for Meetings**

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

i. 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.

ii. The requestor of the meeting must be subject to, or potentially subject to, OMUFA fees. For example, the requestor may be an OTC monograph drug 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.

iii. The meeting request must be submitted to the review division through the CDER NextGen Portal or any successor system.

iv. The written request must provide:

1. 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.

2. A listing of the specific objectives/outcomes the requestor expects from the meeting.

3. A proposed agenda, including estimated time needed for each agenda item.

4. A statement of whether the requestor intends to discuss trade secret or confidential commercial information at the meeting.

5. A listing of planned external attendees.

6. A listing of requested participants or discipline representatives from FDA with an explanation for the request as appropriate.

7. The date that the meeting background package will be sent to the Center. Refer to Table 4 for timeframes for FDA's receipt of background packages.

v. 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 unusual circumstances.

vi. The requestor(s) of the meeting and any of its affiliates must have no overdue unpaid OMUFA fee.

**10. Advisory Committee Meetings**

FDA intends to post on FDA's website notice of a specific subset of OTC monograph-related Advisory Committee meetings at least 100 business days in advance of the meeting. This subset would be OTC monograph-related meetings for which the planned Advisory Committee is not intended to address an emerging safety issue and the existing policy on advance notice in FDA's 2008 Advisory Committee Meetings Guidance does not apply. The Agency recognizes that in these instances such advance notice can help provide stakeholders time to coordinate and prepare for meaningful Advisory Committee discussion.

## F. FDA-INITIATED ORDERS

### 1. FDA-Initiated GRASE Finalizations

FDA will continue work on finalization of GRASE determinations for drugs described in section 505G(a)(3) of the FD&C Act. 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, where applicable (see Table 1). Once FDA begins to request these packages, FDA plans to request packages for up to six ingredients per year.

**2. FDA-Initiated Safety Orders**

FDA may also initiate proposed safety orders. Once FDA has issued an FDA-initiated proposed safety order, FDA intends to follow the same timelines outlined in Table 4, where applicable, regarding the length of the comment period and lengths of time from the end of the comment period to issuance of a final order, subject to the expedited procedure described in section 505G(b)(4) of the FD&C Act.

## G. FDA FORECASTING OF PLANNED MONOGRAPH ORDERS

1. **Procedure:** Each fiscal year, FDA will publish a nonbinding listing of the topics of FDA-initiated orders FDA expects to issue in the coming 3 years, if resources permit.[12] For such FDA-initiated orders 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 packages to be submitted. FDA will publish the list by October 1 of each year.

2. **Performance Goal:** FDA will publish each annual forecasting list within 30 days of October 1.

## H. FDA CROWDSOURCINGS

**1. GRASE Finalization Crowdsourcing**

By February 2027, FDA will run an FDA crowdsourcing[13] to learn from stakeholders their questions about the process FDA intends to use for obtaining data to be used in FDA-initiated GRASE finalizations and how Industry might organize and submit data for both FDA-initiated and Industry-initiated GRASE finalizations. The crowdsourcing will be accessible and transparent to the public and will be open for a minimum of 4 weeks. No later than one year after the crowdsourcing closes, FDA will hold a webinar to answer certain questions submitted in the crowdsourcing related to submissions and requirements for GRASE finalizations for which FDA has established policy; webinars are not the mechanism by which FDA establishes policy, and other mechanisms exist to comment on existing policy.

**2. Test Methods Crowdsourcing:**

FDA will issue a Federal Register notice by December 31, 2026, to solicit stakeholder feedback on test methods in monographs (final orders), given current challenges in updating these methods.

[12] As per section 505G(g)(2)(B) of the FD&C Act.
[13] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/fda-crowdsourcing.

a. Based on the feedback from (a), FDA will run a crowdsourcing to further refine the input on test methods in existing monographs. The crowdsourcing will open no later than July 31, 2027, be accessible and transparent to the public and will be open for a minimum of 4 weeks.

## I. GUIDANCE

### 1. Filing Process

To provide more clarity on step one of the filing process for OMORs proposing new monograph active ingredients ("filing eligibility"), pursuant to section 505G(b)(6) of the FD&C Act, FDA will publish draft guidance on the requirements of this provision and implementation of this filing process no later than July 31, 2029. FDA will aim to publish a revised draft or final guidance within 24 months after the close of the public comment period.

### 2. Confidential Information

FDA will issue draft guidance to provide additional information on confidentiality of information submitted to FDA in connection with proceedings under section 505G, including with respect to an OMOR, by July 31, 2030. FDA will aim to publish a revised draft or final guidance within 24 months after the close of the public comment period.

## J. ORDER/GUIDANCE PAIR REGARDING MINOR CHANGES IN DOSAGE FORM FOR SOLID ORAL OTC MONOGRAPH DRUG PRODUCTS

FDA will work to finalize, under section 505G(c)(3) of the FD&C Act, the order/guidance pair relating to minor changes in dosage form for solid oral OTC monograph drug products, which FDA committed to develop under the terms of the OMUFA I commitment letter.

# II. INFORMATION MANAGEMENT

## A. MONOGRAPH INGREDIENT WEBSITE

FDA will maintain the "Historical Status of OTC Rulemakings" website in its current state through OMUFA II and, starting no later than October 31st, 2028, will ensure on a regular basis that Federal Register links are active.

## B. MONOGRAPH-RELATED EXCLUSIVITY

By October 31, 2029, FDA will post a page on its website addressing monograph-related exclusivity afforded by final administrative orders pursuant to section 505G(b)(5)(C) of the

FD&C Act. The web page will include a table of relevant monograph change(s), requestor(s), the final order date, and the date on which the relevant eDRLS listing update for the OTC monograph drug(s) subject to such a final order was submitted, pursuant to section 505G(e) of the FD&C Act.

For purposes of identifying this listing update, the requestor(s) will send FDA a letter through the CDER NextGen Portal (or any successor system) indicating the date on which the drug listing update required by section 505G(e) was submitted, to be confirmed by FDA. The letter will state that this date is provided for purposes of section II.B.ii. (below) and will indicate that the requester does not object to the letter being made publicly available by FDA.

On the exclusivity webpage, FDA will:

i. Add to the exclusivity table the date on which the drug listing update was submitted;

ii. Indicate that the 18-month period of marketing exclusivity under section 505G(b)(5)(C) of the FD&C Act for drug(s) subject to the final order--as described in the "statement of reasons" accompanying the order--would begin on that listing submission date, if upon that date the requestor(s) has met all applicable requirements for the requestor to lawfully market drug(s) pursuant to the final order; and

iii. May update such website information as appropriate.

### C. CATALOGUING PAPER DOCUMENTS

FDA will utilize an independent contractor to scan the pre-OMUFA paper documents catalogued in OMUFA I. FDA will then post the scanned documents to a public docket. The documents will link to a searchable catalog posted on FDA's website. FDA will submit the scanned documents to the public docket by October 31, 2027.

### D. CDER NEXTGEN PORTAL SUBMISSIONS

To clarify procedures, FDA will host a public webinar by April 30, 2029, to detail steps of how to submit an OMOR using the CDER NextGen Portal.

## III. MONOGRAPH PRODUCT QUALITY ENHANCEMENT

### A. ENHANCING QUALITY SURVEILLANCE

1. **Records Requests**: Starting in FY2027, FDA will take steps (e.g., issuing requests for records under section 704(a)(4) of the FD&C Act) to vet at least 90% of new OTC monograph drug registrants to confirm whether they should be included in CDER's catalog of OTC monograph drugs and establishments within 6 months of registration.

2. **CGMP Workshop**: By the end of FY2028, FDA will hold a workshop intended to assist industry in improving quality and compliance with CGMP requirements.

3. **Site Selection Model**: By the end of FY2028, FDA will update the risk-based Site Selection Model used to prioritize surveillance inspections and the associated MAPP (MAPP 5014.1 *Understanding CDER's Risk-Based Site Selection Model*) to include risk factors associated with OTC monograph drugs, as appropriate. Given an initial observed association between failure to pay OMUFA fees and surveillance inspection outcomes, FDA will evaluate the failure to pay OMUFA fees as an important risk factor to be included if it continues to show an association.

### B. QUALITY INFORMATION TRANSPARENCY

1. **Records Request Information**: FDA will report annually on its website aggregate information about records requests issued to OTC monograph drug manufacturers under section 704(a)(4) of the FD&C Act. Reporting will begin in FY2027 if the aggregate number of requests issued exceeds 20; otherwise, reporting will begin in FY2028.

2. **Warning Letter Webpage**: By the end of FY2027, FDA will enhance the Agency's warning letter webpage to improve its search capability for warning letters issued to OTC monograph drug manufacturers

## IV. USER FEE RESOURCE MANAGEMENT

### A. OMUFA COLLECTIONS

i. Starting in FY2026, FDA will take at least three steps to increase visibility of the OMUFA arrears list, such as highlighting its availability in FDA communications and enhancing outreach to external stakeholders.

ii. By FY2026, FDA will enhance the OMUFA arrears list to specify whether the facility registration is for a foreign or domestic firm.

iii. Starting in FY2028, FDA will use information obtained from records requests issued to OTC monograph drug manufacturers under section 704(a)(4) of the FD&C Act to focus outstanding user fee recovery efforts.

iv. Starting in FY2026, FDA will publish, on a quarterly basis, a list of all facilities that have paid the OMUFA facility fee for the prior fiscal year.

v. Starting with the FY2026 report, FDA will publish in the annual OMUFA Financial Report the following information as of the end of the fiscal year:

   1. The number of facilities that are registered as either foreign or domestic firms.

   2. The number of facilities on the arrears list broken out by foreign and domestic facilities.

3. .The number of dunning letters sent by the FDA in the last fiscal year.

## V. HIRING AND RETENTION OF PROGRAM STAFF

### A. GOALS FOR PROGRAM HIRING

1. **Hiring**

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

a. FY 2026: 6

b. FY 2027: 3

c. FY 2028: 2

d. FY 2029: 0

e. FY 2030: 0

**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 over time. FDA scientific review work is highly technical and specialized, requiring knowledge and skills that must be taught after onboarding. Typically, 2 years are needed 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.

## APPENDIX - DEFINITIONS AND EXPLANATIONS OF TERMS

1. An Over-the-Counter (OTC) monograph describes conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing, under which an OTC drug in a given therapeutic category (e.g., sunscreen, antacid) is GRASE for its intended use.

2. An Over-the-Counter Monograph Order Request (OMOR) is a request for an order submitted under section 505G(b)(5) of the FD&C Act. See also section 744L(7) of the FD&C Act.

3. The term “final order” refers to a final administrative order authorized under section 505G(b) of the FD&C Act.

4. The term “crowdsourcing” involves the practice of asking the public for ideas, information, and opinions to help solve a problem in an innovative way or streamline an intricate process for an organization, using a specific platform.[14]

[14] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/fda-crowdsourcing.