# GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROGRAM ENHANCEMENTS FISCAL YEARS 2028-2032

# GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2028 THROUGH 2032

This document contains the performance goals and program enhancements for the Generic Drug User Fee Amendments (GDUFA) reauthorization for fiscal years (FYs) 2028-2032, known as GDUFA IV. It is commonly referred to as the "Goals Letter" or "Commitment Letter." The Goals Letter represents the product of the Food and Drug Administration's (FDA or the Agency) discussions with the regulated industry and public stakeholders, as mandated by Congress. The performance and procedural goals and program enhancements specified in this letter apply to aspects of the generic drug assessment program and build on the GDUFA program established and enhanced through previous authorizations. New enhancements to the program are designed to maximize the efficiency and utility of each assessment cycle, with the intent to reduce the number of assessment cycles for abbreviated new drug applications (ANDAs) and facilitate timely access to quality, affordable, safe and effective generic medicines. Certain new enhancements are specifically designed to foster the development, assessment, and approval of Complex Generic Products and facilitate domestic manufacturing of generic products. FDA is committed to meeting the performance goals specified in this letter and to continuous improvement of the Agency's performance.

The performance goals and procedures of FDA, as agreed to under the fourth authorization of the generic drug user fee program, are summarized below.

Unless otherwise stated, goals apply to cohorts of each fiscal year. For the purposes of calculating all time periods in this Commitment Letter, FDA will calculate the goal date from the day after a submission, to be consistent with FDA's other user fee programs.

# I. SUBMISSION ASSESSMENT PERFORMANCE GOALS

## A. Original ANDAs and Amendments

1. Assess and act on 90 percent of standard original ANDAs within 10 months of the date of ANDA submission, subject to any adjustments to the goal dates described in this commitment letter.

2. Assess and act on 90 percent of priority original ANDAs within the applicable assessment goal, subject to any adjustments to the goal dates described in this commitment letter.

    a. Assess and act on priority original ANDAs within 8 months of the date of ANDA submission if the applicant submits a Pre-Submission Facility Correspondence (PFC) not later than 60 days prior to the date of ANDA submission, and the PFC is found to be complete and accurate, subject to the limitations set forth in section I(A)(2)(b).

    b. Assess and act on priority original ANDAs within 10 months of the date of ANDA submission if:

        i. the applicant submits a PFC later than 60 days prior to the date of ANDA submission, or does not submit a PFC;

        ii. information in a PFC is found to be incomplete or inaccurate;

        iii. the information submitted in the ANDA differs significantly from what was submitted in the PFC; or

        iv. FDA, upon assessment of a final bioequivalence study report submitted in the ANDA, determines that an inspection of the relevant site or sites is necessary.

3. If, upon initial submission, a standard or priority original ANDA contains a certification that a site/facility listed on the Form FDA 356h is not ready for inspection (i.e., the box "no" is checked in response to "is the site ready for inspection?" in section 28), FDA will set a goal date that is 15 months from the date of submission. FDA will conduct a filing review of such an ANDA but will not commence substantive assessment of the application until an amendment described in subsection I(A)(3)(a) is submitted, or the goal date is reset pursuant to I(A)(3)(b).

    a. During the initial 15-month review period, if the applicant submits an amendment with a Form FDA 356h that certifies all facilities are ready for inspection, FDA will set a new goal date that is 8 months from the date of submission for priority amendments (if a PFC was submitted per I(A)(2)(a)), or 10 months from the date of submission for other amendments.

    b. If the applicant does not submit an amendment described in I(A)(3)(a) by 30 days before the goal date, FDA will reset the goal date for an additional 15 months, i.e., 30 months from the date of original ANDA submission. FDA will assess and act on 90 percent of such ANDAs within 30 months of the date of the original submission as applicable.

4. Assess and act on 90 percent of standard Major Amendments within the applicable assessment goal.

    a. Assess and act on standard Major Amendments within 8 months of the date of amendment submission if pre-approval inspection (PAI) is not required.

    b. Assess and act on standard Major Amendments within 10 months of the date of amendment submission if PAI is required.

5. Assess and act on 90 percent of priority Major Amendment submissions within the applicable assessment goal.

    a. Assess and act on priority Major Amendments within 6 months of the date of amendment submission if preapproval inspection is not required.

    b. Assess and act on priority Major Amendments within 8 months of amendment submission if a preapproval inspection is required, the applicant submits a PFC not later than 60 days prior to the date of amendment submission, and the PFC is found to be complete and accurate, subject to the limitations set forth in section I(A)(6).

6. Assess and act on priority Major Amendments within 10 months of amendment submission if a preapproval inspection is required and if:

    a. the applicant submits a PFC later than 60 days prior to the date of the amendment, or does not submit a PFC;

    b. information in a PFC is found to be incomplete or inaccurate;

    c. the information submitted in the amendment differs significantly from what was submitted in the PFC; or

    d. FDA, upon assessment of a final bioequivalence study report submitted in the amendment, determines that an inspection of the relevant site or sites is necessary.

7. Assess and act on 90 percent of standard and priority Minor Amendments within 3 months of the date of amendment submission.

**Table for Section I(A)(1) and (2): Original ANDAs**

| SUBMISSION TYPE | GOAL |
|---|---|
| **Standard Original ANDAs** | 90% within 10 months of submission date, subject to any adjustment to the goal date described in section I(A)(3). |
| **Priority Original ANDAs** | 90% within 8 months of submission date if applicant meets requirements under section I(A)(2)(a), subject to any adjustment to the goal date described in section I(A)(3). |

| | |
|---|---|
| | 90% within 10 months of submission date if applicant meets any limitations as described under section I(A)(2)(b), subject to any adjustment to the goal date described in section I(A)(3). |

**Table for Section I(A)(4) – (7): Amendments**

| SUBMISSION TYPE | GOAL |
|---|---|
| **Standard Major Amendments** | 90% within 8 months of submission date if preapproval inspection not required. |
| | 90% within 10 months of submission date if preapproval inspection required. |
| **Priority Major Amendments** | 90% within 6 months of submission date if preapproval inspection not required. |
| | 90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under section I(A)(5)(b). |
| | 90% within 10 months of submission date if preapproval inspection required and applicant meets any limitations as described under section I(A)(6). |
| **Standard and Priority Minor Amendments** | 90% within 3 months of submission date. |

## B. PASs and PAS Amendments

1. Assess and act on 90 percent of standard prior approval supplements (PASs) within the applicable assessment goal.

    a. Assess and act on standard PASs within 6 months of the date of PAS submission if preapproval inspection is not required.

    b. Assess and act on standard PASs within 10 months of the date of PAS submission if preapproval inspection is required.

2. Assess and act on 90 percent of priority PASs within the applicable assessment goal.

    a. Assess and act on priority PASs within 4 months of the date of PAS submission if preapproval inspection is not required.

    b. Assess and act on priority PASs within 8 months of the date of PAS submission if a preapproval inspection is required, the applicant submits a PFC not later than 60 days prior to the date of PAS submission, and the PFC is found to be complete and accurate, subject to the limitations set forth in section I(B)(2)(c).

c. Assess and act on priority PASs within 10 months of PAS submission if a preapproval inspection is required and if:

   i. the applicant submits a PFC later than 60 days prior to the date of PAS submission, or does not submit a PFC;

   ii. information in a PFC is found to be incomplete or inaccurate;

   iii. the information submitted in the PAS differs significantly from what was submitted in the PFC; or

   iv. FDA, upon assessment of a final bioequivalence study report submitted in the PAS, determines that an inspection of the relevant site or sites is necessary.

3. Assess and act on 90 percent of Major Amendments to standard PASs within the applicable assessment goal.

   a. Assess and act on Major Amendments to standard PASs within 6 months of the date of amendment submission if preapproval inspection is not required.

   b. Assess and act on Major Amendments to standard PASs within 10 months of the date of amendment submission if preapproval inspection is required.

4. Assess and act on 90 percent of Major Amendments to priority PASs within the applicable assessment goal.

   a. Assess and act on Major Amendments to priority PASs within 4 months of the date of amendment submission if preapproval inspection is not required.

   b. Assess and act on priority Major Amendments to priority PASs within 8 months of amendment submission if a preapproval inspection is required, if the applicant submits a PFC not later than 60 days prior to the date of amendment submission, and the PFC is found to be complete and accurate, subject to the limitations set forth in section I(B)(4)(c).

   c. Assess and act on priority Major Amendments to priority PASs within 10 months of amendment submission if a preapproval inspection is required and if:

      i. the applicant submits a PFC later than 60 days prior to the date of the PAS amendment, or does not submit a PFC;

      ii. information in a PFC is found to be incomplete or inaccurate;

      iii. the information submitted in the PAS amendment differs significantly from what was submitted in the PFC; or

      iv. FDA, upon assessment of a final bioequivalence study report submitted in the amendment, determines that an inspection of the relevant site or sites is necessary.

5. Assess and act on 90 percent of Minor Amendments to standard and priority PASs within 3 months of the date of amendment submission.

**Table for Section I(B)(1) and (2): PASs**

| SUBMISSION TYPE | GOAL |
|---|---|
| **Standard PASs** | 90% within 6 months of submission date if preapproval inspection not required. |
| | 90% within 10 months of submission date if preapproval inspection required. |
| **Priority PASs** | 90% within 4 months of submission date if preapproval inspection not required. |
| | 90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under section I(B)(2)(b). |
| | 90% within 10 months of submission date if preapproval inspection required and applicant meets any limitations as described under section I(B)(2)(c) |

**Table for Section I(B)(3) – (5): PAS Amendments**

| SUBMISSION TYPE | GOAL |
|---|---|
| **Standard PAS Major Amendments** | 90% within 6 months of submission date if preapproval inspection not required. |
| | 90% within 10 months of submission date if preapproval inspection required. |
| **Priority PAS Amendments** | 90% within 4 months of submission date if preapproval inspection not required. |
| | 90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under section I(B)(4)(b). |
| | 90% within 10 months of submission date if preapproval inspection required and applicant meets any limitations as described under section I(B)(4)(c). |
| **Standard and Priority Minor PAS Amendments** | 90% within 3 months of submission date. |

## C. Unsolicited Amendments and PAS Amendments

1. Assess and act on Unsolicited Amendments and PAS amendments submitted during the assessment cycle by the later of the goal date for the original submission/solicited amendment or the goal date assigned in accordance with sections (I)(A)(4), (5), (6) and (7) and (I)(B)(3), (4) and (5), respectively, for the Unsolicited Amendment.

2. Assess and act on Unsolicited ANDA Amendments and PAS amendments submitted between assessment cycles by the later of the goal date for the subsequent solicited

amendment or the goal date assigned in accordance with sections (I)(A)(4), (5), (6), and (7) and (I)(B)(3), (4), and (5), respectively, for the Unsolicited Amendment.

## D. Drug Master Files

Complete the initial completeness assessment for 90 percent of Type II active pharmaceutical ingredient (API) Drug Master Files (DMFs) within 60 days of the later of the date of DMF submission or DMF fee payment.

**Table for Section I(D): DMFs**

| SUBMISSION TYPE | GOAL |
|---|---|
| **Type II API DMF** | 90% of initial completeness assessments within 60 days of the later of the date of DMF submission or DMF fee payment. |

## E. Controlled Correspondence

1. A Controlled Correspondence may be submitted prior to ANDA submission or after issuance of a Complete Response Letter (CRL) or tentative approval, or after ANDA approval. During an ANDA assessment cycle, a Controlled Correspondence may only be submitted if an applicant seeks further feedback on an issue that is not under review by FDA, or to seek a Covered Product Authorization. During an ANDA assessment cycle, all other correspondence will be general correspondence.

   The requestor will provide an ANDA number(s) or pre-assigned ANDA number(s) for the product(s) that is (are) the subject of the Controlled Correspondence submission. If an ANDA number or pre-assigned ANDA number is provided in a Controlled Correspondence, the applicant does not need to submit copies of that Controlled Correspondence and the Agency's response to the correspondence when submitting a subsequent related Controlled Correspondence.

2. Review and respond to 90 percent of Controlled Correspondence within the applicable review goal.

   a. Review and respond to Level 60 Controlled Correspondence within 60 days of the date of submission.

   b. Review and respond to Level 90 Controlled Correspondence within 90 days of the date of submission.

   c. Review and respond to Level 120 Controlled Correspondence within 120 days of the date of submission.

3. If, prior to acceptance of a Controlled Correspondence, FDA determines that required administrative information is missing and that omission would otherwise preclude acceptance of the Controlled Correspondence, FDA will contact the requestor to obtain the missing information. The goal date for that Controlled Correspondence will be extended by the amount of time that FDA's request for the missing information is outstanding with

the requestor. If the requestor does not provide the missing information within 10 days, FDA may decide to close the Controlled Correspondence and notify the requestor through the portal of that decision.

4. If, during substantive review of a Controlled Correspondence, FDA determines that information is missing, FDA may contact the requestor to obtain the missing information. The goal date for that Controlled Correspondence will be extended by the amount of time that FDA's request for the missing information is outstanding with the requestor. If the requestor does not provide the missing information within 10 days, FDA may decide to close the Controlled Correspondence and notify the requestor through the portal of that decision.

5. Requestors may ask for clarification of ambiguities in the Controlled Correspondence response by submitting a TYPE 30 meeting request.

**Table for Section I(E): Controlled Correspondence**

| SUBMISSION TYPE | GOAL |
|---|---|
| **Level 60 Controlled Correspondence** | 90% within 60 days of submission date. |
| **Level 90 Controlled Correspondence** | 90% within 90 days of submission date. |
| **Level 120 Controlled Correspondence** | 90% within 120 days of submission date. |

## II. ORIGINAL ANDA ASSESSMENT PROGRAM ENHANCEMENTS

### A. ANDA Receipt

1. FDA will strive to determine whether to receive ANDAs within 60 days of the date of ANDA submission.

2. To enable FDA to rapidly determine whether to receive an ANDA pursuant to 21 CFR 314.101, and with consideration of final Agency guidances that address ANDA receipt determinations, FDA will communicate minor technical deficiencies (e.g., document legibility), and deficiencies potentially resolved with information in the ANDA at original submission, to provide applicants with an opportunity for resolution within 10 days. If a response that resolves a deficiency is submitted within 10 days of such communication, that deficiency will not be a basis for a refuse-to-receive decision.

3. At the time of receipt, FDA will notify the applicant in the acceptance letter whether the ANDA or PAS is subject to priority or standard assessment.

4. Upon receiving an ANDA for assessment, each assessment discipline will perform an initial assessment of its respective portion of the application to identify issues for which a consult to another discipline, Office, or Center is needed based on this threshold review. Disciplines will promptly initiate such consults and request that the consult responses be

provided before the mid-point of the assessment. Disciplines will incorporate potential deficiencies identified based on such consult responses into their Mid-Cycle DRLs.

## B. ANDA Assessment Transparency and Communications Enhancements

To promote transparency and communication between FDA and ANDA applicants, FDA will apply the assessment program enhancements below to the assessment of all ANDAs. The goal of these program enhancements is to improve predictability and transparency, promote the efficiency and effectiveness of the review process, minimize the number of assessment cycles necessary for approval, increase the overall rate of approval, and facilitate greater access to generic drug products.

1. Information Requests (IRs) and Discipline Review Letters (DRLs):

    a. IRs and DRLs do not stop the assessment clock.

    b. In the first assessment cycle, FDA will issue the appropriate IR(s) and/or DRL(s) from each assessment discipline by the mid-point of the assessment (with further details about the Labeling discipline described in subsection II(B)(2) below).

        i. In a Mid-Cycle DRL, the assessment discipline will assign a due date for response and identify major and minor deficiencies.

        ii. If an applicant responds by the response due date, FDA will assess a response to minor deficiencies within the originally assigned goal date for the submission, subject to the exceptions described in II(B)(1)(iii).

        iii. Responses to any major deficiencies, or to minor deficiencies that include data and information that require comparable FDA assessment resources to those required for major deficiencies, for example, a consult, will be considered Major Amendments. FDA will extend the goal date consistent with the number of months needed to assess a comparable standard or priority Major Amendment (see section I(A)(4)-(6)).

    c. FDA will issue IRs and DRLs after the midpoint of the first assessment cycle and at any time in subsequent assessment cycles, when, in FDA's judgment, there are one or more minor deficiencies in a discipline that, if resolved using an IR or DRL, could lead to approval or tentative approval of an ANDA in the current assessment cycle. FDA will issue the IR or DRL and provide a due date for the applicant's response before the goal date.

        i. If the applicant responds to the minor deficiencies in the IR or DRL by the due date, and FDA finds the amendment to satisfactorily address all of the issues identified in the IR or DRL, and the response does not contain unsolicited information, FDA may extend the goal date consistent with section II(B)(1)(c)(ii). Goal dates will only be extended when necessary to provide adequate time to review the applicant's response and take action on the application. FDA will strive to avoid extending the goal date for amendments in response to IRs or DRLs that do not contain new substantive information.

ii. If a goal date is extended under section II(B)(1)(c)(i), the new goal date will be 90 days from the date of the applicant's response to the IR or DRL, unless the applicant has elected in its initial ANDA submission or resubmission of the application that only one goal date extension under section II(B)(1)(c)(i) will be available to FDA in the current assessment cycle. If the applicant makes such an election, FDA will extend the current goal date by 90 days.

iii. FDA's decision to extend the goal date will be communicated in an amendment acknowledgement letter.

iv. FDA will continue to issue IRs and/or DRLs late in the assessment cycle for original submissions and amendments until it is no longer feasible within the current assessment cycle for the applicant to develop and FDA to assess a response to the IR and/or DRL. For IRs and DRLs issued past the mid-point of the assessment cycle, the assessment discipline generally will assign a due date for response and identify major and minor deficiencies. DRLs issued without a response due date likely will signify a forthcoming CRL.

d. If the applicant does not provide a complete response to an IR and/or DRL by the response due date (or any agreed-upon extension), FDA may include the same deficiencies from the IR or DRL in a CRL and assess the response during the next assessment cycle.

e. If a discipline identifies a Significant Major deficiency, that deficiency will be communicated in a CRL as soon as is feasible.

2. Specific commitments related to IRs and DRLs for labeling:

a. In the first assessment cycle, the Labeling Discipline will:

i. upon receiving an ANDA for assessment, make an initial determination whether there is a need for a consult to be issued to another review discipline, including for a consult regarding an applicant's request to "carve out" language in the proposed labeling protected by patents or exclusivities, and will initiate such consults;

ii. strive to issue any DRL by the mid-point of the assessment, with the exception that there may be a delay of the issuance of any labeling deficiencies that result from changes to the labeling of the reference listed drug (RLD) or a new exclusivity or patent listing;

iii. if labeling deficiencies are identified at the mid-point, and the applicant timely responds to an IR or DRL with revised labeling that addresses those deficiencies, strive to perform a second labeling assessment before the goal date, with the aim of avoiding goal date extensions solely due to labeling;

iv. continue to assess labeling to enable an action within the assessment cycle if other disciplines are acceptable in an application, and for such applications, strive to review revised labeling submitted by the applicant in response to changes to the RLD labeling within 30 days of receipt; and

v. generally provide labeling comments in track changes format for deficiencies in the proposed prescribing information and patient labeling. Narrative comments will generally be provided for deficiencies in proposed carton or container labeling.

b. Labeling IRs and DRLs in all assessment cycles:

FDA will minimize issuing CRLs that contain only labeling deficiencies and will strive to avoid goal date extensions due solely to labeling by, for example, using later-cycle IRs and the imminent action process.

3. Imminent Actions:

   a. FDA will continue assessment of an ANDA past the goal date if, in FDA's judgment, it may be possible to approve or tentatively approve an ANDA within 60 days after the goal date. Such circumstances may include:

      i. When the application meets the requirements for tentative approval by the goal date, but the legally permissible ANDA approval date is within 60 days after the goal date, and FDA may be able to approve the ANDA when it becomes legally permissible to do so.

      ii. When FDA may be able to approve or tentatively approve an application submitted by a first applicant by the 30-month forfeiture date described in section 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)(5)(D)(i)(IV)).

      iii. When, at the sole discretion of FDA, and subject to resources, one or more small issues remain from one or more disciplines that in FDA's judgment may be resolved within 60 days after the goal date.

   b. If an ANDA is approved or tentatively approved within 60 days after the goal date, the goal date will be considered to have been met.

4. FDA will strive to act prior to a goal date, or the 60-day period for an imminent action, when the assessment is complete and there are no outstanding deficiencies.

5. To facilitate the labeling assessment, an applicant will clearly state in the cover letter to an ANDA, ANDA amendment, PAS, or PAS Amendment that the submission includes a proposed labeling carve-out.

6. Communication regarding Deficiencies and Actions:

   a. With respect to imminent actions, applicants may inquire and FDA will promptly respond to an applicant inquiry seeking information as to whether FDA intends to work through the goal date in accordance with section II(B)(3). This communication will be preliminary and subject to change.

   b. If a regulatory project manager (RPM) learns that a major deficiency is likely forthcoming, the RPM will notify the applicant. The RPM will not be expected to

discuss the nature of the specific forthcoming deficiencies prior to issuance of the CRL.

c. If an RPM learns that FDA is likely to miss the goal date for an ANDA, no later than the goal date, the RPM will notify the applicant of the delay in taking an action, describe the issue causing the delay consistent with confidentiality obligations including the outstanding discipline(s), if any, and will either indicate the estimated time for FDA's action on the application or, for ANDAs covered by section II(B)(9) below, notify the applicant of the new goal date.

d. The applicant may periodically request a Review Status Update for each discipline. In response to the applicant's request, the RPM will timely provide a Review Status Update for each discipline as described in Manual of Policies and Procedures (MAPP) 5200.12.

e. If FDA identifies a potential complex data issue that could affect approvability of the application, FDA will promptly communicate the existence of such issue to the applicant without identifying the site or facility.

7. FDA will indicate the assessment classification for a responding amendment in a CRL and include FDA's basis for classifying a responding amendment as Major.

8. Applicants who receive a CRL have the following options to engage with FDA prior to responding to the CRL:

    a. A TYPE 30 meeting to seek clarification concerning deficiencies identified in a CRL, subject to the conditions described in section III(C).

    b. Submission of a Controlled Correspondence as described in section I(E); or

    c. A TYPE 90 meeting to request scientific advice on possible approaches to address deficiencies identified in a CRL related to establishing equivalence, subject to the conditions described in section III(C).

9. If the goal date for an original ANDA (including a resubmission) will be missed by more than 60 days for any reason, including due to a complex regulatory issue:

    a. FDA will assign a new goal date that is 6 months from the missed goal date.

    b. If this newly assigned goal date is not met, no subsequent new goal date will be assigned to the submission, but FDA will contact the applicant by the goal date to inform them that the goal date will not be met and will offer the applicant an opportunity for a meeting with the Agency.

    c. FDA will strive to issue IRs and/or DRLs by the original goal date, noting any outstanding deficiencies that, in its judgment, are unrelated to the issue causing the original goal date miss.

        i. For outstanding deficiencies that, in FDA's judgment, could be resolved before the newly assigned 6-month goal date, FDA will provide a due date for the applicant's response to the IR or DRL, and if the applicant responds by the

due date with information to address the deficiency, FDA will assess the response and endeavor to work with the applicant to resolve the deficiency by the new goal date.

ii. For outstanding deficiencies that, in FDA's judgment, cannot be resolved before the newly assigned 6-month goal date, the Agency will still strive to issue a DRL noting the deficiency, but will not provide a response due date. Such DRLs without a response date generally signify a forthcoming CRL that may include any deficiencies identified in the DRL once FDA addresses the issue causing the goal date miss. FDA will not assess a response to the DRL within the current assessment cycle but will instead defer review to the next assessment cycle.

d. If the reason the goal date will be missed is due to a complex data issue, which, in FDA's judgment, cannot be fully assessed and resolved for appropriate action by the goal date, FDA will also contact the relevant site or facility for which a complex data issue has been identified. If an opportunity for a meeting is offered under section II(B)(9)(b), this meeting will be offered to the relevant site or facility, and the applicant may also participate in the meeting if the relevant site or facility provides FDA written authorization of such participation in advance of the meeting.

e. For an ANDA for which a goal date is missed on or after October 1, 2027 and that has been pending for more than 60 days after its original goal date, but for which FDA has not yet assigned a new goal date under section II(B)(9)(a), the process under section II(B)(9)(a)-(b) will apply. If FDA determines it would be appropriate to facilitate resolution of outstanding issues, FDA will issue the IRs and/or DRLs described in section II(B)(9)(c) no later than 70 days from the original goal date.

f. For an ANDA with a missed goal date that is pending with FDA as of October 1, 2027, FDA will strive to timely address unresolved issues to take action on the application. In addition, to the extent FDA has not already done so, FDA will provide the applicant with an opportunity for a meeting and strive to issue IRs and/or DRLs noting any outstanding deficiencies that, in FDA's judgment, are unrelated to the issue causing the original goal date miss, consistent with section II(B)(9)(b) and II(B)(9)(c).

10. Goal Date Extensions following a post-PAI meeting for original ANDAs

a. When a meeting request package containing substantive information related to a response to deficiencies observed during a PAI is submitted prior to a post-PAI meeting, as described in section VI(D) or substantive information is provided to FDA by the facility or the applicant following a post-PAI meeting, FDA may extend the goal date by 90 days.

b. FDA's decision to extend the goal date should, except in rare circumstances, be limited to occasions when an extension would permit review of the new information provided, and there is a reasonable likelihood that the new information provided could address outstanding facility deficiencies relevant to the application and lead to approval or tentative approval in the current assessment cycle.

c. An extension will not be applied under this provision if the applicant has elected that only one goal date extension will be available to FDA in the current assessment cycle and the goal date has already been extended by 90 days per section II(B)(1)(c)(ii).

11. FDA will promptly notify the applicant when observations identified during a surveillance inspection are conveyed to a facility named in the ANDA (through Form FDA 483) that may cause the facility to be classified as Official Action Indicated (OAI). If a potential OAI (pOAI) alert results from a surveillance inspection of a facility named in the ANDA and occurs within 90 days of the applicable goal date, and there are no other major deficiencies, FDA will extend the goal date by 120 days from the close of the inspection. For disciplines other than facilities, FDA will continue to work toward the original goal date.

## C. Assessment Classification Changes During the Assessment Cycle

1. If during the assessment of an ANDA, ANDA Amendment, PAS, or PAS amendment, the assessment classification changes from Standard to Priority, FDA will notify the applicant within 14 days of the date of the change.

2. An applicant may request a change in the assessment classification at any time during the assessment.

3. Once an ANDA or PAS submission is classified as being subject to priority assessment, the application will retain such priority assessment classification status for the duration of that assessment cycle.

4. FDA will include an explanation of the reasons for any denial of an assessment status reclassification request.

5. If an applicant requests a videoconference as part of its request to reclassify a Major Amendment or standard assessment status, FDA will schedule and conduct the videoconference and decide 90 percent of such reclassification requests within 30 days of the date of FDA's receipt of the request for a videoconference. This goal only applies when the applicant accepts the first scheduled videoconference date offered by FDA. This goal does not apply to a Major Amendment in response to a CRL that was deemed major only due to a facility deficiency ("Facility-Based Major CRL Amendment") described in section II(C)(7).

6. An amendment in response to a CRL classified by FDA as Minor that is submitted more than one year after the date FDA issued the CRL will be reclassified as a Major Amendment, except for ANDAs for products that are on the drug shortage list under section 506E of the FD&C Act (21 U.S.C. 356e), or are the subject of a response to a Public Health Emergency as declared by the Secretary of the U.S. Department of Health and Human Services under section 319 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d), or are anticipated to be subject to the same criteria as apply to such a declaration, at the time of submission.

7. Reclassification of Facility-Based Major CRL Amendments

    a. Upon submission of a Facility-Based Major CRL Amendment, an applicant can request that FDA reclassify the Major Amendment to minor.

    b. A request for reclassification must be made at the time of amendment submission and include supporting information detailing why the facility deficiency has been resolved and no additional facility assessment is needed.

    c. FDA will grant the request to reclassify the Facility-Based Major CRL Amendment if FDA determines that none of the following are necessary to complete the assessment of the amendment:

        i. A facility inspection

        ii. Use of alternate tools for facility assessment

        iii. Continued assessment of inspection deficiency responses

    d. If FDA denies the request, the Agency will communicate the substantive basis of the denial to the applicant and the ANDA amendment will be assigned a 6-, 8-, or 10-month goal date, as applicable, from the original date of the amendment submission.

    e. FDA will make a decision on a request for reclassification of a Facility-Based Major CRL Amendment within 30 days from the date of submission for priority amendments, and within 60 days from the date of submission for standard amendments. If the Facility-Based Major CRL Amendment is reclassified as minor, the goal date will be 3 months from the end of the 30- or 60-day decisional period, as applicable.

    f. The goal dates for decisions on requests for reclassification and amendment assessment for which a request for reclassification is submitted are as follows:

**Table for Section II(C)(7): Goal Date Decisions on Requests for Reclassification**

| SUBMISSION TYPE | FDA RESPONSE REGARDING MAJOR TO MINOR RECLASSIFICATION | NEW ANDA GOAL DATE IF RECLASSIFICATION GRANTED | ANDA GOAL DATE IF RECLASSIFICATION DENIED |
|---|---|---|---|
| **Standard Major Amendment** | Within 60 days of submission date | Within 5 months of submission date | Within 8 months of submission date if preapproval inspection is not required |
| | | | Within 10 months of submission date if preapproval inspection is required |
| **Priority Major Amendment** | Within 30 days of submission date | Within 4 months of submission date | Within 6 months of submission date if |

| | | | |
|---|---|---|---|
| | | | preapproval inspection is not required |
| | | | Within 8 months of submission date if preapproval inspection required and applicant meets the requirements under section I(A)(5)(b) |
| | | | Within 10 months of submission date if preapproval inspection required and applicant meets any limitations as described under section I(A)(6) |

**D. ANDA Approval and Tentative Approval**

If applicants submit and maintain ANDAs consistent with the statutory requirements for approval under 505(j) of the FD&C Act; respond to IRs and DRLs completely and within the time frames requested by FDA; and timely submit all required information under 21 CFR parts 314 and 210, including information concerning notice (21 CFR 314.95), litigation status (21 CFR 314.107), and commercial marketing (21 CFR 314.107); then FDA will strive to:

1. Approve approvable ANDAs in the first assessment cycle;

2. Approve First Generics on the earliest lawful approval date, if known to FDA; and

3. Tentatively approve or approve ANDAs for "First Applicants" as described in section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act to avoid forfeiture of 180-day exclusivity.

**E. Dispute Resolution**

1. An applicant may pursue a request for reconsideration within the assessment discipline at the Division-level or original signatory authority, as needed.

2. The Office of Generic Drugs, Office of Regulatory Operations Associate Director will track each request for Division-level reconsideration through resolution.

3. Following resolution of a request for reconsideration, an applicant may pursue formal dispute resolution above the Division-level, pursuant to procedures set forth in guidance for industry *Formal Dispute Resolution: Sponsor Appeals Above the Division Level Guidance for Industry and Review Staff* (November 2017).

4. FDA will respond to 90 percent of appeals above the Division-level within 30 days of Center for Drug Evaluation and Research (CDER)'s receipt of the written appeal.

5. CDER's Formal Dispute Resolution Project Manager (or designee) will track each formal appeal above the Division-level through resolution.

## F. Pre-Submission Facility Correspondence

1. For the purposes of section I(A) and I(B) above, FDA will consider a PFC to be complete and accurate if the submission consists of the following:

    a. For each manufacturing and testing facility involved in manufacturing processes and testing for the ANDA and corresponding Type II API DMF:

        i. facility name, operation(s) performed, facility contact name, address, FDA Establishment Identifier (FEI) number (if a required registrant or one has been assigned), DUNS number, registration information (for required registrants), and a confirmation that the facility is ready for inspection,

        ii. information needed to inform FDA's decision regarding the need for a preapproval inspection, such as a description of the manufacturing process and controls of critical steps, identification of any anticipated differences between pilot/exhibit scale and commercial scale processes, and as otherwise described in the guidance for industry *ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions* (June 2025) and any revisions, and

        iii. a certification by the applicant that any Type II DMF has similarly complete and accurate facility information, including complete facility information (i.e., facility name, operation, facility contact name, address, FEI number and DUNS number, and a confirmation that the facility is ready for inspection).

    b. Information needed to inform FDA's decision regarding the need for a preapproval inspection, such as a description of the drug substance manufacturing process, that is included in a corresponding Type II DMF is not required to be duplicated in the PFC for the ANDA if it is included in a corresponding Type II DMF.

    c. For all sites or organizations involved in all bioequivalence and clinical studies used to support the ANDA submission: site names, addresses, and website; the study numbers; a list and description of all study investigators consistent with the guidance *ICH E3 Structure and Content of Clinical Study Reports* (July 1996) section 16.1.4; the study conduct dates; and study protocols and any available amendments.

    d. For all sites or organizations involved in analytical studies used to support the ANDA submission the following are required: analytical site name, address, and website. For those studies that were initiated no later than 60 days prior to the ANDA submission, additional requirements are:

        i. a list of investigator name(s);

        ii. study conduct dates; and

iii. if the analytical method validation was completed before dosing, the analytical method validation study report(s).

e. This information is provided using a standardized electronic format and includes unique identifiers that are current and accurate.

2. Changes to information contained in a PFC when submitted in an ANDA that are considered a "significant change" include changes in the identified facilities for manufacture of the drug substance or drug product, the proposed manufacturing operations or operating principles, and the order of manufacturing unit operations, as described in the guidance *ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions* (June 2025) and any revisions.

### G. Other ANDA Assessment Program Aspirations

1. FDA aspires to continually improve the efficiency of the ANDA Assessment program.

2. The absence of a GDUFA IV commitment for a specific program function does not imply that the program function is not important. For example, other program functions include determining whether listed drugs were voluntarily withdrawn from sale for reasons of safety or effectiveness and ANDA proprietary name evaluations.

## III. SUITABILITY PETITIONS, PRODUCT SPECIFIC GUIDANCE, AND APPLICATION-RELATED MEETINGS

### A. Suitability Petitions

1. FDA will conduct a completeness assessment for petitions submitted under section 505(j)(2)(C) of the FD&C Act (commonly referred to as "suitability petitions") submitted in FY 2028-2032. The timeframe for the completeness assessment will be:

    a. 21 days after the date of petition submission; or

    b. If an IR is issued as part of the completeness assessment and the petitioner submits a response, FDA will finish the completeness assessment within 21 days after the date of receipt of the IR response.

2. Any suitability petition submitted in FY 2028-2032 will receive a goal date described in section III(B)(5).

3. The date of submission for the purposes of determining the fiscal year of submission will be the date of FDA's completion of the completeness assessment.

4. FDA will prioritize the review of suitability petitions for a drug product that:

    a. could mitigate or resolve a drug shortage and prevent future shortages;

    b. addresses a public health emergency declared by the Secretary of the U.S. Department of Health and Human Services under section 319 of the PHS Act, or anticipated under the same criteria as apply to such a declaration;

c. is for a new strength of a parenteral product that could aid in eliminating pharmaceutical waste or mitigating the number of vials needed per dose by addressing differences in patient weight, body size, or age; or

d. is subject to special review programs under the President's Emergency Plan for AIDS Relief (PEPFAR).

5. FDA will review and respond to 90 percent of suitability petitions that have been assigned a goal date within 6 months after the completeness assessment, up to a maximum of 90 suitability petitions completed per fiscal year.

6. As a general matter, if FDA misses goal dates on suitability petitions due to increased submissions, FDA will prioritize the review of suitability petitions for which a goal date was missed prior to reviewing newly submitted suitability petitions for the current fiscal year, except for those suitability petitions that are prioritized under section III(B)(4).

## B. Product-Specific Guidance

1. FDA will continue to issue Product Specific Guidance (PSG) identifying the methodology for generating evidence needed to support ANDA approval.

2. FDA will issue PSGs consistent with the following goals:

   a. For Complex Products approved in new drug applications (NDAs) on or after October 1, 2022, a PSG will be issued for 50 percent of such NDA products within 2 years after the date of approval, and for 75 percent of such NDA products within 3 years after the date of approval.

   b. FDA will continue to develop PSGs for Complex Products approved prior to October 1, 2022, for which no PSG has been published.

   c. For non-Complex Products approved in NDAs on or after October 1, 2022, that contain a new chemical entity (NCE) (as described in section 505(j)(5)(F)(ii) of the FD&C Act), a PSG will be issued within 2 years after the date of approval for 90 percent of such products.

3. Information on PSG Development:

   a. FDA will provide on its website information related to upcoming new and revised PSGs to support the development and approval of safe and effective generic drug products, including the projected date of PSG publication, which may be subject to change. When FDA becomes aware that it will not meet the issuance date listed on the website, FDA will update the website to provide a new projected issuance date in the next scheduled update.

   b. FDA will update the information on this website approximately quarterly.

   c. PSGs will be developed (or revised) and issued in accordance with FDA's Good Guidance Practices and will be reviewed by senior management and other

designated subject matter experts prior to publication and after consideration of any public comments submitted to the relevant docket of a published draft or final PSG.

4. Prioritization of PSG Development:

    a. FDA will make available on its website information on how the Agency prioritizes the development of PSGs.

    b. Industry may request via the portal for Controlled Correspondence that FDA develop a PSG. FDA will consider this request in prioritizing PSG development but will not consider this to be a Controlled Correspondence.

    c. FDA will seek public input on prioritization of PSGs annually during the public meeting on research prioritization described in section IV(D)(2).

    d. For Complex Products, FDA generally will prioritize the development of PSGs for Complex Products that contain an NCE (as described in section 505(j)(5)(F)(ii) of the FD&C Act) over Complex Products that do not contain an NCE.

5. When FDA intends to issue a new or revised PSG and there are ANDAs under review that may be impacted by changes to the new or revised PSG, FDA will ensure that at least Division-level program leadership is aware of the potential impact on the pending ANDAs for drug products with related new or revised PSGs.

## C. Application-Related Meetings

1. Formal GDUFA meetings between an applicant or prospective applicant and FDA consist of TYPE 30, TYPE 60, TYPE 90, and TYPE 120 meetings, as described in paragraphs (2) through (5) below. The purpose of these meetings is to provide a forum for a scientific exchange on specific issues (e.g., a proposed study design, alternative approach, additional study expectations, or questions) in which FDA will provide targeted advice regarding an ongoing ANDA program meaning that there is an associated pre-assigned ANDA number(s) or ANDA number(s) (including a pre-assigned ANDA number requested for submission of the meeting request). Meetings are appropriate for questions and issues that cannot be adequately addressed through Controlled Correspondence.

2. **TYPE 30 Meeting**. The purpose of a TYPE 30 meeting is for the applicant or prospective applicant to request clarification regarding a prior interaction with FDA or the impact of a change to a PSG on an ongoing ANDA program. The applicant or prospective applicant can request either a face-to-face (videoconference only) or written response format.

    a. Examples of TYPE 30 meetings include requests for clarification of:

        i. Deficiencies identified in a CRL submitted within 15 days of issuance of the CRL;

        ii. The impact of a change to a PSG (in vitro or in vivo) on an ongoing ANDA program submitted within 60 days after publication of the new or revised PSG;

iii. The rationale for any deficiency identified in a mid-cycle DRL for a Complex Generic Product, or to ask questions related to FDA's assessment of the data or information in an ANDA for a Complex Generic Product, if the request is submitted within 7 days of receiving the last mid-cycle DRL; and

iv. A response to a Controlled Correspondence or to a WRO or minutes of a prior meeting, if the request is submitted within 15 days of receipt.

b. Subject to section III(C)(6)(c), FDA will grant a TYPE 30 meeting if, in FDA's judgment:

i. A complete meeting package is submitted with the meeting request, identifying the issue from the prior interaction with FDA on which clarification is sought or the PSG was changed and the specific question(s) for discussion.

ii. The meeting request is submitted within the applicable timeframe specified in section III(C)(2)(a) above. Subject to the availability of resources, FDA may grant meeting requests submitted outside these timeframes; however, GDUFA IV goal dates will not apply to scheduling and conducting those meetings.

c. FDA generally will not provide preliminary comments in advance of the meeting.

d. FDA will hold the meeting or provide the written response within 30 days after receipt of the request.

3. **TYPE 60 Meeting**. The purpose of a TYPE 60 meeting is for the applicant or prospective applicant to request substantive follow up on the same topic as a prior interaction with FDA or to discuss the feasibility of a proposed ANDA development strategy for a Complex Generic Product. The applicant or prospective applicant can request either a face-to-face meeting (videoconference or in-person) or written response format.

a. Examples of TYPE 60 meetings include:

i. Substantive follow-up to a prior meeting, videoconference, Controlled Correspondence response, or ANDA submission that addressed the topic. To be eligible, the meeting package should address no more than one topic, include no more than five questions, and involve no more than three disciplines or review divisions.

ii. Protocol questions related to implementation of an existing PSG recommendation for a Complex Generic Product.

iii. Pre-submission meetings for a Complex Generic Product intended to provide an applicant for a complex generic product the opportunity to present unique or novel data or information that will be included in the ANDA submission such as formulation, key studies, justifications, and/or methods used in product development, as well as the interrelationship of the data and information in the ANDA.

iv. Requests to ask questions related to a proposed scientific approach to address possible deficiencies identified in the mid-cycle DRL(s) for a Complex Generic Product, if the request is submitted within 14 days of receiving the last mid-cycle DRL. An applicant may ask questions about potential new data or information to address the deficiencies. FDA will discuss the data and information but will not substantively assess the data or information provided by the applicant at the meeting. For this category of TYPE 60 meeting, FDA will extend the ANDA goal date by 60 days. FDA will extend the response due date for the relevant DRL(s) by recalculating the response due date starting from the date of the meeting (e.g., if the response was due 30 days after the DRL was issued, it will now be due 30 days after the TYPE 60 meeting).

v. Complex Generic Initial Advisory (CGIA) meeting to evaluate feasibility of a proposed ANDA development strategy for a Complex Generic Product in situations when FDA guidance is not available. During this meeting, FDA will provide scientific and regulatory advice before an applicant or prospective applicant begins significant development work and this meeting does not involve substantive review of summary data or full study reports.

b. Subject to section III(C)(6)(c), FDA will grant a TYPE 60 meeting if, in FDA's judgment, the applicant or prospective applicant submits a complete meeting package with the meeting request identifying the substantive issue from the prior interaction with FDA on the same topic on which it is seeking follow-up (if applicable) and the specific question(s) for discussion.

c. For meetings granted in written response format, FDA will provide the written response to the applicant or prospective applicant within 60 days after receipt of the request.

d. For meetings granted in face-to-face format, FDA will provide preliminary comments to the applicant or prospective applicant by the earlier of 60 days after receipt of the request, or 7 days before the meeting.

e. FDA will hold the meeting no later than 7 days after the meeting goal date (which is 60 days after receipt of the request).

4. **TYPE 90 Meeting**. The purpose of a TYPE 90 meeting is to provide an applicant or prospective applicant the opportunity to raise a new issue with FDA limited to a single topic. The applicant or prospective applicant can request either a face-to-face meeting (videoconference or in-person) or written response format.

a. Examples of TYPE 90 meetings include:

i. Questions on a single topic related to development of a Complex Generic Product. The purpose of this meeting is to provide a forum for scientific exchange on a specific issue in which FDA will provide targeted advice regarding an ongoing ANDA development program. Examples of such single topics are provided in paragraph (4)(g) below. Requests involving multiple topics should be submitted as TYPE 120 meetings (see section III(C)(5)).

ii. Bridging approach for a non-Complex Product without a marketed reference listed drug or reference standard.

iii. Alternative approaches to a PSG for a non-Complex Generic Product.

iv. Scientific advice on a proposed approach to address deficiencies identified in a CRL either for a Complex Generic Product related to establishing equivalence that is different from the approach used in the submitted ANDA or for a non-Complex Generic Product that raises issues that cannot be adequately addressed through Controlled Correspondence and are best addressed through a meeting.

b. Subject to section III(C)(6)(c), FDA will grant a TYPE 90 meeting if, in FDA's judgment, the meeting request contains a summary of the intended meeting package and all questions to be discussed at the meeting, and the new issue identified for discussion is appropriate for this meeting type.

c. The complete meeting package is due within 30 days of FDA's receipt of the meeting request.

d. For meetings granted in written response format, FDA will provide the written response to the applicant or prospective applicant within 90 days after receipt of the request.

e. For meetings granted in face-to-face format, FDA will provide preliminary comments to the applicant or prospective applicant by the earlier of 90 days after receipt of the meeting request, or 7 days before the meeting.

f. FDA will hold the meeting no later than 7 days after the meeting goal date (which is 90 days after receipt of the request).

g. Examples of eligible single topics for a meeting under paragraph (4)(a)(i) above include:

i. An alternative bioequivalence approach to that which is provided in a PSG for a Complex Generic Product or a bioequivalence approach for a Complex Generic Product with no PSG;

ii. A comparative use human factors study or other user interface comparison or alternative;

iii. Active ingredient sameness;

iv. Implementation of characterization-based approaches in a PSG (e.g., physicochemical characterization of complex active and inactive ingredients and complex formulations/devices; in vitro drug release testing for bioequivalence and/or quality purpose(s) for Complex Generic Products; in vitro permeation testing);

v. Immunogenicity;

vi. Pharmacology/toxicology;

vii. Quantitative medicine;

viii. Clinical endpoint bioequivalence study; or

ix. One of the following three product quality topics: drug substance, drug product or facilities (including manufacturing).

5. **TYPE 120 Meeting**. The purpose of a TYPE 120 meeting is for the applicant or prospective applicant to discuss multiple topics or topics that require additional FDA coordination to provide a substantive response. The applicant or prospective applicant can request either a face-to-face meeting (videoconference or in-person) or written response format.

    a. Examples of TYPE 120 meetings include:

        i. Discussion of questions on multiple topics related to development of a Complex Generic Product. The purpose of this meeting is to provide a forum for scientific exchange on multiple specific issues for which FDA will provide targeted advice regarding an ongoing ANDA development program. If an applicant seeks to discuss a single such issue, it can request a TYPE 90 meeting, as outlined in section III(C)(4) above.

        ii. Discussion of questions on crosscutting issues that may impact multiple ANDAs (e.g., a device platform or modeling approach proposed for use with multiple products).

        iii. Discussion of an approach or question with which FDA has limited experience in the ANDA program.

        iv. Review of a Comparative Use Human Factors study protocol.

    b. Subject to section III(C)(6)(c), FDA will grant a TYPE 120 meeting if, in FDA's judgment, the meeting request contains a summary of the intended meeting package and all questions to be discussed at the meeting, and the issues identified for discussion are appropriate for this meeting type.

    c. The complete meeting package is due within 45 days of FDA's receipt of the meeting request.

    d. For meetings granted in written response format, FDA will provide the written response to the applicant or prospective applicant within 120 days after receipt of the request.

    e. For meetings granted in face-to-face format, FDA will provide preliminary comments by the earlier of 120 days after receipt of the meeting request or 7 days before the meeting.

    f. FDA will hold the meeting no later than 7 days after the meeting goal date (which is 120 days after receipt of the request).

6. General Considerations for Application-Related Meetings

a. For all meeting types described in paragraphs (2) through (5) above:

   i. The applicant or prospective applicant will provide an ANDA or pre-assigned ANDA number(s) for the product(s) that is (are) the subject of the meeting request.

   ii. FDA will grant or deny the meeting request within 14 days of receipt.

   iii. FDA will provide meeting minutes within 30 days of the meeting date.

   iv. FDA may deny or cancel a meeting if the meeting package is incomplete at submission for a TYPE 30 or 60 meeting or at the meeting package due date for a TYPE 90 or 120 meeting.

b. Meeting Format

   i. As described in paragraphs (2) through (5) above, a face-to-face (i.e., in-person or videoconference) or written response format may be requested for TYPE 60, 90 and 120 meetings. For TYPE 30 meetings, a videoconference or written response format may be requested. FDA will prioritize face-to-face interactions for meetings for Complex Generic Products lacking PSGs, meetings to discuss a proposed alternative approach to a PSG, and meetings requesting discussion of other complex scientific or regulatory issues for which FDA judges that such interaction would be beneficial. Written responses will provide meaningful information to the prospective applicant or applicant that will inform drug development and/or regulatory decision-making.

   ii. For any request for a face-to-face meeting, if FDA determines an alternative format, such as a written response, is the most appropriate means for providing feedback and advice, FDA will notify the applicant of its initial format determination, and the applicant may then provide a rationale in a follow-up correspondence for why a face-to-face meeting is valuable and warranted, and FDA will reconsider the format upon receiving such a request. If FDA does not revise its initial format determination, it will provide its rationale for maintaining the alternative format. Such a request for reconsideration of the format for a meeting request does not change the goal dates associated with the meeting.

c. Conversions of Meeting Type

   i. FDA may convert a meeting request to a different meeting type or to a Controlled Correspondence, or may convert Controlled Correspondence to a meeting request, when, in FDA's judgment, the issue(s) or question(s) raised are more appropriately addressed through the converted type. Any conversions will be communicated at the time the meeting request is granted. For a TYPE 90 Meeting request, FDA will issue Written Response Only as opposed to converting to a Controlled Correspondence if such conversion would result in a longer review timeline, provided the issues or questions raised in the request are not appropriate for a TYPE 120 meeting.

ii. When feasible, FDA will strive to convert meeting requests to the most appropriate type (e.g., another meeting type or Controlled Correspondence) rather than reject them. For conversions to TYPE 120 meetings in particular, FDA may convert a meeting request for a TYPE 60 or TYPE 90 meeting to a TYPE 120 meeting if, upon reviewing the request, the agency determines the issue(s) raised will require input from additional disciplines, expanded internal consultation, or more time to prepare than is typical for a TYPE 60 or TYPE 90 meeting. The agency will apply a high threshold for such meeting conversions, using this approach only in rare circumstances. If FDA converts a meeting request to a TYPE 120 meeting for this reason, FDA will also convert the meeting to a face-to-face format (i.e., videoconference or in-person).

iii. If a portion of a meeting request is appropriate for the requested type but another portion is not, FDA may carve out the question(s) or issue(s) for which the requested type is not appropriate from the meeting request and grant the meeting request to discuss the remaining question(s) or issue(s). Before carving out question(s) or issues(s), FDA will provide the applicant with an explanation for the proposed carve-out and the path forward on the carved-out question(s) or issue(s), and provide the applicant 1 business day to determine whether they want to move forward with the meeting with the carve-out. If the applicant or prospective applicant does not wish to move forward with a meeting on the remaining question(s) or issue(s), the applicant or prospective applicant can request the meeting be canceled or converted to a TYPE 120 meeting with the question(s) or issue(s) FDA had previously proposed to carve out.

d. An applicant or prospective applicant may request a meeting on a topic not specifically enumerated in paragraphs (2) through (5) above. FDA may grant such a meeting request if, in FDA's judgment, doing so would significantly improve ANDA assessment efficiency and the question identified in the meeting request cannot be effectively addressed via a Controlled Correspondence.

e. Meeting Request Timing

i. A request can be made for any of the meeting types in paragraphs (2) through (5) above before the applicant submits an original ANDA, supplement, or resubmission in response to a CRL. An applicant may submit multiple meeting requests on separate topics and multiple meeting requests may be concurrently pending with FDA for the same ongoing ANDA program.

ii. During a review cycle, FDA will only consider a question in one venue at a time. An applicant may not submit a request to meet about an issue that is already under review in the context of another submission from the applicant, such as in the applicant's ANDA. For example, if an applicant wishes to discuss an issue raised in a DRL or IR before the applicant responds to the DRL or IR, but the applicant then submits a response to the DRL or IR prior to the meeting, the meeting will be canceled and the agency will instead consider the issue in its assessment of the applicant's DRL or IR response.

iii. If an applicant submits both a Controlled Correspondence and a meeting request raising the same question, FDA will delete one at its discretion and address the question in the context of the remaining request.

f. Performance goal: FDA will meet 90 percent of goal dates outlined in paragraphs (2) through (6) above for TYPE 30, 60, 90 and 120 meetings.

g. FDA aspires to continually improve the effectiveness of its Application-Related Meetings activities.

**Table for Section III(C):** Meetings Summary

| Meeting Type | TYPE 30 | TYPE 60 | TYPE 90 | TYPE 120 |
|---|---|---|---|---|
| Format | Face-to-Face (Videoconference ONLY) or WRO | Face-to-Face or WRO (Videoconference or In-Person) | | |
| Meeting Package Due | With the request | | 30 days after the request | 45 days after the request |
| Grant/Deny* | 14 days after the request | | | |
| *For written response meeting formats* | | | | |
| Written Responses* | By the goal date (*i.e.*, 30 days, 60 days, 90 days, or 120 days after receipt of the request) | | | |
| *For face-to-face meeting formats* | | | | |
| Preliminary Comments* | None | The earlier of the goal date (*i.e.*, 60 days, 90 days, or 120 days after receipt of the request) or 7 days before the meeting | | |
| Meeting Held* | By the goal date (*i.e.*, 30 days after receipt of the request) | Within 7 days of the goal date (*i.e.*, 60 days, 90 days, or 120 days after receipt of the request) | | |
| Meeting Minutes* | 30 days after the meeting | | | |

**Timelines are subject to 90 percent performance goals*

# IV. ADDITIONAL PROGRAM ENHANCEMENTS

## A. Inactive Ingredient Database Enhancement

FDA will update the Inactive Ingredient Database (IID) on an ongoing basis, and post quarterly notices of updates made. Such notices will include for each change made during the previous quarter, the new information, and the information that was replaced.

1. With each update, FDA will add to the IID any inactive ingredient newly and accurately identified in labeling approved by FDA on or after October 1, 2027. The IID entry will include the inactive ingredient name, route of administration, dosage form, chemical abstract service (CAS) Number, and unique ingredient identifier (UNII).

2. For an inactive ingredient newly and accurately identified in FDA-approved labeling that was approved before October 1, 2027, FDA will add such inactive ingredient to the IID in the next update upon receipt of a request that identifies the inactive ingredient and provides a copy of the FDA-approved labeling. The entry will include the same information described in section IV(A)(1).

3. FDA will continue the transition in the IID from providing Maximum Potency to Maximum Daily Exposure (MDE) information, enabling users to conduct electronic queries that yield accurate MDE information for each route of administration associated with each listed inactive ingredient.

**B. Maximum Daily Dose Database**

1. By the end of FY 2028, FDA will establish a public database of Maximum Daily Dose (MDD) values for RLDs and initially populate that database with at least 500 MDD values. In selecting which MDD values to include among the initial values, FDA will consider public input received on the types of MDD values that should be prioritized to initially populate the database. Throughout GDUFA IV, FDA will continue to add verified values to the database.

2. Each fiscal year, FDA will seek public input on the utility of, and potential improvements to, the public MDD database. FDA may solicit such input through the annual regulatory science public meeting, or through other mechanisms, as appropriate.

3. By the end of FY 2030, FDA will assess the resources needed to provide and maintain a full-coverage public MDD database and share that information with industry.

**C. Standardizing Information in ANDA Submissions**

1. To improve review efficiency, FDA will provide or update standard tables and format information for applicants to use when submitting the following data in an ANDA:

    a. Bioequivalence Study Summary Tables

    b. Bioequivalence Site Information

    c. Drug Substance and Impurity Structures

    d. Pharmacokinetic Study Data from individual subjects

2. FDA will provide external training on each of these topics and industry will aspire to submit data using the provided tables and to follow provided format recommendations to enhance the efficiency of the ANDA review process.

**D. Regulatory Science Enhancements**

1. FDA will conduct internal and external research to support fulfilment of submission assessment and pre-ANDA commitments set forth in sections I and III, respectively.

2. Annually, FDA will conduct a public workshop to solicit input from industry and stakeholders for inclusion in an annual list of GDUFA IV regulatory science initiatives. Interested parties may propose regulatory science initiatives via email to genericdrugs@fda.hhs.gov. After considering industry and stakeholder input, FDA will post the list on FDA's website.

3. If industry forms a GDUFA regulatory science working group, then upon request of the working group to the Director of the Office of Research and Standards in the Office of Generic Drugs, FDA will meet with the working group twice yearly to discuss current and emerging challenges and concerns. FDA will post minutes of these meetings on its website.

4. Annually, FDA will report on its website the extent to which GDUFA regulatory science-funded projects support the development of generic drug products, the generation of evidence needed to support efficient assessment and timely approval of ANDAs, and the establishment of new approaches to evaluate generic drug equivalence.

# V. DMF ASSESSMENT PROGRAM

## A. Communication of DMF Assessment Comments

1. FDA will ensure that DMF assessment comments submitted to the DMF holder are issued at least in parallel with the issuance of review comments relating to the DMF for the ANDA.

2. This commitment applies to comments to the applicant issued in any ANDA CRL and comments issued in the first IR letter by the drug product assessment discipline.

## B. Videoconferences to Clarify DMF First Cycle Assessment Deficiencies

1. FDA will grant and conduct videoconferences when requested to clarify deficiencies in first cycle DMF deficiency letters.

2. DMF holders must request such videoconferences in writing within 30 days of issuance of the first cycle DMF deficiency letter, identifying specific issues to be addressed. FDA may initially provide a written response to the request for clarification, but if the DMF holder indicates that a videoconference is still desired, FDA will schedule the videoconference.

3. FDA will strive to grant such videoconferences within 30 days of receipt of the initial videoconference request, giving priority to DMFs based on the priority of the referencing ANDA.

4. In lieu of a videoconference, the DMF holder may submit a request for an email exchange between FDA and the DMF holder. The request must identify specific issues to be addressed. After FDA responds to the request, the DMF holder may submit, and FDA will respond to, one follow-up email to obtain additional clarification.

## C. DMF First Adequate Letters

Once a DMF has undergone a full scientific assessment and has no open issues related to the assessment of the referencing ANDA, FDA will issue a First Adequate Letter.

**D. DMF No Further Comment Letters**

Once a DMF has undergone a full scientific assessment and the ANDA referencing the DMF has been approved or tentatively approved, FDA will issue a "no further comment" letter.

**E. DMF Review Prior To ANDA Submission**

1. A holder of a DMF may submit a request for assessment of the DMF 6 months prior to the planned submission date for: 1) an original ANDA, 2) an ANDA amendment containing a response to a CRL, or 3) an amendment seeking approval of an ANDA that previously received a tentative approval. In each case, the submission needs to include reference to a DMF for which FDA has not conducted a substantive assessment, and one of the following criteria needs to be met:

    a. All patents and exclusivities will expire within 24 months of the planned submission date of the ANDA;

    b. The submission is for a drug product for which there are not more than three approved drug products listed in FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book"), for which there are no blocking patents or exclusivities listed for the RLD, and the ANDA applicant is not seeking approval for less than all of the conditions of use on the RLD labeling, e.g., a "carve-out." In other words, there are fewer than four approved therapeutically equivalent drug products, including the RLD, listed in the Orange Book, no blocking patents or unexpired exclusivities for the RLD in the Orange Book, and the applicant is not seeking to "carve out" any conditions of use;

    c. The submission is for a drug product that could help mitigate or resolve a drug shortage and prevent future shortages, including submissions related to products that are listed on FDA's Drug Shortage List at the time of the submission;

    d. The submission is for a drug product that either could help address a public health emergency declared by the Secretary of the U.S. Department of Health and Human Services under section 319 of the PHS Act, or anticipated under the same criteria as apply to such a declaration;

    e. The submission is for a drug product for which (1) there is only one approved drug product listed in the Prescription Drug Product List (i.e., the "Active Section") of the Orange Book and that product is approved under an ANDA (i.e., the RLD is in the "Discontinued Section" and there is not more than one ANDA in the "Active Section"); (2) the approved ANDA for the drug product listed in the "Active Section" was not approved pursuant to a suitability petition under section 505(j)(2)(C) of the FD&C Act; (3) there are no blocking patents or exclusivities for the RLD; and (4) the submission does not qualify for prioritization under any other factor listed in MAPP 5240.3: *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*; or

f. The submission is for a drug product for which the above criteria (a-e) do not apply, but the application references a DMF for a complex API. FDA will grant four such eligible requests (if submitted) per fiscal year. FDA may grant additional requests subject to available resources.

2. A holder of a DMF may submit a request for assessment of the DMF 6 months prior to the planned submission date for a PAS to add a new API source, provided that:

    a. The PAS is for a drug product that could help mitigate or resolve a drug shortage and prevent future shortages, including submissions related to products that are listed on FDA's Drug Shortage List at the time of the submission;

    b. The PAS is for a drug product that either could help address a public health emergency declared by the Secretary of the U.S. Department of Health and Human Services under section 319 of the PHS Act, or anticipated under the same criteria as apply to such a declaration; or

    c. The PAS is for a drug product for which the above criteria (a and b) do not apply, but the PAS seeks to add a new API source and all facilities manufacturing under Current Good Manufacturing Practice (CGMP) to produce the API from that source are located in the United States. FDA will grant 12 such eligible requests (if submitted) per fiscal year. FDA may grant additional requests subject to available resources.

3. To be eligible for this early review, a DMF holder must submit with its request for review:

    a. at least one Letter of Authorization with one pre-assigned ANDA number;

    b. a reference to the corresponding RLD listed in the Orange Book;

    c. a completed Prior Assessment Cover Letter Template;

    d. a completed FDA Form 3938; and

    e. documentation that the DMF holder has paid a GDUFA DMF fee under section 744B(a)(2)(A) of the FD&C Act (21 U.S.C. 379j-42(a)(2)(A)).

4. FDA will strive to send first cycle IRs related to these DMF submissions 30 days before the planned ANDA submission date. FDA acknowledges that an IR issued during this process will generally not result in a Refuse to Receive action, including when the response leads to changes to the ANDA referencing the DMF, provided the ANDA is substantially complete and otherwise receivable under 21 CFR 314.101. For DMFs referenced by a PAS (as in subsection (E)(2) above), if the DMF holder responds to the first cycle IR within 30 days of the date that the Agency sent the IR, FDA will strive to send a second IR (if applicable) within 70 days of the response to the DMF first cycle IR or submission of the referencing ANDA, whichever is later.

## F. FDA Assessment of Solicited DMF Amendments

1. FDA will assess solicited DMF amendments related to original ANDAs and PASs upon receipt even if the original ANDA or PAS in which the DMF is referenced is not currently under assessment.

2. Such assessments will be conducted based on the assessment status of the DMF and other disciplines in the related ANDAs, with priority being given to those amendments related to ANDAs for which acceptability of the DMF assessment may result in an approval.

### G. FDA Communication Related to DMF Amendments and ANDAs

FDA will communicate publicly to industry that prior to submitting a DMF amendment, the DMF holder should coordinate with the ANDA applicant that references the DMF to avoid delaying approval or tentative approval of the ANDA.

## VI. FACILITIES

### A. Foreign Regulators

1. Export Support and Education of Other Health Authorities: FDA will support the export of safe and effective pharmaceutical products by the U.S.-based pharmaceutical industry, including but not limited to providing timely updates to FDA's Inspection Classification Database as described below, and educating other health authorities regarding FDA's surveillance inspection program and the meaning of inspection classifications.

2. Communications to Foreign Regulators: Upon receipt of a written or email request by an establishment physically located in the U.S. that has been included as part of a marketing application submitted to a foreign regulator, issue within 30 days of the date of receipt of the request a written communication to that foreign regulator conveying the current compliance status for the establishment.

### B. Communication Regarding Inspections

1. When FDA conducts a PAI of a facility or site named in the ANDA, PAS, or associated Type II DMF and identifies outstanding issues that could prevent approval of an ANDA or PAS, the applicant will be notified that issues exist through an IR, DRL or CRL pursuant to section II(B) above.

2. FDA agrees to ongoing periodic engagement with industry stakeholders to provide updates on Agency activities and seek stakeholder feedback.

3. FDA agrees to communicate to the facility owner final inspection classifications that do not negatively impact approvability of any pending application within 90 days of the end of the inspection.

### C. Inspection Classification Database

The Inspection Classification Database will be updated every 30 days and will reflect FDA's final assessment of the facility or site following an FDA inspection and assessment of the inspected entity's timely response to any documented observations.

**D. Post-PAI Meetings**

Post-PAI meetings are intended to provide transparency and enable resolution where possible of any outstanding facility-related deficiencies by the original goal date.

1. After FDA completes a PAI for a facility named in an original ANDA or associated Type II DMF and reviews the observations and responses to the Form FDA 483, FDA intends to inform the applicant when observations communicated to a facility on the Form FDA 483 may result in a CRL.

2. After such notification, the facility may request a meeting with FDA to discuss inspection observations that may affect application approval and proposed corrective actions, with the goal of facilitating transparency on whether the proposed corrective actions are responsive to the issues identified that may affect application approvability. The applicant may participate in the meeting if the facility provides FDA written authorization of such participation in advance of the meeting.

3. Upon receiving a request from a facility for a post-PAI meeting, FDA will strive to respond to the meeting requester in writing within 14 days of receipt of the request. FDA will only grant meeting requests that include a complete meeting package with the request.

4. FDA will generally not grant requests for PAI meetings to facilities with a violative compliance status or when the deficiencies identified on inspection are significant and unlikely to be resolved during the current assessment cycle.

5. When a post-PAI meeting is granted, FDA will strive to schedule the meeting within 30 days of receipt of the request.

6. FDA intends to send preliminary responses to the questions in the meeting package 4-7 days prior to the meeting. Prior to the date of the meeting, the facility will notify FDA whether the meeting is still needed and if it is, will provide the anticipated agenda at least 1 business day in advance of the meeting.

7. FDA will include representatives from relevant functions in the post-PAI meeting.

8. During the meeting, FDA will strive to provide specific actionable feedback. If providing such feedback is not feasible at the time, FDA may opt to defer comment on acceptability of the corrective actions and approvability of the application.

9. When a post-PAI meeting is granted, FDA will strive to hold the meeting to facilitate first cycle approval or tentative approval (presuming there are no other deficiencies) by the originally assigned GDUFA goal date, but may extend the goal date per section II(B)(10) of this commitment letter.

10. FDA intends to provide meeting minutes within 30 days of the meeting.

## E. Requests for Surveillance Inspections for Domestic Facilities

1. Facilities that meet the following conditions may request a surveillance inspection prior to submission of an original ANDA, PAS, or associated Type II DMF:

    a. The facility is registered and physically located in the U.S. and is expanding production to manufacture a new generic drug product (or the API to be used in such product),

    b. The facility will be referenced in an ANDA or PAS for that drug product or a DMF for that API that is planned for submission in the timeframes described in paragraph (2) below,

    c. The facility has paid a generic drug facility fee or active pharmaceutical ingredient facility fee in the prior fiscal year,

    d. The facility has not had an FDA-classified surveillance inspection in the prior 3 fiscal years, and

    e. The facility is not in a violative compliance status (i.e., not pOAI or OAI) and is not in arrears for any GDUFA-related user fee at the time of the request.

2. FDA will consider requests that meet the conditions above and are submitted at least 9 months but no more than 24 months prior to the planned ANDA, PAS, or DMF submission date.

3. Upon receipt of such a request, FDA will evaluate the request to confirm that the conditions outlined above are met, and that conducting the surveillance inspection would be consistent with FDA's risk-based inspection approach. FDA will issue a grant/deny letter for 90 percent of requests within 30 days of receipt of the request.

4. For 90 percent of the requests that are granted, FDA will complete the inspections and issue a final classification [ (i.e., No Action Indicated (NAI), Voluntary Action Indicated (VAI), Official Action Indicated (OAI)] before the planned ANDA, PAS, or DMF submission date.

## F. Post-Warning Letter Meetings

1. An eligible facility described in section VI(F)(3) may request a meeting with FDA regarding the facility's remediation for deviations identified in a warning letter (Post-Warning Letter Meeting).

    a. This meeting generally will take place 6 months or later after the facility submits an initial response to an FDA warning letter.

    b. A facility may request that the meeting take place prior to 6 months after an initial response to a warning letter has been submitted. However, it is at FDA's discretion

to grant an earlier meeting if the Agency determines it would be beneficial to both parties.

2. The purpose of the Post-Warning Letter Meeting is to obtain preliminary feedback from FDA on the adequacy and completeness of the facility's corrective action plans.

3. To be eligible for the Post-Warning Letter Meeting:

    a. The facility CGMP compliance status is "Official Action Indicated" as a result of an FDA inspection;

    b. The facility has paid a GDUFA facility fee as described in section 744B(a)(4) of the FD&C Act for the current fiscal year, or is named in a pending ANDA application; and

    c. The regulatory action (e.g., warning letter) is limited only to violations or deviations from Section 501 of the FD&C Act (21 U.S.C. 351) related to human drug manufacturing, including manufacturing of a drug-device combination product.

4. The meeting request will be granted only if the facility has submitted to FDA a thorough and complete corrective action and preventive action (CAPA) plan that addresses all items cited in the warning letter, and reasonable progress has been made toward remediation.

5. Any supplemental information submitted by a facility on remediation progress to be discussed at the meeting must be submitted at least 60 days prior to the meeting.

6. FDA may deny a request for a Post-Warning Letter Meeting if FDA determines that a facility is ineligible for a meeting or does not appear to be ready for a meeting as evidenced by an incomplete CAPA plan, and/or insufficient progress being made to remediate the facility issues. If FDA denies the meeting:

    a. In general, FDA intends to respond briefly with comments regarding why the meeting package is not sufficiently developed or complete (e.g., where the facility has not presented a proposed CAPA plan for all items in the warning letter or where the firm does not appear to have made reasonable efforts to implement its proposed CAPA plan).

    b. A facility may resubmit a new meeting request no sooner than 3 months after the first meeting request is denied by FDA.

7. Only two Post-Warning Letter Meeting requests per warning letter may be made under this section.

8. FDA may defer a Post-Warning Letter Meeting if FDA has made a decision that a re-inspection is the most appropriate next step (i.e., defer in favor of re-inspection). In this case, FDA will notify the facility of the decision to re-inspect rather than grant a meeting.

9. FDA may schedule meetings by videoconference, teleconference, or face-to-face, at FDA's discretion.

10. FDA will grant, deny, or defer in favor of re-inspection 80 percent of eligible requests for a Post-Warning Letter meeting within 30 days of request.

11. The commitment to hold a Post-Warning Letter Meeting:

    a. Does not preclude FDA from taking any regulatory actions necessary, including a follow-up inspection at any time (including prior to the Post-Warning Letter Meeting); and

    b. As with other regulatory meetings, FDA advice is not binding on the Agency.

**G. Generic Drug Manufacturing Facility Re-Inspection**

1. An eligible facility as described in section VI(G)(2) may request a re-inspection.

2. To be eligible for the facility re-inspection process reflected in this subsection:

    a. The facility CGMP compliance status is "Official Action Indicated" as a result of an FDA inspection;

    b. The facility has paid a GDUFA facility fee as described in section 744B(a)(4) of the FD&C Act for the current fiscal year, or is named in a pending ANDA application; and

    c. The regulatory action (e.g., warning letter) is limited only to violations or deviations from Section 501 of the FD&C Act related to human drug manufacturing, including manufacturing of a drug-device combination product.

3. FDA will review the request and if FDA determines that the requesting facility has appropriately completed CAPAs that sufficiently address all of the deficiencies in a warning letter, with the exception of ongoing monitoring, and FDA agrees that the facility appears ready for inspection, FDA will generate an inspectional assignment.

4. FDA agrees to notify the facility of the Agency's decision to re-inspect within 30 days of receipt of the request for re-inspection.

5. If FDA declines the request to reinspect:

    a. FDA agrees to notify the facility of its decision and provide a brief high-level explanation, for example, that the firm has not made sufficient progress to complete certain CAPAs identified as necessary to resolve a violation cited in the warning letter.

    b. The facility may submit a second request for a re-inspection no earlier than 3 months after receiving FDA's initial decision.

    c. If the second request is denied, the facility will be considered to no longer meet the eligibility criteria in section VI(G)(2).

6. The processes and timelines set forth in this section apply only to the first re-inspection after a warning letter. If the warning letter is not resolved after re-inspection, the facility will be considered to no longer meet the eligibility criteria in section VI(G)(2).

7. If a re-inspection request is granted, FDA agrees to notify the facility and issue an inspectional assignment in conjunction with the notification.

    a. For 80 percent of the requests for re-inspection that are granted for domestic facilities, FDA will re-inspect the facility within 4 months of the letter to the facility indicating FDA's intent to re-inspect.

    b. For 80 percent of requests for re-inspection that are granted for international facilities, FDA will re-inspect the facility within 8 months of the letter to the facility indicating FDA's intent to re-inspect.

# VII. USER FEE RESOURCE MANAGEMENT

## A. Sustainability of GDUFA Program Resources

1. FDA is committed to ensuring the sustainability of the GDUFA program resources and to enhancing the operational agility of the GDUFA program.

2. FDA will continue to ensure optimal use of user fee resources and the alignment of staff to workload through the continued maturation and assessment of the Agency's resource capacity planning capability.

3. FDA also will continue activities to promote transparency of the use of financial resources in support of the GDUFA program.

## B. Resource Capacity Planning

1. FDA will continue activities to mature the Agency's resource capacity planning function, including utilization of modernized time reporting to support enhanced management of GDUFA resources in GDUFA IV and utilization of the Capacity Planning Adjustment (CPA).

2. The CPA shall be limited to workload driven by:

    a. ANDA Originals and Resubmissions/Amendments

    b. ANDA Supplements (PAS and "Changes Being Effected" (CBE) supplements) and Amendments

    c. Controlled Correspondence as defined in Section X(I)-(K)

    d. Application-Related Meetings as defined in Section III(C)

    e. Surveillance inspections

    f. Post-marketing safety activities

g. Suitability Petitions

## C. Financial Transparency and Efficiency

1. FDA is committed to ensuring GDUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner. FDA will conduct activities to evaluate the financial administration of the GDUFA program to help identify areas to enhance operational and fiscal efficiency. FDA will also conduct activities to enhance transparency of how GDUFA program resources are used.

2. FDA will publish a GDUFA 5-year financial plan no later than the second quarter of FY 2028. FDA will publish updates to the 5-year plan no later than the second quarter of each subsequent fiscal year. The plan and its annual updates will include the following topics:

    a. Shared Services

        i. A discussion of the Agency efforts to consolidate services into the Shared Services organization. This will include discussion of the types of services that have been consolidated, including the financial impact of this consolidation on the GDUFA program, and discussion of continuing or evolving efforts to consolidate services into the Shared Services organization.

        ii. The planned user fee obligations for FDA's Shared Services program, for the 5 years represented by the GDUFA IV authorization. The annual updates to this plan will provide actual amounts for the preceding fiscal year, as well as updated planned amounts for the remaining fiscal years.

        iii. Discussion of factors contributing to any variation from planned to actual amounts in excess of 10 percent.

3. FDA will include the following items in the annual Financial Report submitted to Congress each year:

    a. A discussion of the operating reserve tracking, reserving, and reporting (OR TRR), as related to section [xxx] of the FD&C Act and FDA's objective to hire and retain staff, including:

        i. The OR TRR payroll target for the fiscal year,

        ii. A comparison of the actual payroll to the OR TRR payroll target;

        iii. A discussion of whether FDA has met the OR TRR payroll target; and

        iv. If FDA has not met the OR TRR payroll target, the amounts in the operating reserve that are set aside for payroll for hiring and retaining staff.

    b. Enhanced reporting on personnel compensation and benefits to include payroll, awards, overtime, and benefits for current and former personnel.

4. FDA will offer one technical staff meeting per year with industry focused on program finances. These meetings will be expected to:

a. Occur after the publication of the fee-setting Federal Register Notice each fiscal year in the August – September timeframe, with the first meeting in 2028.

b. Include topics relevant to the fee-setting or finances of the GDUFA program.

Within 30 days after the conclusion of each technical staff meeting, FDA will publish meeting minutes to its website. The meeting minutes will describe, in sufficient detail, the topics and significant points discussed in each meeting.

5. Following authorization of GDUFA IV, FDA will make GDUFA coversheets for annual fees available online by August 15th or the next business day.

6. FDA will review existing websites and other materials to assess the availability of public-facing information regarding the statutory timeframe for penalties for non-payment of GDUFA fees.

## VIII. GUIDANCE AND MAPPS

FDA will draft or modify relevant MAPPs and guidance to reflect the commitments and goals in this Commitment Letter, including, but not limited to:

**A.** To revise MAPP 5200.12 Communicating Abbreviated New Drug Application Review Status Updates with Industry on or before September 30, 2028, to reflect the general principles for review status updates for relevant disciplines agreed to as part of the reauthorization of GDUFA IV.

**B.** FDA will issue a draft guidance or other appropriate communication on or before September 30, 2029, outlining best practices for ANDA submissions to facilitate early identification of issues requiring consults, and will also provide external training on this topic on a recurring basis during FY 2028-2032 (GDUFA IV).

**C.** FDA will issue a MAPP on or before September 30, 2029, describing the Agency's policies and procedures for using the imminent action process when one or more small issues remain from one or more disciplines that, in FDA's view, may be resolved within 60 days after the goal date. Before issuing the MAPP, FDA will consider any feedback provided by industry regarding this process, including the value of including illustrative examples.

**D.** By October 1, 2028, FDA will strive to publish draft guidance to address post-PAI meetings, including meeting procedures, timelines, eligibility conditions for the meeting, best practices when submitting meeting request packages, and considerations regarding goal date extensions. FDA will strive to finalize the guidance within 24 months following close of the comment period on the draft guidance.

**E.** By September 30, 2028, FDA will strive to issue guidance with information pertaining to TYPE 30, TYPE 60, TYPE 90, and TYPE 120 meetings as described in section III(C).

## IX. PERFORMANCE REPORTING

## A. Monthly Reporting Metrics

FDA will publish the following monthly metrics on its website, using a consistent, publicly disclosed reporting methodology:

1. Number of ANDAs and amendments, CBE supplements, and PASs submitted in the reporting month delineated by type of submission;

2. Number of ANDAs and PASs FDA refused for receipt in the reporting month;

3. Number of actions taken in the reporting month delineated by the type of action. For purposes of the metrics, actions shall include final approvals, tentative approvals, CRLs, IRs, and DRLs (or other such nomenclature as FDA determines to reflect the concepts of an information request or CRL). FDA will further delineate the information on final approvals and tentative approvals by whether the product subject to the action is a complex or non-complex generic product;

4. Number of finalized DMF Completeness Assessments in the reporting month;

5. Number of DMF fees paid in the reporting month;

6. Number of first-cycle approvals and tentative approvals in the reporting month, delineated by whether the action was for a complex or non-complex generic product;

7. Number of first-time generic approvals in the reporting month, delineated by whether the action was for a complex or non-complex generic product; and

8. Number of approval and tentative approval imminent actions in the reporting month, delineated by whether the action was for a complex or non-complex generic product.

## B. Quarterly Reporting Metrics

FDA will publish the following quarterly metrics on its website, using a consistent, publicly disclosed reporting methodology:

1. Number of ANDAs and PASs withdrawn in each reporting month;

2. Number of ANDAs awaiting applicant action;

3. Number of ANDAs awaiting FDA action;

4. Mean and median approval and tentative approval times for the quarterly action cohort, delineated by times for complex versus non-complex generic products;

5. Number of original ANDAs for Complex Generic Products submitted;

6. Number of requests for reclassification of a Facility-Based Major CRL Amendment received, and number of requests granted and denied; and

7. Number of Level 60, Level 90, and Level 120 Controlled Correspondence submitted.

### C. Fiscal Year Performance Report Metrics

FDA will publish the following metrics annually as part of the GDUFA Performance Report:

1. Mean and median approval and tentative approval times for ANDAs by FY receipt cohort;

2. Mean and median ANDA approval times, including separate reporting of mean and median times for first-cycle approvals by FY receipt cohort;

3. Mean and median number of ANDA assessment cycles to approval and tentative approval by FY receipt cohort;

4. Number of applications received and refused to receive, and average time to receipt decision;

5. Number of GDUFA-related meetings granted, denied, and conducted, broken down by meeting types under section III(C), post-Warning Letter Meetings, and post-PAI meetings, and in addition for post-Warning Letter Meetings, the number deferred in favor of re-inspection;

6. Number of inspections conducted by domestic or foreign establishment location and inspection type (preapproval inspection, surveillance, bioequivalence clinical and bioequivalence analytical) and facility type (finished dosage form, API);

7. Median time from beginning of inspection to Form FDA 483 issuance;

8. Median time from Form FDA 483 issuance to Warning Letter, Import Alert and Regulatory Meeting for inspections with final classification of "Official Action Indicated" (or equivalent);

9. Median time from date of Warning Letter, Import Alert or Regulatory Meeting to resolution of the "Official Action Indicated" status (or equivalent);

10. Number of ANDAs accepted for standard assessment and priority assessment;

11. Percentage of suitability petitions completed within 6 months after FDA completes the completeness assessment, the total number submitted, and total number completed;

12. Number of citizen petitions to determine whether a listed drug has been voluntarily withdrawn from sale for reasons of safety or effectiveness pending a substantive response for more than 270 days from the date of receipt;

13. Percentage of ANDA proprietary name requests evaluated within 180 days of receipt;

14. Number of DMF First Adequate Letters issued;

15. Number of videoconferences granted, and number of email exchanges requested and conducted in lieu of videoconferences to clarify deficiencies in first cycle DMF deficiency letters;

16. Percent of PSGs for non-Complex Product NCE NDAs within 2 years of NDA approval;

17. Percent of PSGs for Complex Generic Product NDAs, including NCEs, published within 2 and 3 years of NDA approval;

18. Percentage of facility re-inspections carried out within 4 or 8 months after the letter to the facility indicating FDA's intent to re-inspect for domestic or foreign facilities, respectively;

19. For the total number of original ANDAs, amendments, PASs, PAS amendments, and meeting requests submitted in a fiscal year, FDA will publish the number of actions completed (as of the annual publication date), and the percent completed by the goal date. FDA also will publish this data annually on its website, further enumerated by goal-date subcategory, and will include metrics regarding timeframes for acting on meeting requests;

    a. For example, in the GDUFA Performance Report, the priority PAS submission goal will be reported as the number of actions and the percent completed combined for the 4-, 8- and 10-month goals.

    b. For the Annual Web Posting, the priority PAS submission goals will be reported as the number of actions and the percent completed individually for the 4-, 8- and 10-month goals.

20. Percent Controlled Correspondence (Level 60, Level 90, and Level 120) responded to within the applicable goal date (i.e., 60, 90, and 120 days, respectively);

21. Number of missed goal dates for original ANDAs by more than 6, 9, and 12 months, as well as number of applications assigned a second goal date under section II(B)(9)(a) (excluding applications described in section II(B)(9)(d)), and number of those applications for which the second goal date was met, and

22. Number of original ANDAs described in section II(B)(9)(d) and assigned a second goal date under section II(B)(9)(a), and number of those applications for which the second goal date was met. These ANDAs will not be included in either the numerator or the denominator when calculating the 90 percent performance goal under section I(A).

**D. Fiscal Year Web Posting**

In addition to the data that will be reported annually on the web described in section IX(C)(19), FDA will also post the following data annually on its website:

1. The number of requests for review of a DMF prior to ANDA or PAS submission, as described in sections V(E)(1) and V(E)(2), the number granted, and the number completed;

2. Number of priority and non-priority "off-cycle" solicited DMF amendments reviewed as described in section V(F); and

3. Number of original approvals taken that are Imminent Actions.

4. Percentage of requests for surveillance inspections for domestic facilities for which a grant/deny letter was issued within 30 days of receipt of the request.

5. Percentage of granted requests for surveillance inspections for domestic facilities for which FDA completed the inspection and issued a final classification before the planned application or DMF submission date.

## X. DEFINITIONS

**A. Act on –** with respect to an application, means FDA will either issue a CRL, an approval, a tentative approval, or a refuse-to-receive action.

**B. Ambiguity in the Controlled Correspondence response –** means the Controlled Correspondence response or a critical portion of it merits further clarification.

**C. Review Status Update –** means a response from the RPM to the applicant to update the applicant concerning, at a minimum, the categorical status of relevant assessment disciplines, with respect to the submission at that time, including Labeling, Bioequivalence and Quality (broken down by drug substance, drug product, and facilities), and Risk Evaluation Mitigation Strategy (REMS), as applicable. The RPM will advise the applicant that the update is preliminary only, based on the RPM's interpretation of the submission, and subject to change at any time.

**D. Capacity Planning Adjustment –** Methodology that annually adjusts inflation-adjusted target revenue to account for additional resource needs due to sustained increases in workload for the GDUFA program.

**E. Complete Response Letter –** refers to a written communication to an applicant or DMF holder from FDA usually describing all of the deficiencies that the Agency has identified in an ANDA (including pending amendments) or a DMF that must be satisfactorily addressed before the ANDA can be approved. Complete response letters will reflect a Complete Assessment, which includes an application-related facilities assessment and will require a complete response from industry to restart the clock. Refer to 21 CFR 314.110 for additional details. When a citizen petition may impact the approvability of the ANDA, FDA will strive to address, where possible, valid issues raised in a relevant citizen petition in the complete response letter. If a citizen petition raises an issue that would delay only part of a complete response, a response that addresses all other issues will be considered a complete response.

**F. Complete Assessment –** refers to a full Division-level assessment from all relevant assessment disciplines, including inspections, and includes other matters relating to the ANDAs and associated DMFs as well as consults with other Agency components.

**G. Complex Product –** generally includes:

1. Products with complex active ingredients (e.g., peptides, polymeric compounds, complex mixtures of APIs, naturally sourced ingredients); complex formulations (e.g., liposomes, colloids); complex routes of delivery (e.g., locally acting drugs such as dermatological products, complex ophthalmological products, and otic dosage forms that are formulated as suspensions, emulsions or gels) or complex dosage forms (e.g., transdermal systems, metered dose inhalers, extended release injectables);
2. Complex drug-device combination products (e.g., pre-filled auto-injector products, metered dose inhalers); and
3. Other products where complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement.

**H. Complex Generic Product –** refers to a generic version of a Complex Product.

**I. Controlled Correspondence - Level 60** – means correspondence submitted to the Agency:

1. Requesting information on a specific element of generic drug product development:
    a. Prior to ANDA submission;
    b. After issuance of a CRL or tentative approval;
    c. After ANDA approval; or
2. Concerning post-approval submission requirements that are not covered by CDER post-approval changes guidance and are not specific to an ANDA.

**J. Controlled Correspondence – Level 90 –** means correspondence that meets the definition of Level 60 correspondence, and:

1. Requests evaluation of a proposed MDD;
2. Requests a Covered Product Authorization to obtain sufficient quantities of an individual covered product subject to a REMS with Elements to Assure Safe Use (ETASU) when development and testing does not involve clinical trials;
3. Requests evaluation of an alternative bioequivalence approach to what is provided for in a PSG for a non-complex generic product and does not require input from another office or center; or
4. Requests evaluation of an alternative bioequivalence approach to what is provided for in a PSG for a Complex Generic Product or bioequivalence approach for a Complex Generic Product with no PSG.

**K. Controlled Correspondence - Level 120 –** means correspondence that meets the definition of Level 60 correspondence, and:

1. Involves evaluation of clinical content (excluding MDD evaluations);
2. Requests a Covered Product Authorization and review of bioequivalence protocols for development and testing that involves human clinical trials for an ANDA where the RLD is subject to a REMS with ETASU;
3. Requests evaluations of proposed bioequivalence approaches (e.g., pharmacokinetic, in vitro, clinical) for non-Complex Products with no PSG; or
4. Requires formal input from another office or center, e.g., questions regarding device constituent parts of a combination product.

**L. Covered Product Authorization –** a letter from FDA authorizing an eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for product development and testing purposes, as described in section 610 of Division N of the Further Consolidated Appropriations Act, 2020 (21 U.S.C. 355-2), commonly referred to as the "CREATES Act."

**M. Days –** unless otherwise specified, means calendar days.

**N. Discipline Review Letter –** means a letter used to convey preliminary thoughts on possible deficiencies found by a discipline assessor and/or assessment team for its portion of the pending application at the conclusion of the discipline assessment.

**O. Earliest lawful ANDA approval date –** the first date on which no patent or exclusivity prevents approval of an ANDA.

**P. First Adequate Letter –** a communication from FDA to DMF holder indicating that the DMF has no open issues related to the assessment of the referencing ANDA. This communication is issued only at the conclusion of the first DMF assessment cycle that determines the DMF does not have any open issues.

**Q. First Generic –** any received ANDA: (1) for a First Applicant as described in section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act or for which there are no blocking patents or exclusivities; and (2) for which there is no previously approved ANDA for the drug product.

**R. Information Request –** means a communication that is sent to an applicant during an assessment to request further information or clarification that is needed or would be helpful to allow completion of the discipline assessment.

**S. Major Amendment –** means a Major Amendment as described in the guidance for industry *ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA* (September 2024), and any subsequent revision.

T. **Mid-point of assessment cycle –** The mid-point of an assessment cycle is half the length of an assessment period plus or minus 30 days.

U. **Minor Amendment –** means a minor amendment as described in the guidance for industry *ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA* (September 2024), and any subsequent revision.

V. **Priority –** means submissions affirmatively identified as eligible for expedited assessment pursuant to MAPP 5240.3, *Prioritization of the Review of Original ANDAs, Amendments and Supplements*, as revised (the CDER Prioritization MAPP).

W. **Significant Major deficiency –** means a major deficiency, the resolution of which is required before the continued assessment by multiple disciplines, e.g., a reformulation, or a major deficiency that impacts the test drug product used in a bioequivalence study.

X. **Small Issue** – for the purposes of Imminent Actions in section II(B)(3), means a deficiency that can be assessed by FDA within 60 days because it can be addressed by: 1) a clarification of scientific information regarding data already submitted, 2) the limited submission of additional data, or 3) the submission of administrative information (e.g., completion of a form or a change in an address).

Y. **Standard –** means submissions not affirmatively identified as eligible for expedited assessment pursuant to the CDER Prioritization MAPP.

Z. **Unsolicited Amendment –** an amendment with information not requested by FDA except for those unsolicited amendments considered routine or administrative in nature that do not require scientific review (e.g., requests for final ANDA approval, patent amendments, and general correspondence).