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## **GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROGRAM ENHANCEMENTS FISCAL YEARS 2023-2027**

This document contains the performance goals and program enhancements for the Generic Drug User Fee Amendments (GDUFA) reauthorization for fiscal years (FYs) 2023-2027, known as GDUFA III. 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 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. FDA is committed to meeting the performance goals specified in this letter and to continuous improvement of the Agency’s performance.

### **GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2023-2027**

The performance goals and procedures of FDA, as agreed to under the third 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 section I(A)(3).
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 section I(A)(3).

- 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 preapproval inspection is not required.
  - b. Assess and act on standard Major Amendments within 10 months of the date of amendment submission if preapproval inspection 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**

<b>Submission Type</b>	<b>Goal</b>
<b>Standard Original ANDAs</b>	90% within 10 months of submission date, subject to any adjustment to the goal date described in section I(A)(3).
<b>Priority Original ANDAs</b>	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**

<b>Submission Type</b>	<b>Goal</b>
<b>Standard Major Amendments</b>	90% within 8 months of submission date if preapproval inspection not required.
	90% within 10 months of submission date if preapproval inspection required.
<b>Priority Major Amendments</b>	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).
<b>Standard and Priority Minor Amendments</b>	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**

<b>Submission Type</b>	<b>Goal</b>
<b>Standard PASs</b>	90% within 6 months of submission date if preapproval inspection not required.
	90% within 10 months of submission date if preapproval inspection required.
<b>Priority PASs</b>	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**

<b>Submission Type</b>	<b>Goal</b>
<b>Standard PAS Major Amendments</b>	90% within 6 months of submission date if preapproval inspection not required.
	90% within 10 months of submission date if preapproval inspection required.
<b>Priority PAS Amendments</b>	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).
<b>Standard and Priority Minor PAS Amendments</b>	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 (DMFs)**

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

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

<b>Submission Type</b>	<b>Goal</b>
<b>Type II API DMF</b>	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 by or on behalf of a generic drug manufacturer or related industry prior to ANDA submission. Under the GDUFA II framework, correspondence seeking regulatory and/or scientific advice after issuance of a Complete Response Letter (CRL) or tentative approval, or after ANDA approval, was considered general correspondence. Under GDUFA III, these types of correspondence can be submitted as Controlled Correspondence. During an ANDA assessment cycle, a Controlled Correspondence may only be submitted if an applicant seeks further feedback from FDA after a product-specific guidance (PSG) Teleconference, as described in section III(C)(5)(c), below, or to seek a Covered Product Authorization. During an ANDA assessment cycle, all other correspondence will be general correspondence.
2. Review and respond to 90 percent of Controlled Correspondence within the applicable review goal.
  - a. Review and respond to Level 1 Controlled Correspondence within 60 days of the date of submission.
  - b. Review and respond to Level 2 Controlled Correspondence within 120 days of the date of submission.
3. FDA will review and respond to 90 percent of submitter requests to clarify ambiguities in the Controlled Correspondence response within 21 days of receipt of the request. The response to the submitter’s request will provide clarification or advice concerning the ambiguity in the Controlled Correspondence response.

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

<b>Submission Type</b>	<b>Goal</b>
<b>Level 1 Controlled Correspondence</b>	90% within 60 days of submission date.
<b>Level 2 Controlled Correspondence</b>	90% within 120 days of submission date.
FDA will review and respond to 90% of submitter requests to clarify ambiguities in the Controlled Correspondence response within 21 days of request receipt.	

## **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 within 10 days of original ANDA submission. If a deficiency is resolved within 10 days, that deficiency will not be a basis for a refuse-to-accept 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.

### **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 the exception of the Labeling discipline as 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 by 90 days from the date of the applicant's response.
    - ii. FDA's decision to extend the goal date will be communicated in an amendment acknowledgement letter.
    - iii. 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 at approximately months 6-7 of the assessment for those ANDAs with a 10-month goal date, or months 5-6 of the assessment for those ANDAs with an 8-month goal date, 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. limit the assessment of labeling to one IR/DRL if other disciplines will not be acceptable during the first cycle; and
- iv. continue to assess labeling to enable an action within the assessment cycle if other disciplines are acceptable.

b. Labeling IRs and DRLs in all assessment cycles:

FDA will minimize issuing CRLs that contain only labeling deficiencies by, for example, utilizing 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, 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, the RPM will notify the applicant of the delay in taking an action, identify the general reason for the delay including the outstanding discipline(s), if any, and the estimated time for FDA's action on the application.
  - 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.
- 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 with respect to engaging with FDA prior to responding to the CRL:
  - a. A post-CRL teleconference to seek clarification concerning deficiencies identified in a CRL. FDA will grant appropriate requests for teleconferences requested by applicants upon receiving first-cycle CRLs and upon receiving subsequent CRLs. An appropriate request is one that clearly identifies the specific deficiencies to be discussed and the reason why such deficiencies are not clear. FDA will provide a scheduled date for 90 percent of post-CRL teleconferences within 14 days of the request for a teleconference and conduct 90 percent of such post-CRL teleconferences, if granted, within 30 days of receipt of the written request;
  - b. Submission of a Controlled Correspondence as described in section I(E); or
  - c. A post-CRL Scientific 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 IV(C).

### **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 teleconference as part of its request to reclassify a Major Amendment or standard assessment status, FDA will schedule and conduct the teleconference and decide 90 percent of such reclassification requests within 30 days of the date of FDA's receipt of the request for a teleconference. This goal only applies when the applicant accepts the first scheduled teleconference 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:

Submission Type	FDA Response Regarding Major to Minor Reclassification	New ANDA Goal Date if Reclassification Granted	ANDA Goal Date if Reclassification Denied
<b>Standard Major Amendment</b>	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
<b>Priority Major Amendment</b>	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 *Formal Dispute Resolution: Sponsor Appeals Above the Division Level Guidance for Industry and Review Staff* (May 2019).
4. FDA will respond to 90 percent of appeals above the Division level within 30 days of 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 on *ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence)* (November 2017) 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 application 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 of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence)* (November 2017) 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 III 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. PRE-ANDA PROGRAM**

### **A. Goal of Pre-ANDA Program**

1. The goal of the pre-ANDA program is to clarify regulatory expectations for prospective applicants early in product development, assist applicants in developing more complete submissions, promote a more efficient and effective ANDA assessment process, and reduce the number of assessment cycles required to obtain ANDA approval.
2. Some elements of these programs are tailored to enhance the development of Complex Generic Products. Complex Generic Products can raise unique scientific and regulatory considerations, and FDA is committed to providing further transparency and clarity on Complex Generic Product development and assessment to help increase the availability of these products.

### **B. Suitability Petitions**

1. In FY 2023, FDA will work diligently to enhance the Agency's processes for reviewing and responding to petitions submitted under section 505(j)(2)(C) of the FD&C Act (commonly referred to as "suitability petitions"), and to review and respond to pending suitability petitions.
2. Prior to FY 2024, FDA will take appropriate action to determine if petitioners who submitted suitability petitions prior to FY 2023 remain interested in a response.
3. FDA will conduct a completeness assessment for suitability petitions submitted in FY 2024-2027. 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.

4. Any suitability petition submitted in FY 2024-2027 will receive a goal date described in section III(B)(7). Any suitability petitions submitted to FDA prior to FY 2024 will not receive a goal date. If a petitioner wants to receive a goal date on a suitability petition submitted prior to FY 2024, the petitioner may withdraw and submit a new suitability petition in FY 2024-2027.
5. 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.
6. 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. 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;
  - 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).
7. Beginning in FY 2024, FDA will review and respond to suitability petitions that have been assigned a goal date pursuant to the following goals:
  - a. In FY 2024, 50 percent of submissions within 6 months after completeness assessment, up to a maximum of 50 suitability petitions completed;
  - b. In FY 2025, 70 percent of submissions within 6 months after completeness assessment, up to a maximum of 70 suitability petitions completed;
  - c. In FY 2026, 80 percent of submissions within 6 months after completeness assessment, up to a maximum of 80 suitability petitions completed; and
  - d. In FY 2027, 90 percent of submissions within 6 months after completeness assessment, up to a maximum of 90 suitability petitions completed.
8. 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)(6). See Appendix for additional information on FDA's review of suitability petitions in GDUFA III.

### **C. Product-Specific Guidance**

1. FDA will continue to issue 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 drug 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 routinely will update the information on this website approximately every 4 months.
  - 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 V(B)(2).
  - d. For Complex Products, FDA generally will prioritize the development of PSGs for Complex Products that contain a 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 a new or revised PSG is published and an applicant or prospective applicant has already commenced an in vivo bioequivalence study (i.e., the study protocol has been signed by the study sponsor and/or the contract research organization) the applicant or prospective applicant may request a PSG Teleconference to obtain Agency feedback on the potential impact of the new or revised PSG on its development program.
- a. To be eligible for a PSG Teleconference, the applicant or prospective applicant must submit with the meeting request the signature page of the relevant in vivo study protocol signed by the study sponsor and/or the contract research organization.
  - b. FDA will hold a PSG Teleconference within 30 days after the receipt of the meeting request. The PSG Teleconference will be scheduled for 60 minutes.
  - c. If the applicant seeks further feedback from FDA after a PSG Teleconference, the applicant may utilize the Controlled Correspondence process or request an additional meeting. The purpose of this meeting is to provide a forum in which industry can discuss the scientific rationale for an approach other than the approach recommended in the PSG to ensure that the approach complies with the relevant statutes and regulations.
    - i. If the applicant has not submitted an ANDA, the prospective applicant can submit a request for a Pre-Submission PSG Meeting. FDA will grant or deny the meeting within 14 days after receipt of the request and if granted, will schedule the meeting within 120 days after receipt of the request.
    - ii. If the applicant has submitted an ANDA, the applicant can submit a request for a Post-Submission PSG Meeting. FDA will grant or deny the meeting within 14 days after receipt of the request, and if granted, will schedule the meeting within 90 days after receipt of the request.



- iii. FDA may deny a Pre- or Post-Submission PSG Meeting if the request is incomplete, or the inquiry would be more appropriately resolved through a Controlled Correspondence. FDA may grant a Pre- or Post-Submission Meeting request after such a Controlled Correspondence if the Agency determines that any issue(s) remain unresolved or would be more appropriately resolved in a meeting.
  - iv. Applicants and prospective applicants are eligible to request a Pre-Submission PSG Meeting or Post-Submission PSG Meeting regardless of whether they have had a Product Development Meeting or a post-CRL Scientific Meeting.
6. 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.

#### **D. Product Development Meetings**

1. A prospective applicant can request a pre-ANDA submission Product Development Meeting. The purpose of the meeting 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 development program.
2. FDA will grant a prospective applicant a Product Development Meeting if, in FDA's judgment:
  - a. The requested Product Development Meeting concerns:
    - i. Development of a Complex Generic Product for which FDA has not issued a PSG; or
    - ii. An alternative equivalence evaluation, i.e., change in study type, such as in vitro to clinical, for a Complex Generic Product for which FDA has issued a PSG;
  - b. The prospective applicant submits a complete meeting package, including a data package and specific proposals;
  - c. A Controlled Correspondence response would not adequately address the prospective applicant's questions; and
  - d. A Product Development Meeting would significantly improve ANDA assessment efficiency.

3. Dependent on available resources, FDA may grant a prospective applicant a Product Development Meeting concerning development issues other than those described in Section III(D)(2) if, in FDA's judgment:
  - a. The prospective applicant submits a complete meeting package, including a data package and specific proposals;
  - b. A Controlled Correspondence response would not adequately address the prospective applicant's questions; and
  - c. A Product Development Meeting would significantly improve ANDA assessment efficiency.
4. FDA will grant or deny 90 percent of Product Development Meeting requests within 14 days after receipt of the meeting request.
5. FDA will conduct 90 percent of Product Development Meetings within 120 days after the meeting is granted.
6. FDA can meet the Product Development Meeting goal by either conducting a meeting or providing a meaningful written response that will inform drug development and/or regulatory decision-making to the prospective applicant, within the applicable goal date.
7. Unless FDA is providing a written response to satisfy the Product Development Meeting goal, FDA will provide preliminary written comments before each Product Development Meeting (and aspire to provide the written comments 5 days before the meeting) and will provide meeting minutes within 30 days following the meeting.

#### **E. Pre-Submission Meetings**

1. Prospective applicants may request a Pre-Submission Meeting. The purpose of a Pre-Submission Meeting is to provide an applicant 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. FDA will grant a Pre-Submission Meeting, if the applicant was granted a Product Development Meeting for the same Complex Generic Product or FDA believes in its sole discretion that the Pre-Submission Meeting would improve assessment efficiency.
2. For Pre-Submission Meetings, FDA will:
  - a. Identify the ANDA assessment team members who will attend the meeting;

- b. Identify additional content for the meeting in the letter granting the meeting request, including information on what topics should be addressed in the meeting in addition to those identified in the meeting request by the applicant; and
  - c. Identify at the meeting, items or information for clarification before the applicant's submission of the ANDA.
3. FDA will not provide a substantive assessment of summary data or full study reports at the meeting.
4. An applicant's decision not to request a Pre-Submission Meeting will not prejudice the receipt or assessment of an ANDA.
5. FDA will grant or deny 90 percent of Pre-Submission Meeting requests within 30 days.
6. If granted, FDA will conduct 90 percent of Pre-Submission Meetings within 60 days of the meeting request.
7. FDA will provide preliminary written comments 5 days before each meeting, and meeting minutes within 30 days after the meeting.

#### **IV. ANDA Assessment Meeting Program**

##### **A. Goal of the ANDA Assessment Meeting Program**

1. The goal of the ANDA Assessment Meeting Program is to provide or continue to provide targeted, robust advice to ANDA applicants as they work to meet the standards for ANDA approval.
2. Some elements of this program are tailored to enhance the development of Complex Generic Products.

##### **B. Mid-Cycle Review Meetings and Enhanced Mid-Cycle Review Meetings**

1. If an applicant for a Complex Generic Product was granted a Product Development Meeting for the same product, they may, within 7 days of receiving the last mid-Cycle DRL, submit a request for a Mid-Cycle Review Meeting or an Enhanced Mid-Cycle Meeting. The request should describe the specific deficiency(ies) to be discussed.
2. Mid-Cycle Review Meetings:
  - a. The purpose of a Mid-Cycle Review Meeting is for the applicant to ask for the rationale for any deficiency identified in the mid-cycle DRL(s), and/or to ask

questions related to FDA's assessment of the data or information in the ANDA. An applicant may not present any new data or information at this meeting.

- b. The Mid-Cycle Review Meeting will take place within 30 days after the date the sponsor submits a meeting request.
3. Enhanced Mid-Cycle Review Meetings:
- a. The purpose of this meeting is for the applicant to ask questions related to a proposed scientific path to address possible deficiencies identified in the mid-cycle DRL(s). An applicant may ask questions about potential new data or information to address any possible deficiencies identified in the mid-cycle DRL(s). FDA will discuss the data and information but will not provide substantive assessment of data or information provided by the applicant at the meeting.
  - b. If an Enhanced Mid-Cycle Review Meeting is requested, the meeting will take place within 90 days after issuance of the last mid-cycle DRL.
  - c. FDA will extend the ANDA goal date by 60 days if an applicant requests an Enhanced Mid-Cycle Review Meeting. FDA also 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 Enhanced Mid-Cycle Review Meeting.
  - d. An applicant may submit an Unsolicited Amendment after an Enhanced Mid-Cycle Review Meeting, which could result in an additional goal date extension consistent with section I(C).

### **C. Post-CRL Scientific Meetings**

1. An applicant can request a Post-CRL Scientific Meeting. The purpose of this meeting is to provide an applicant scientific advice on possible approaches to address deficiencies identified in a CRL related to establishing equivalence.
  - a. An applicant's meeting\_request must discuss:
    - iii. a new equivalence study needed to address the deficiencies in the design identified in the CRL,
    - iv. an approach that is different from that submitted in the ANDA, e.g., a change in study type from in vivo to in vitro,

- v. a new comparative use human factors study, or
  - vi. a new approach to demonstrating sameness of a complex active ingredient;  
and
  - b. FDA will grant the meeting if it is for a Complex Generic Product or in FDA's judgment the request raises issues that are best addressed via this meeting process and cannot be adequately addressed through Controlled Correspondence.
  - c. An applicant may have a post-CRL teleconference described in section II(B)(8)(a) prior to requesting this meeting.
2. FDA will grant or deny the Post-CRL Scientific Meeting request within 14 days after receipt of the request.
  3. FDA will hold the Post-CRL Scientific Meeting within 90 days after the date the meeting is granted.
  4. Applicants are eligible to request a Post-CRL Scientific Meeting even if they have not had a Product Development Meeting.

## **V. ADDITIONAL PROGRAM ENHANCEMENTS AND ASPIRATIONS**

### **A. Inactive Ingredient Database Enhancement**

FDA will update the Inactive Ingredient Database 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.

### **B. Regulatory Science Enhancements**

1. FDA will conduct internal and external research to support fulfillment 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 III regulatory science initiatives. Interested parties may propose regulatory science initiatives via email to [genericdrugs@fda.hhs.gov](mailto: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 III 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.

### **C. Other Pre-ANDA and Assessment Meeting Program Aspirations**

FDA aspires to continually improve the effectiveness of its Pre-ANDA and ANDA Assessment Meeting activities.

## **VI. DMF ASSESSMENT PROGRAM ENHANCEMENTS**

### **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. Teleconferences to Clarify DMF First Cycle Assessment Deficiencies**

1. FDA will grant and conduct teleconferences when requested to clarify deficiencies in first cycle DMF deficiency letters.
2. DMF holders must request such teleconferences 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 teleconference is still desired, FDA will schedule the teleconference.
3. FDA will strive to grant such teleconferences within 30 days of receipt of the initial teleconference request, giving priority to DMFs based on the priority of the referencing ANDA.
4. In lieu of a teleconference, 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 six 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 must include reference to a DMF for which FDA has not conducted a substantive assessment, and one of the following criteria must be met:
  - a. All patents and exclusivities will expire within 12 months of the planned submission date;
  - 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; or
  - 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 Rev. 5: Prioritization of the Review of Original ANDAs, Amendments, and Supplements.
2. A holder of a DMF may submit a request for assessment of the DMF six 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; or
  - 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.
3. To be eligible for this 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; and
  - c. documentation that the DMF holder has paid a GDUFA DMF fee as described in section 744B(a)(2)(A) of the FD&C Act (21 U.S.C. 379j-41(a)(2)(A)) for the current fiscal year.



## **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.

# **VII. 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 preapproval inspection 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 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.

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

### **C. GDUFA III 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. FDA will update the existing publicly available Inspection Classification Database webpage and will develop communication materials to provide further information to industry and foreign regulators on how FDA determines which facilities to select for a drug surveillance inspection, including how FDA uses its risk-based site selection model to determine the frequency of surveillance inspections.

### **D. Post-Warning Letter Meetings**

1. An eligible facility described in section VII(D)(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 Current Good Manufacturing Practice (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 video conference, teleconference, or face-to-face, at FDA's discretion.

10. The following goals apply to FDA’s decision to grant, deny, or defer in favor of re-inspection a Post-Warning Letter Meeting:
  - a. In FY 2024, 50 percent of eligible requests within 30 days of request.
  - b. In FY 2025, 70 percent of eligible requests within 30 days of request.
  - c. In FY 2026 and FY 2027, 80 percent of eligible requests 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.
12. Guidance related to Post-Warning Letter Meeting process set forth in this section VII(D):
  - a. FDA will issue guidance regarding the Post-Warning Letter Meeting process, including recommendations on items facilities should submit as part of a meeting request.
  - b. If more than 50 percent of first-time meeting requests are denied because FDA makes an assessment that the facility is not ready, FDA agrees to take appropriate action to provide additional information on meeting requests, which could include updating the guidance described in VII(D)(12)(a) to provide further information on how facilities can avoid issues that have commonly led to meeting requests being denied.

**E. Generic Drug Manufacturing Facility Re-inspection**

1. An eligible facility as described in section VII(E)(2) may request a re-inspection.
2. To be eligible for the facility re-inspection process reflected in this section:
  - 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, facility will be considered to no longer meet the eligibility criteria in section VII(E)(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 VII(E)(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. The applicable goals for domestic facilities are:
  - a. In FY 2024, for 60 percent of the requests for reinspection that are granted, FDA will re-inspect the facility within 4 months of the letter to the facility indicating FDA's intent to reinspect.
  - b. In FY 2025, for 70 percent of the requests for reinspection that are granted, FDA will re-inspect the facility within 4 months of the letter to the facility indicating FDA's intent to reinspect.

- c. In FY 2026 and FY 2027, for 80 percent of the requests for reinspection that are granted, FDA will re-inspect the facility within 4 months of the letter to the facility indicating FDA's intent to reinspect.
8. The applicable goals for international facilities are:
  - a. In FY 2024, for 60 percent of the requests for reinspection that are granted, FDA will re-inspect the facility within 8 months of the letter to the facility indicating FDA's intent to re-inspect.
  - b. In FY 2025, for 70 percent of requests for reinspection that are granted, FDA will re-inspect the facility within 8 months of the letter to the facility indicating FDA's intent to re-inspect.
  - c. In FY 2026 and FY 2027, for 80 percent of requests for reinspection that are granted, FDA will re-inspect the facility within 8 months of the letter to the facility indicating FDA's intent to re-inspect.

## **VIII. CONTINUED ENHANCEMENT OF 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 build on the financial enhancements included in GDUFA II and continue activities in GDUFA III 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 III and implementation of the Capacity Planning Adjustment (CPA).
2. Resource Capacity Planning Implementation
  - a. By the end of the second quarter of FY 2023, FDA will publish an implementation plan that will describe how resource capacity planning and time

reporting will continue to be utilized during GDUFA III. This implementation plan will address topics relevant to the maturation of resource capacity planning including, but not limited to, detailing FDA's approach to:

- i. The continued maturation of the Agency's resource capacity planning capability;
  - ii. The continual improvement of time reporting and its utilization in the CPA;
  - iii. The integration of resource capacity planning analyses in the Agency's resource and operational decision-making processes; and
  - iv. The implementation of the CPA, with a first year of adjustment for FY 2024 user fees.
- b. FDA will provide annual updates on the FDA website on the Agency's progress relative to activities detailed in this implementation plan by the end of the second quarter of each subsequent fiscal year.
  - c. FDA will document in the annual GDUFA Financial Report how any CPA fee revenues are being utilized.
  - d. Resources obtained from the CPA shall be used, consistent with user fee appropriations, to support CDER or ORA staff engaged in GDUFA program work, or other non-CDER staff who are directly supporting GDUFA review work.
  - e. The CPA shall be limited to workload driven by:
    - i. ANDA Originals and Resubmissions/Amendments
    - ii. ANDA Supplements (PAS and "Changes Being Effected" (CBE) supplements) and Amendments
    - iii. Controlled Correspondence as defined in Section XI(I)-(J)
    - iv. Pre-ANDA Meetings, which include Pre-Submission, Product Development, and Pre-Submission PSG Meetings
    - v. Surveillance inspections

vi. Post-marketing safety activities

vii. Suitability Petitions

### **C. Resource Capacity Planning Assessment**

1. By the end of FY 2025, an independent contractor will complete and publish an evaluation of the resource capacity planning capability. This will include an assessment of the following topics:
  - a. The ability of the CPA to forecast resource needs for the GDUFA program, including an assessment of the scope of the workload drivers in the CPA and their ability to represent the overall workload of the GDUFA program;
  - b. Opportunities for the enhancement of time reporting toward informing resource needs; and
  - c. The integration and utilization of resource capacity planning information within resource and operational decision-making processes of the GDUFA program.
2. The contractor will provide options and recommendations in the evaluation regarding the continued enhancement of the above topics as warranted. The evaluation findings and any related recommendations will be discussed at the FY 2026 GDUFA 5-year financial plan public meeting. The findings and recommendations of the evaluation may inform the CPA methodology for future reauthorizations.

### **D. 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 2023. FDA will publish updates to the 5-year plan no later than the second quarter of each subsequent fiscal year.
3. FDA will convene a public meeting no later than the third quarter of each fiscal year starting in FY 2024 to discuss the GDUFA 5-year financial plan, along with the



Agency's progress in implementing modernized time reporting and resource management planning.

#### **E. Improving the Hiring of Review Staff**

1. Enhancements to the generic drug review program require that FDA hire the necessary technical and scientific experts to efficiently conduct assessments of generic drug applications and supporting activities.
2. During GDUFA III, FDA will:
  - a. Hire 128 staff for the generic drug review program in FY 2023; and
  - b. Confirm progress in the hiring of GDUFA III staff in the GDUFA 5-year financial plan.

#### **IX. GUIDANCE AND MAPPS**

- A. FDA will draft or modify relevant Manuals of Policies and Procedures (MAPPs) to reflect the commitments and goals in this Commitment Letter, including, but not limited to, the following:
  1. To direct project managers, assessors, and other assessment program staff to actively work towards an action for an ANDA with a missed or extended goal date.
  2. To revise MAPP 5200.12 Communicating Abbreviated New Drug Application Review Status Updates with Industry, to include communications related to imminent actions on or before April 30, 2023.
- B. FDA will issue a Federal Register Notice on or before April 30, 2023, to solicit public comment on the content of Appendix A in the guidance for industry on *ANDA Submissions – Amendments to Abbreviated New Drug Applications Under GDUFA* (July 2018) and will use evaluations and/or training to assure consistency in ANDA amendment classification.
- C. FDA will issue a MAPP on the process for Reclassification of Facility-Based Major CRL Amendments set forth in section II(C)(7) on or before June 30, 2024.
- D. FDA will issue a MAPP on the prioritization of FDA assessment of solicited DMF amendments described in section VI(F)(2) on or before June 30, 2024.
- E. FDA will issue guidance clarifying the regulatory status of active pharmaceutical ingredient-excipient mixtures for GDUFA purposes.

## **X. 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):
4. Number of finalized DMF Completeness Assessments in the reporting month;
5. Number of DMF fees paid in the reporting month; and
6. Number of first-cycle approvals and tentative approvals in the reporting month.

**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,
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 1 and Level 2 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 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 and teleconferences requested, granted, denied, and conducted, broken down by type of meeting or teleconference, 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 teleconferences granted, and number of email exchanges requested and conducted in lieu of teleconferences to clarify deficiencies in first cycle DMF deficiency letters;

16. Percent of PSGs for non-Complex Product NCE NDAs within two years of NDA approval;
17. Percent of PSGs for Complex Product NDAs, including NCEs, published within two and three 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 reinspect 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; and
20. Percent Controlled Correspondence Level 1 and Level 2 responded to within the applicable goal date (i.e., 60 and 120 days, respectively);
21. Number of missed goal dates for original ANDAs by more than 6, 9, and 12 months.

#### **D. Fiscal Year Web Posting**

In addition to the data that will be reported annually on the web described in section XI(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 describe in sections VI(E)(1) and VI(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 VI(F); and
3. Number of original approvals taken that are Imminent Actions.

## XI. 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-approve 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. 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 1** – means correspondence submitted to the Agency, by or on behalf of a generic drug manufacturer or related industry:

1. Requesting information on a specific element of generic drug product development:
  - a. Prior to ANDA submission;
  - b. After a PSG Teleconference if a prospective applicant or applicant seeks further feedback from FDA;
  - c. After issuance of a CRL or tentative approval;
  - d. 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 2** – means correspondence that meets the definition of Level 1 correspondence, and:

1. Involves evaluation of clinical content;
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 Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU);
3. Requests a Covered Product Authorization to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU when development and testing does not involve clinical trials;
4. Requests evaluations of alternative bioequivalence approaches (e.g., pharmacokinetic, in vitro, clinical); or
5. Requires input from another office or center, e.g., questions regarding device constituent parts of a combination product.

- K. **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.”
- L. **Days** – unless otherwise specified, means calendar days.
- M. **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.
- N. **Earliest lawful ANDA approval date** – the first date on which no patent or exclusivity prevents approval of an ANDA.
- O. **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.
- P. **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.
- Q. **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.
- R. **Major Amendment** – means a Major Amendment as described in the guidance for industry on *ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA* (July 2018), and any subsequent revision.
- S. **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.
- T. **Minor Amendment** – means a minor amendment as described in the guidance for industry on *ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA* (July 2018), and any subsequent revision.
- U. **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).

- V. **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.
- W. **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).
- X. **Standard** – means submissions not affirmatively identified as eligible for expedited assessment pursuant to the CDER Prioritization MAPP.
- Y. **Teleconference** – means a verbal communication by telephone, and not a written response, unless otherwise agreed to by the applicant.
- 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).



## **Appendix: Prioritization of Suitability Petitions**

Prior to GDUFA III, FDA received approximately 20-30 suitability petitions per year and had approximately 170 suitability petitions currently pending as of July 2021. Pursuant to this Commitment Letter, in GDUFA III FDA has agreed to set goal dates for review and response to suitability petitions. To receive a goal date, pending petitions submitted prior to FY 2024 must be withdrawn and resubmitted.

If FDA does not respond to all petitions submitted in a given fiscal year, FDA has committed to prioritizing suitability petitions that are carried over to the following fiscal year over new petitions received in that fiscal year (subject to the prioritization outlined in section III(B)(6)). The following hypothetical example describes how FDA will prioritize suitability petitions if FDA is unable to respond to all suitability petitions in a given fiscal year. This example assumes a significantly higher number of incoming petitions and a high number of carryover petitions to illustrate how petitions that are carried over will be prioritized.

### Example

For FY 2024, FDA's goal is to respond to 50 percent of all suitability petitions received within six months of the completeness assessment, up to a maximum of 50 suitability petitions. In FY 2024, FDA receives and performs the completeness assessment for 100 suitability petitions. To meet the goal, FDA must respond to 50 of those petitions within six months after the completeness assessment. At the end of FY 2024, FDA has responded to 50 petitions within 6 months, and 10 in greater than six months. FDA therefore met the FY 2024 goal of 50 percent within six months (i.e., 50 petitions), and the additional 40 petitions still pending roll into FY 2025.

For FY 2025, FDA's goal is to respond to 70 percent of all suitability petitions received within six months of the completeness assessment, up to a maximum of 70 suitability petitions. In FY 2025, FDA receives 40 suitability petitions. To meet the FY 2025 goal, FDA must respond to 28 of those petitions within six months of the completeness assessment. FDA will prioritize any suitability petitions received in FY 2025 prioritized as outlined in section III(B)(6) and the 40 pending petitions from FY 2024 over any other suitability petitions received in FY25, in that order. By the end of FY 2025, FDA has responded to all 40 petitions from the FY 2024 cohort and 28 of the 40 from FY 2025 within 6 months of the completeness assessment. Twelve petitions from the FY 2025 cohort remain pending. FDA has met the FY 2025 goal, and the remaining 12 petitions still pending will be carried over into FY 2026 and prioritized.