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# Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)**

**October 2022  
Generic Drugs**

**Revision 1**

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*Contains Nonbinding Recommendations*

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# Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry<sup>1</sup>

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

## I. INTRODUCTION

This guidance describes an enhanced pathway for discussions between FDA and a prospective applicant preparing to submit to FDA or an applicant that has submitted to FDA an abbreviated new drug application (ANDA) for a complex product, as defined in this guidance. Specifically, this guidance provides information on requesting and conducting product development meetings, pre-submission meetings, mid-cycle review meetings (MCRMs),<sup>2</sup> enhanced mid-cycle review meetings (EMCRMs), and post-complete response letter (CRL) scientific meetings with FDA.

This guidance reflects a unified approach to formal meetings between FDA and prospective ANDA applicants or ANDA applicants for complex products under the pre-ANDA program and the ANDA assessment program.<sup>3,4,5</sup> This guidance will assist applicants in generating and submitting to FDA a meeting request and the associated meeting package for complex products,

<sup>1</sup> This guidance has been prepared by the Office of Generic Drugs (OGD) in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. You may submit comments on this guidance at any time. Submit comments to Docket No. FDA-2017-D-5739 (available at <https://www.regulations.gov/docket?D=FDA-2017-D-5739>).

<sup>2</sup> The name of this meeting has been changed in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III commitment letter) to mid-cycle review meeting from mid-review cycle meeting in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II commitment letter). The GDUFA III commitment letter is available at <https://www.fda.gov/media/153631/download> and the GDUFA II commitment letter is available at <https://www.fda.gov/media/101052/download>.

<sup>3</sup> For purposes of this guidance, a formal meeting includes any meeting that is requested by a prospective ANDA applicant or ANDA applicant following the request procedures provided in this guidance, as well as any meeting offered by the Agency following the procedures in this guidance, and includes meetings conducted in any format (e.g., teleconference, videoconference, face-to-face, written responses only).

<sup>4</sup> *Applicant* is defined as “any person who submits an...ANDA...under this part to obtain FDA approval of a new drug and any person who owns an approved...ANDA.” 21 CFR 314.3(b). This guidance uses the term *ANDA applicant* when discussing meetings that occur after an ANDA is received (i.e., MCRM, EMCRM, and post-CRL scientific meeting), the term *prospective ANDA applicant* when discussing meetings that occur before an ANDA is received (i.e., the product development and pre-submission meetings), and the term *applicants* when referring to both prospective ANDA applicants and ANDA applicants.

<sup>5</sup> GDUFA III commitment letter at 21-29.

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as defined in this guidance, that are or will be the subject of ANDAs submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 355(j)), and as contemplated in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III commitment letter).<sup>6</sup>

This guidance revises the guidance of the same title issued in November 2020. This revision is being issued to incorporate information on the complex product meeting types and performance goals included in the GDUFA III commitment letter, including information on requesting these meetings and FDA's procedures for handling these meetings.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

## **II. BACKGROUND**

The Generic Drug User Fee Amendments of 2012 (GDUFA I)<sup>7</sup> amended the FD&C Act to authorize FDA to assess and collect user fees to provide the Agency with resources<sup>8</sup> to help ensure patients have access to quality, affordable, safe, and effective generic drugs. GDUFA fee resources bring greater predictability and timeliness to the review of generic drug applications. GDUFA has been reauthorized every 5 years to continue FDA's ability to assess and collect GDUFA fees, and this user fee program has been reauthorized two times since GDUFA I, most recently in the Generic Drug User Fee Amendments of 2022. As described in the GDUFA III commitment letter applicable to this latest reauthorization, FDA has agreed to performance goals and program enhancements regarding aspects of the generic drug assessment program that build on previous authorizations of GDUFA. New enhancements to the program are designed to maximize the efficiency and utility of each assessment cycle, with the intent of reducing the number of assessment cycles for ANDAs and facilitating timely access to generic medicines for American patients.

As described in the GDUFA III commitment letter, the pre-ANDA program includes product development meetings and pre-submission meetings and is intended to clarify regulatory expectations for prospective ANDA 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.<sup>9</sup> The ANDA assessment meeting program for complex products includes MCRMs,

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<sup>6</sup> See footnote 2.

<sup>7</sup> Title III of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144.

<sup>8</sup> User fees are available for obligation in accordance with appropriations acts.

<sup>9</sup> GDUFA III commitment letter at 21. The pre-ANDA program includes additional enhancements other than meetings, such as product-specific guidances, that are outside the scope of this guidance.

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EMCRMs, and post-CRL scientific meetings.<sup>10</sup> The ANDA assessment meeting program is intended to provide or continue to provide targeted, robust advice to ANDA applicants as they work to meet the standards for ANDA approval. Some elements of these programs are tailored to enhance the development of complex generic products.<sup>11</sup>

As defined in the GDUFA III commitment letter, complex products generally include:

1. Products with complex active ingredients (e.g., peptides, polymeric compounds, complex mixtures of [active pharmaceutical ingredients], 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.<sup>12</sup>

To facilitate development of complex products that may be submitted in an ANDA, FDA and industry agreed to different types of meetings between applicants and FDA to discuss the proposed complex product and support submission of a high-quality, approvable ANDA, as well as to provide or continue to provide targeted, robust advice as applicants work to meet the standards for ANDA approval.<sup>13,14</sup>

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<sup>10</sup> GDUFA III commitment letter at 27-29. In addition to these meetings for complex products, other meetings described in the GDUFA III commitment letter are available for both complex and non-complex products, including post-CRL clarification teleconferences, product-specific guidance teleconferences, pre-submission product-specific guidance meetings, and post-submission product-specific guidance meetings. For more information on these meetings, see the guidance for industry *Post-Complete Response Clarification Between FDA and ANDA Applicants Under GDUFA* (October 2022) and the GDUFA III commitment letter at 24-25. For the most recent version of a guidance, check the FDA Drugs guidance web page at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

<sup>11</sup> GDUFA III commitment letter at 27.

<sup>12</sup> GDUFA III commitment letter at 45-46. See also CDER's Manual of Policies and Procedures (MAPP) 5240.10 *Classifying Approved New Drug Products and Drug-device Combination Products as Complex Products for Generic Drug Development Purposes*, available at <https://www.fda.gov/media/157675/download>.

<sup>13</sup> Although only prospective ANDA applicants and ANDA applicants can request meetings under the pre-ANDA and ANDA Assessment Meeting programs (GDUFA III commitment letter at 21, 27), an applicant may include other relevant entities in the meeting, e.g., consultants or drug master file holders.

<sup>14</sup> FDA has received, responded to, and granted certain meeting requests for products that do not fit within the definition of a complex product as defined in the GDUFA III commitment letter and as used in this guidance. Meeting requests for products that do not fit within the scope of this guidance will be granted based on the workload and availability of staff and the anticipated value to the ANDA assessment process.

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### III. MEETING TYPES

#### A. Product Development Meetings

Product development meetings for complex products that may be submitted in an ANDA 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 agreed to provide targeted advice regarding an ongoing ANDA development program.<sup>15</sup> To engage in a substantive discussion, FDA expects that the prospective ANDA applicant has enough knowledge of the complex product to allow FDA to provide appropriate feedback that will advance product development early in the process (e.g., the prospective ANDA applicant has generated its own data to be discussed). FDA recommends that the prospective ANDA applicant submit no more than one request for a product development meeting for the specific complex product per year, but FDA anticipates that some prospective ANDA applicants of complex products may request more than one product development meeting. If, following a product development meeting, a prospective ANDA applicant is seeking further clarification or has new questions related to what was discussed at the meeting, we recommend that the applicant submit such a request, with any new information or data, in a controlled correspondence for FDA's review.<sup>16</sup> If the prospective ANDA applicant has new information, data, or questions for Agency input that will not be adequately addressed in a controlled correspondence, the prospective ANDA applicant can request an additional product development meeting. The Agency will determine whether to grant the subsequent product development meeting based on the content of the meeting request and meeting package and available resources.

The GDUFA III commitment letter identifies when a product development meeting *will* and when a product development meeting *may* be granted.<sup>17</sup>

A product development meeting *will* be granted if, in FDA's judgment:

1. The requested meeting concerns (1) development of a complex generic product for which FDA has not issued a product-specific guidance, or (2) an alternative equivalence evaluation (i.e., change in study type, such as in vitro to clinical) for a complex product for which FDA has issued a product-specific guidance;
2. FDA determines the prospective ANDA applicant's meeting package is complete, including any data generated and specific proposals for product development (e.g., details regarding the proposed product development plan, such as an alternative study design, and sufficient justification to support the proposal), as applicable;
3. A controlled correspondence response would not adequately address the prospective ANDA applicant's questions; and

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<sup>15</sup> GDUFA III commitment letter at 25.

<sup>16</sup> See the guidance for industry *Controlled Correspondence Related to Generic Drug Development* (December 2020).

<sup>17</sup> GDUFA III commitment letter at 25-26.



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4. A product development meeting would significantly improve ANDA assessment efficiency (e.g., ultimately decrease the number of review cycles for the application).<sup>18</sup>

FDA *may* grant a product development meeting, dependent on available resources, if, in FDA's judgment:

1. The requested meeting concerns complex development issues other than those identified above (e.g., FDA has developed a product-specific guidance and the prospective ANDA applicant is not proposing an alternative equivalence evaluation);
2. FDA determines the prospective ANDA applicant's meeting package is complete, including any data generated and specific proposals for product development (e.g., details regarding the proposed product development plan, such as an alternative study design, and sufficient justification to support the proposal), as applicable;
3. A controlled correspondence response would not adequately address the prospective ANDA applicant's questions; and
4. A product development meeting would significantly improve ANDA assessment efficiency (e.g., ultimately decrease the number of review cycles for the application).<sup>19</sup>

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 ANDA applicant, within the applicable goal date.<sup>20</sup>

### **B. Pre-Submission Meetings**

Prospective ANDA applicants of complex products may request a pre-submission meeting. The purpose of a pre-submission meeting is to provide a prospective ANDA 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.<sup>21</sup>

The pre-submission meeting does not include substantive assessment of summary data or full study reports, but FDA will identify items or information that should be clarified before submission of the ANDA. The pre-submission meeting is not an opportunity to determine whether the application is acceptable for receipt.<sup>22</sup>

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<sup>18</sup> GDUFA III commitment letter at 25.

<sup>19</sup> GDUFA III commitment letter at 26.

<sup>20</sup> *Ibid.*

<sup>21</sup> *Ibid.* In general, a prospective ANDA applicant should not submit questions in a pre-submission meeting request. If a prospective ANDA applicant has questions related to its ANDA development program, those questions should be submitted in a product development meeting request.

<sup>22</sup> For example, the prospective ANDA applicant should not request or expect guidance on whether certain components needed for receipt consideration may be omitted from the ANDA.

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FDA anticipates that the pre-submission meeting request will be submitted approximately 6 to 8 months before submission of the ANDA. FDA attendees at the pre-submission meeting will generally include staff that attended the product development meeting, if held, and ANDA assessment team members that may assess the ANDA once received.

FDA recommends that a prospective ANDA applicant of a complex product seek FDA's input via a product development meeting prior to submitting a request for a pre-submission meeting so that FDA has knowledge of the prospective ANDA applicant's development program at the time of the pre-submission meeting.<sup>23</sup> Prospective ANDA applicants, however, can request a pre-submission meeting whether or not they had a product development meeting. FDA agreed to grant a pre-submission meeting if the prospective ANDA 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.<sup>24,25</sup>

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

During the first assessment cycle, an ANDA applicant for a complex product that was granted a prior product development meeting for the same complex product may request either an MCRM or an EMCRM.<sup>26,27,28</sup> The request should be submitted within 7 days<sup>29</sup> of receiving the last mid-cycle discipline review letter (DRL) (i.e., the latter of the quality DRL and the bioequivalence or clinical bioequivalence DRL).<sup>30</sup> For example, if the bioequivalence or clinical bioequivalence DRL is received on November 1, 2022, and the quality DRL is received on November 14, 2022,

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<sup>23</sup> A prospective ANDA applicant that had a product development meeting or received written responses only from FDA is not obligated to request a pre-submission meeting.

<sup>24</sup> See GDUFA III commitment letter at 26. FDA can meet the product development meeting goal by either conducting a meeting or providing a written response. See also section IV.A of this guidance.

<sup>25</sup> See GDUFA commitment letter at 26. FDA may also grant pre-submission meetings for a prospective ANDA applicant of a non-complex product if FDA decides the pre-submission meeting would improve ANDA assessment efficiency and dependent on available resources. In general, pre-submission meeting requests for non-complex products will be denied.

<sup>26</sup> See GDUFA commitment letter at 27. Such ANDA applicants will be notified in the ANDA Filing Acknowledgment letter that they are eligible to request an MCRM or EMCRM.

<sup>27</sup> ANDA applicants of complex products that have participated only in a pre-submission meeting may be eligible to request an MCRM or EMCRM during the first assessment cycle at Agency discretion and will be notified in the ANDA Filing Acknowledgment letter if they are eligible to request an MCRM or EMCRM.

<sup>28</sup> ANDA applicants for a drug product designated as a competitive generic therapy (CGT) may be eligible to request an MCRM during the first assessment cycle. ANDA applicants for a complex drug product designated as a CGT may be eligible to request an EMCRM during the first assessment cycle. FDA will notify an ANDA applicant for a drug designated as a CGT of its eligibility to request an MCRM or EMCRM in the ANDA Filing Acknowledgment letter or the CGT Designation Grant letter. For more information on MCRMs and EMCRMs for applications for drug products designated as CGT, see the guidance for industry *Competitive Generic Therapies* (October 2022).

<sup>29</sup> See the GDUFA III Commitment Letter at 47, stating that “[d]ays – unless otherwise specified, means calendar days.”

<sup>30</sup> GDUFA III commitment letter at 27. Mid-cycle DRLs include two separate letters addressing quality potential deficiencies and bioequivalence potential deficiencies. Applicants eligible for MCRMs or EMCRMs should submit a meeting request within 7 days of receiving the latter of the two DRLs. If an applicant requests an MCRM or an EMCRM more than 7 days after receiving the latter of the DRLs or prior to receiving the last DRL, the request will be denied.

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the applicant should submit the request for an MCRM or an EMCRM within 7 days of November 14, 2022.

The MCRM provides the ANDA applicant an opportunity 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.<sup>31</sup> An ANDA applicant cannot present any new data or information at this meeting.<sup>32</sup>

The EMCRM provides the ANDA applicant an opportunity to ask questions related to a proposed scientific path to address possible deficiencies identified in the mid-cycle DRL(s).<sup>33</sup> An applicant may ask questions about potential new data or information to address any possible deficiencies identified in the mid-cycle DRL(s).<sup>34</sup> FDA will discuss the data and information but will not provide substantive assessment of the data or information provided by the ANDA applicant at the meeting.<sup>35</sup>

An ANDA applicant should not respond to a DRL prior to the MCRM or EMCRM if the ANDA applicant intends to ask questions regarding that DRL in an MCRM or EMCRM. If the response due date for a DRL is before the date by which an ANDA applicant must request the MCRM or EMCRM, an ANDA applicant should request an extension to respond to that DRL. If an ANDA applicant responds to a DRL prior to the MCRM or EMCRM, FDA will deny an MCRM or EMCRM request for the questions related to that DRL or will cancel the MCRM or EMCRM.

FDA will only grant one request in the first assessment cycle (i.e., an MCRM or an EMCRM, not both) subject to the criteria described above. FDA recommends that an ANDA applicant request an EMCRM when the ANDA applicant has questions that are within the scope of both an MCRM and an EMCRM. Requests for MCRMs that contain questions that are within the scope of both an MCRM and an EMCRM may be granted an MCRM for the questions that are within the scope of an MCRM and will receive a denial for the questions within the scope of an EMCRM.

If an ANDA applicant requests and FDA grants an MCRM, FDA will extend the response due date for the relevant DRL(s), with the response due 15 days after the date of the MCRM.

If an ANDA applicant requests and FDA grants an EMCRM, FDA will extend the ANDA goal date by 60 days (i.e., FDA will add 60 days to the goal date).<sup>36</sup> FDA also will extend the response due date for the relevant DRL(s). FDA will recalculate the response due date starting from the date of the meeting and will extend the response due date by the number of days that were included for a response in the DRL.<sup>37</sup> For example, if the response was due 30 days after the DRL was issued, the response will be due 30 days after the date of the EMCRM.

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<sup>31</sup> GDUFA III commitment letter at 27-28.

<sup>32</sup> *Ibid* at 28.

<sup>33</sup> *Ibid*.

<sup>34</sup> *Ibid*.

<sup>35</sup> *Ibid*.

<sup>36</sup> *Ibid*.

<sup>37</sup> *Ibid*.

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An applicant may submit an Unsolicited Amendment after an EMCRM, which could result in an additional goal date extension, as described in section I(C) of the GDUFA III commitment letter.<sup>38</sup>

In addition, an applicant's response to a DRL (regardless of whether the applicant had an MCRM or EMCRM) may result in an additional goal date extension.<sup>39</sup>

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

ANDA applicants can request post-CRL scientific meetings for FDA to provide scientific advice on possible approaches to address deficiencies identified in a CRL related to establishing equivalence.<sup>40</sup> ANDA applicants can request a post-CRL scientific meeting even if they have not had a product development meeting. FDA agreed to 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.<sup>41</sup> An ANDA applicant may have a post-CRL teleconference to seek clarification concerning deficiencies identified in a CRL (post-CRL clarification teleconference) prior to requesting this meeting.<sup>42</sup>

An ANDA applicant's post-CRL scientific meeting request must discuss one or more of the following as it relates to establishing equivalence:

1. New equivalence study needed to address the deficiencies in the design identified in the CRL;
2. Approach that is different from that submitted in the ANDA, e.g., a change in study type from in vivo to in vitro;
3. New comparative use human factors study; or
4. New approach to demonstrating sameness of a complex active ingredient.<sup>43</sup>

In a post-CRL scientific meeting request, an ANDA applicant can submit questions both within the scope described above as well as clarifying questions. In contrast, a post-CRL clarification teleconference is limited to clarifying questions. ANDA applicants that have only clarifying questions, therefore, should consider requesting a post-CRL clarification teleconference within 10 days of the issuance of the CRL.<sup>44</sup>

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<sup>38</sup> Ibid at 10. In general, an unsolicited amendment submitted prior to the meeting will not be discussed during the EMCRM (or MCRM) because the unsolicited amendment is not included in the meeting package.

<sup>39</sup> See the guidance for industry *Information Requests and Discipline Review Letters Under GDUFA* (October 2022). See also the GDUFA III commitment letter at 13.

<sup>40</sup> GDUFA III commitment letter at 28.

<sup>41</sup> Ibid. at 29.

<sup>42</sup> Ibid. at 29, 16. See also the guidance for industry *Post-Complete Response Letter Clarification Teleconferences Between FDA and ANDA Applicants Under GDUFA* (October 2022).

<sup>43</sup> GDUFA III commitment letter at 28-29.

<sup>44</sup> See the guidance for industry *Post-Complete Response Letter Clarification Teleconferences Between FDA and ANDA Applicants Under GDUFA* (October 2022).

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### **IV. GDUFA III PERFORMANCE GOALS**

As reflected in the GDUFA III commitment letter, FDA committed to meet certain performance goals associated with the pre-ANDA and ANDA assessment meetings for complex products described in this guidance.<sup>45</sup> The goals described below in subsections A, B, and D only apply to meetings related to complex products under GDUFA III (i.e., requests submitted on or after October 1, 2022, and subject to the criteria described in this guidance). The goals described below in subsection C only apply to ANDAs found acceptable for filing on or after October 1, 2022, and subject to the criteria described in this guidance.<sup>46</sup>

#### **A. Performance Goals for Product Development Meetings**

FDA agreed to grant or deny 90 percent of product development meeting requests within 14 days after receipt of the meeting request. If granted, FDA agreed to conduct 90 percent of product development meetings within 120 days after the meeting is granted.<sup>47</sup>

FDA can also meet the product development meeting goal by providing a meaningful written response to the prospective ANDA applicant, within the applicable goal date, that will inform drug development and/or regulatory decision-making.<sup>48</sup>

#### **B. Performance Goals for Pre-Submission Meetings**

FDA agreed to grant or deny 90 percent of pre-submission meeting requests within 30 days. If granted, FDA agreed to conduct 90 percent of pre-submission meetings within 60 days of the meeting request.<sup>49</sup>

#### **C. Performance Goals for MCRMs and EMCRMs**

If an MCRM is requested and granted, the meeting will take place within 30 days after the date the ANDA applicant submits the meeting request. If an EMCRM is requested and granted, the meeting will take place within 90 days after issuance of the last mid-cycle DRL (i.e., the latter of the quality DRL and the bioequivalence or clinical bioequivalence DRL).<sup>50</sup>

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<sup>45</sup> Consistent with FDA's other user fee programs, FDA will calculate the goal date from the day after a submission. GDUFA III commitment letter at 4. Please also refer to FDA's guidance for industry *Providing Regulatory Submissions in Electronic Format – Receipt Dates* (February 2014) for information on how FDA calculates receipt dates for regulatory submissions in electronic format. As described in that guidance, requests will be received by the Agency Monday through Friday from 12:00 a.m. to 11:59 p.m. Eastern Standard Time/Eastern Daylight Time, excluding Federal holidays and days when the FDA office that will review the request is closed.

<sup>46</sup> For ANDAs found acceptable for filing during GDUFA II and that are eligible for a mid-review cycle meeting under the GDUFA II commitment letter, FDA will initiate scheduling the meeting. See the GDUFA II Commitment Letter.

<sup>47</sup> GDUFA III commitment letter at 26.

<sup>48</sup> *Ibid.*

<sup>49</sup> *Ibid.* at 27.

<sup>50</sup> *Ibid.* at 28.

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### **D. Performance Goals for Post-CRL Scientific Meetings**

FDA agreed to grant or deny the post-CRL scientific meeting request within 14 days after receipt of the request.<sup>51</sup> If granted, FDA agreed to hold the post-CRL scientific meeting within 90 days after the date the meeting is granted.<sup>52</sup>

### **V. MEETING REQUESTS**

A request for a product development meeting, pre-submission meeting, MCRM, EMCRM, or post-CRL scientific meeting should be submitted electronically, as explained below in this section.

If FDA determines that the request does not contain the information specified in this section, the request will not be considered to be submitted for purposes of GDUFA III performance goals.

#### **A. Product Development and Pre-Submission Meetings**

A request for a product development or pre-submission meeting for complex products that may be submitted in an ANDA should be sent electronically through the CDER Direct NextGen Collaboration Portal.<sup>53</sup> A request for a pre-submission meeting should clearly indicate whether the prospective ANDA applicant had a product development meeting with FDA. If no product development meeting was held, the prospective ANDA applicant should explain why a pre-submission meeting should be granted. A product development or pre-submission meeting request should include the following information:

1. Pre-assigned ANDA number.<sup>54</sup>
2. Meeting type being requested (i.e., product development or pre-submission).
3. Reference listed drug (RLD) and its application number.
4. Established Name.
5. Dosage form, route of administration, and strength.
6. A statement indicating whether the submission is being made by the prospective ANDA applicant or by a U.S. agent on behalf of the prospective ANDA applicant.

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<sup>51</sup> Ibid at 29.

<sup>52</sup> Ibid.

<sup>53</sup> The CDER Direct NextGen Collaboration Portal may be accessed at [https://edm.fda.gov/EDMIDPLlogin/welcome?response\\_type=code&client\\_id=00a1as7rb2poiYTch297&scope=openid%20profile&state=1802935594\\_1580919665259&redirect\\_uri=https%3A%2F%2Fedm.fda.gov%2Foidclient%2Fedmnp](https://edm.fda.gov/EDMIDPLlogin/welcome?response_type=code&client_id=00a1as7rb2poiYTch297&scope=openid%20profile&state=1802935594_1580919665259&redirect_uri=https%3A%2F%2Fedm.fda.gov%2Foidclient%2Fedmnp).

<sup>54</sup> See information regarding requesting a pre-assigned application number available on FDA's website at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm114027.htm>.

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7. Contact person for the meeting (i.e., the person submitting the meeting request), with their title and affiliation, secure email address,<sup>55</sup> and phone number. This is the person with whom FDA will communicate about the meeting.
8. The meeting package (see section VIII of this guidance), which should be submitted at the time of the meeting request for both product development and pre-submission meetings.

### **B. MCRMs and EMCRMs**

A request for an MCRM or EMCRM should be submitted to the ANDA via the Electronic Submissions Gateway (ESG) within 7 calendar days of receiving the latter of the quality DRL and the bioequivalence or clinical bioequivalence DRL.<sup>56</sup> The cover page should identify the submission as a “**Mid-Cycle Review Meeting Request**” or “**Enhanced Mid-Cycle Review Meeting Request.**” ANDA applicants should also e-mail a copy of the cover page that was submitted via the ESG to the Regulatory Project Manager.

An MCRM request should include the following information:

1. The specific deficiency(ies) that the ANDA applicant is requesting the rationale for and/or the questions related to FDA’s assessment of the data or information in the ANDA.
2. The meeting package (see section VIII of this guidance), which should be submitted at the time of the request for the MCRM.

An EMCRM request should include the following information:

1. If applicable, the specific deficiency(ies) that the ANDA applicant is requesting the rationale for and/or the questions related to FDA’s assessment of the data or information in the ANDA.
2. Questions related to a proposed scientific path to address possible deficiencies identified in the mid-cycle DRL(s) and any questions about potential new data or information to address possible deficiencies identified in the mid-cycle DRL(s).
3. The meeting package (see section VIII of this guidance), which should be submitted at the time of the request for the EMCRM.

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<sup>55</sup> Secure email between CDER and ANDA applicants and prospective ANDA applicants is useful for informal communications when confidential information (e.g., trade secrets or patient information) may be included in the message. Secure email should not be used for formal regulatory submissions. For more information on establishing a secure email link with CDER, please contact [SecureEmail@fda.hhs.gov](mailto:SecureEmail@fda.hhs.gov).

<sup>56</sup> See footnote 30.

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

A request for a post-CRL scientific meeting should be submitted to the ANDA via the ESG. The cover page should identify the submission as a **“Post-Complete Response Letter Scientific Meeting Request.”** A complete post-CRL scientific meeting request package should include the following information:

1. The specific approaches to address deficiencies identified in the CRL related to establishing equivalence, grouped by discipline. An applicant’s post-CRL scientific meeting request must discuss one or more of the following as it relates to establishing equivalence, and the meeting request should identify which one(s) the applicant wants to discuss: (1) a new equivalence study needed to address the deficiencies in the design identified in the CRL, (2) an approach that is different from that submitted in the ANDA, e.g., a change in study type from in vivo to in vitro, (3) a new comparative use human factors study, or (4) a new approach to demonstrating sameness of a complex active ingredient.<sup>57</sup>
2. The meeting package (see section VIII of this guidance), which should be submitted at the time of the request for the post-CRL scientific meeting.

## **VI. EVALUATING MEETING REQUESTS**

FDA will determine whether to grant a product development meeting request, pre-submission meeting request, MCRM or EMCRM request, or post-CRL scientific meeting request for complex products, and a response will be provided to the applicant by granting or denying the meeting request pursuant to the performance goals stated in the GDUFA III commitment letter (see section IV of this guidance) and as described below. Although applicants can request a particular format, FDA evaluates each meeting request and determines whether or not the request should be granted, the final meeting type, and the appropriate format.

### **A. Meeting Request Denied**

If a meeting request is denied, written notification to the applicant will include an explanation of the reason for the denial.

Denials of meeting requests submitted in conformity with the GDUFA III performance goals will be based on a substantive reason, not merely on the absence of a minor element of the meeting request or meeting package items. For example:

- A product development or pre-submission meeting request may be denied because the product does not meet the criteria for a complex product as provided in section II of this guidance or because a meeting is premature for the stage of product development in light of the insufficiency of the data generated.

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<sup>57</sup> GDUFA III commitment letter at 28-29.



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- An MCRM request or EMCRM request may be denied if the applicant did not participate in a prior product development meeting or pre-submission meeting or the product does not meet the criteria for a complex product as provided in section II of this guidance. In addition, the request will be denied if the request is made before issuance of the last mid-cycle DRL or the request is made more than 7 days after the issuance of the last mid-cycle DRL.
- A post-CRL scientific meeting request may be denied because the product does not meet the criteria for a complex product as provided in section II of this guidance, in FDA's judgment the request raises issues that can be adequately addressed through controlled correspondence, or the meeting request does not discuss one of the following as it relates to establishing equivalence:
  - a new equivalence study needed to address the deficiencies in the design identified in the CRL,
  - an approach that is different from that submitted in the ANDA, e.g., a change in study type from in vivo to in vitro,
  - a new comparative use human factors study, or
  - a new approach to demonstrating sameness of a complex active ingredient.<sup>58</sup>

If a meeting request is denied, a subsequent request to schedule a meeting will be considered as a new request (i.e., a request that is assigned a new set of time frames as described in section IV of this guidance).

### **B. Meeting Request Granted**

If a request for a meeting is granted, FDA will provide written notification to the applicant of the decision. FDA may indicate that the request is granted in part for the questions that are appropriate for the meeting type requested and denied in part for the questions that are not appropriate for the meeting type requested. If FDA will be providing a written response only instead of holding a meeting or teleconference, FDA will advise the applicant that a written response only is forthcoming. If FDA plans to hold a meeting or teleconference, FDA will schedule the meeting or teleconference by determining the date, time, length, format, and expected FDA participants. All of the scheduling information will be forwarded to the applicant either with the notification granting the meeting or teleconference or as soon as possible following notification that the request has been granted, and the meeting or teleconference will be scheduled within the specified GDUFA III performance goals (see section IV of this guidance).

## **VII. RESCHEDULING AND CANCELING MEETINGS**

### **A. Rescheduled Meetings**

Occasionally, circumstances may arise that necessitate the rescheduling of a meeting. If a meeting needs to be rescheduled, FDA will work to reschedule it as soon as possible after the

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<sup>58</sup> GDUFA III commitment letter at 28-29.

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original date. A new meeting request should not be submitted. Applicants and FDA should take reasonable steps to avoid rescheduling meetings. For example, if an attendee becomes unavailable, a substitute can be identified, or comments on the topic that the attendee would have addressed can be forwarded to the applicant following the meeting. It will be at FDA's discretion whether the meeting should be rescheduled depending on the specific circumstances.

A meeting may be rescheduled by FDA if, for example:

1. The assessment team determines that additional information is needed from the applicant to address the applicant's questions.
2. Essential attendees are no longer available for the scheduled date and time because of an emergency.
3. Attendance by additional FDA offices not originally anticipated or requested by the applicant is critical and the offices' availability precludes holding the meeting on the original date.
4. There is a regulatory policy issue that is yet to be resolved that may affect the response to the applicant's questions.
5. The Federal Government is closed or opening is delayed due to inclement weather, emergency, or other reason.

If an applicant requests that a meeting be rescheduled, FDA will evaluate the request and it will be at FDA's discretion whether to grant the request to reschedule. FDA will try to ensure a rescheduled meeting occurs within the goal date (see section IV of this guidance).<sup>59</sup> If FDA, in its discretion, decides to reschedule the meeting and is unable to reschedule it within the original goal date, FDA will notify the applicant of the reason for the rescheduled date, and FDA will still consider the performance goal met if the Agency is able to schedule and conduct the meeting within 30 days of the original goal date.

### **B. Canceled Meetings**

Occasionally, circumstances may arise that necessitate the canceling of a meeting. If a meeting is canceled, a subsequent request to schedule a meeting will be considered a new request. Applicants and FDA should take reasonable steps to avoid canceling meetings (unless the meeting is no longer necessary). It will be at FDA's discretion whether the meeting should be canceled depending on the specific circumstances.

A product development meeting may be canceled if, for example:

1. The prospective ANDA applicant withdraws the meeting request,

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<sup>59</sup> FDA does not recommend that applicants request to reschedule MCRMs or EMCRMs due to the timeframe for conducting these meetings (see section IV.C) and because these meetings are conducted during the assessment cycle.

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2. The prospective ANDA applicant informs FDA that its questions have been adequately answered by the preliminary written comments, or
3. FDA issues product-specific guidance on establishing bioequivalence to the RLD that is the basis of submission for the prospective ANDA applicant and which addresses the questions in the meeting package.<sup>60</sup>

If a prospective ANDA applicant requests to cancel a product development meeting after preliminary responses are issued, FDA will count the performance goal as met. If FDA cancels the meeting on its own initiative, the meeting request will not be counted for performance goal purposes.

A pre-submission meeting may be canceled if, for example:

1. the prospective ANDA applicant withdraws the meeting request, or
2. the applicant submits the ANDA.

An MCRM may be canceled if, for example:

1. The ANDA applicant withdraws the meeting request, or
2. The ANDA applicant submits a response to the DRL(s) that the questions in the meeting package are based on.

An EMCRM may be canceled if, for example:

1. The ANDA applicant withdraws the meeting request,
2. The ANDA applicant informs FDA that its questions have been adequately answered by preliminary written comments, or
3. The ANDA applicant submits a response to the DRL(s) that the questions in the meeting package are based on.

If an ANDA applicant requests to cancel an EMCRM after the goal date has been extended, the extended goal date will remain.

A post-CRL scientific meeting may be canceled if, for example:

1. The ANDA applicant withdraws the meeting request,

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<sup>60</sup> FDA publishes new and revised product-specific guidances describing the Agency's current recommendations for demonstrating bioequivalence and certain other approval requirements. Please check for the availability of new and revised product-specific guidances in the *Federal Register* and on the FDA website at the following address: <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075207.htm>.

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2. The ANDA applicant informs FDA that its questions have been adequately answered by the preliminary written comments, or
3. The applicant submits a response to the CRL.

### **VIII. MEETING PACKAGE CONTENT AND SUBMISSION**

Pre-meeting preparation is critical for achieving a productive discussion or exchange of information at meetings for complex products that may be submitted or have been submitted in an ANDA. Preparing the meeting package should help the applicant focus on describing its principal areas of interest. The meeting package should provide information relevant to the discussion topics and enable FDA to prepare adequately for the meeting. The meeting package should clearly indicate the type of meeting the applicant is requesting and should include adequate information for FDA to assess the potential utility of the meeting and to identify the appropriate staff that should attend the meeting.

#### **A. Timing of Submission**

The meeting package should be submitted to FDA so that it is received concurrently with the meeting request.

#### **B. Where and How Many Copies of Meeting Packages to Send**

Both the product development and pre-submission meeting packages should be submitted electronically to the CDER Direct NextGen Collaboration Portal at the same time as the meeting request.

The MCRM, EMCRM, and post-CRL scientific meeting packages should be submitted to the ANDA via the ESG at the same time as the meeting request.

It is not necessary to submit any paper copies of the meeting package.

#### **C. Meeting Package Content**

The meeting package should provide information relevant to the product, development stage, and meeting type requested, in addition to any supplementary information needed to help FDA develop responses to issues raised by the applicant. The meeting package should contain sufficient detail to meet the intended meeting objectives.

To facilitate FDA review, the meeting package content should be organized according to the proposed agenda. The meeting package should be a sequentially paginated document (individual sections can be numbered separately, as long as there is an overall pagination covering the whole submission) with a table of contents, appropriate indices, appendices, cross-references, and tabs differentiating sections.

## *Contains Nonbinding Recommendations*

### *1. General Meeting Package Content*

Meeting packages for each of the meeting types included in this guidance generally should include the following information:

1. Pre-assigned ANDA number or ANDA number.
2. Established name.
3. RLD and application number.
4. A brief statement of the purpose and objectives of the meeting. This statement should include a brief background of the issues underlying the agenda.

### *2. Product Development Meetings*

For product development meetings, in addition to the information in subsection 1 – General Meeting Package Content, meeting packages should generally also include:

1. Chemical structure.
2. Dosage form, route of administration, and dosing regimen (frequency and duration).
3. Proposed indications (e.g., prospective ANDA applicant is not seeking approval for all of the RLD's indications).
4. A brief statement indicating how the product meets the criteria for a complex product (see section II).
5. A background section that includes the following:
  - A brief history of the development program.
  - The status of product development.

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6. The requested format<sup>61</sup> — face-to-face,<sup>62</sup> videoconference,<sup>63</sup> teleconference,<sup>64</sup> or written response only.<sup>65</sup> For requested formats other than written response only, the meeting request package should also include the following information:
  - A proposed agenda and discussion topics, outlining how the 60-minute time frame allotted for the product development meeting should be apportioned for discussing each agenda item.
  - Suggested dates and times (e.g., morning or afternoon) for the meeting that are within the time frame for a product development meeting. Nonavailability dates and times should also be included.
  - A list of all individuals, with their titles and affiliations, who will participate in the requested meeting from the applicant's organization, including consultants and interpreters.<sup>66</sup>
7. A list of questions for discussion, grouped by discipline, as applicable, with each question clearly numbered (e.g., 1, 2, 3 without subquestions). For each question, there should be a brief explanation of the context and purpose of the question and any supporting rationale or data, as applicable. The prospective ANDA applicant should consider the duration of the proposed meeting when determining the proposed questions. The package should be organized such that following a summary list of all questions, each question is followed by the corresponding supporting justification, rationale, or data, as applicable, followed by the next question.
8. Data to support discussion organized by discipline and question. The level of detail should be appropriate to the meeting type requested and the product development stage (e.g., if an approach or alternative approach is proposed for establishing equivalence, sufficient rationale together with at least preliminary data should be provided).

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<sup>61</sup> For prospective ANDA applicants that meet the criteria in the GDUFA III commitment letter for a product development meeting, FDA will generally grant the prospective ANDA applicants' requested format. If FDA, in its discretion, provides the opportunity for a product development meeting to a prospective ANDA applicant that does not meet the criteria in the GDUFA III commitment letter, FDA has the discretion to select the format.

<sup>62</sup> Face-to-face meetings are those in which the majority of attendees participate in person at the FDA.

<sup>63</sup> Videoconferences are meetings in which the attendees participate from various remote locations via a video connection.

<sup>64</sup> Teleconference means a verbal communication by telephone, and not a written response, unless otherwise agreed to by the applicant. GDUFA III commitment letter at 48.

<sup>65</sup> Written response only responses are sent in lieu of a meeting or teleconference when requested by or otherwise agreed to by the applicant.

<sup>66</sup> The applicant should notify their FDA point of contact (POC) immediately if the list of meeting participants from the applicant's organization and consultants changes. In this situation, FDA may reschedule the meeting if the revised list of meeting participants requires additional FDA personnel. In the event this meeting is ultimately rescheduled outside the 120-day window, FDA will consider the GDUFA III goal of conducting the meeting within 120 days of granting the meeting request met.

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### *3. Pre-Submission Meetings*

For pre-submission meetings, in addition to the information in subsection 1 – General Meeting Package Content, meeting packages should generally also include:<sup>67</sup>

1. Chemical structure.
2. Dosage form, route of administration, and dosing regimen (frequency and duration).
3. Proposed indications (e.g., prospective ANDA applicant is not seeking approval for all of the RLD's indications).
4. A brief statement indicating how the product meets the criteria for a complex product (see section II).
5. A background section that includes the following:
  - A brief history of the development program.
  - The status of product development.
6. The requested format<sup>68</sup> — face-to-face or videoconference. The meeting request package should also include the following information:
  - A proposed agenda and discussion topics, outlining how the 60-minute time frame allotted for the pre-submission meeting should be apportioned for discussing each agenda item.
  - Suggested dates and times (e.g., morning or afternoon) for the meeting that are within the time frame for a pre-submission meeting. Nonavailability dates and times should also be included.

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<sup>67</sup> In general, high-level information is sufficient for the pre-submission meeting package. The meeting package can be in the format of a draft meeting presentation. For a suggested pre-submission meeting presentation outline template with recommendations on information that should be included, see Appendix B of this guidance. If the meeting request is granted, the draft presentation may be updated up to 21 days prior to the meeting date so that FDA may provide preliminary comments on the presentation 5 days before the meeting. The final presentation should be sent to the FDA no later than 48 hours before the meeting.

<sup>68</sup> For prospective ANDA applicants that meet the criteria in the GDUFA III commitment letter for a pre-submission meeting, FDA will generally grant the prospective ANDA applicants' requested format. If FDA, in its discretion, provides the opportunity for a pre-submission meeting to a prospective ANDA applicant that does not meet the criteria in the GDUFA III commitment letter, FDA has the discretion to select the format. Due to the nature of the pre-submission meeting, teleconference and written response only are not options for this meeting type.

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- A list of all individuals, with their titles and affiliations, who will participate in the requested meeting from the applicant's organization, including consultants and interpreters.<sup>69</sup>
7. Whether the prospective applicant had a product development meeting with FDA. If no product development meeting was held, the prospective applicant should explain why a pre-submission meeting should be granted.
  8. The event IDs for previously granted product development meeting(s).
  9. A summary of the advice provided at the product development meeting(s).
  10. The estimated timeline for when the prospective ANDA applicant plans to submit its ANDA.<sup>70</sup>
  11. 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.

#### *4. MCRMs*

For MCRMs, in addition to the information in subsection 1 – General Meeting Package Content, meeting packages should generally also include:

1. The specific deficiency(ies) that the applicant is requesting the rationale for and/or the questions related to FDA's assessment of the data or information in the ANDA.
2. The requested format<sup>71</sup> — teleconference or written response only. For requested teleconferences, the request package should also include the following information:
  - A proposed agenda outlining how the 30-minute time frame allotted for the MCRM should be apportioned for discussing each agenda item.

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<sup>69</sup> The applicant should notify their FDA POC immediately if the list of meeting participants from the applicant's organization and consultants changes. In this situation, FDA may reschedule the meeting if the revised list of meeting participants requires additional FDA personnel. In the event this meeting is ultimately rescheduled outside the 60-day window, FDA will consider the GDUFA III goal of conducting the meeting within 60 days of granting the meeting request met.

<sup>70</sup> FDA recommends that a prospective ANDA applicant submits its pre-submission meeting request approximately 6 to 8 months before submission of the ANDA.

<sup>71</sup> For applicants that meet the criteria in the GDUFA III commitment letter for an MCRM, FDA will generally grant the ANDA applicants' requested format. If FDA, in its discretion, provides the opportunity for an MCRM to an ANDA applicant that does not meet the criteria in the GDUFA III commitment letter, FDA has the discretion to provide a written response only instead of a teleconference.



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- Suggested dates and times (e.g., morning or afternoon) for the teleconference that are within the time frame of an MCRM. Nonavailability dates and times should also be included.
- A list of all individuals, with their titles and affiliations, who will participate in the requested meeting from the applicant's organization, including consultants and interpreters.<sup>72</sup>
- A list of specific assessment disciplines asked to participate in the requested teleconference based on the questions to be discussed. FDA has discretion to determine which assessment disciplines attend the teleconference. FDA will have appropriate staff participate in the teleconference to respond to the applicant's questions, which may be from different disciplines than the disciplines that the applicant requested to participate.

#### 5. *EMCRMs*

For EMCRM, in addition to the information in subsection 1 – General Meeting Package Content, meeting packages should generally also include:

1. If applicable, the specific deficiency(ies) that the applicant is requesting the rationale for and/or the questions related to FDA's assessment of the data or information in the ANDA.
2. Questions related to a proposed scientific path to address possible deficiencies identified in the mid-cycle DRL(s) and any questions about potential new data or information to address possible deficiencies identified in the mid-cycle DRL(s).<sup>73</sup>
3. The requested format<sup>74</sup> — face-to-face, video conference, teleconference, or written response only. For requested formats other than written response only, the meeting request package should also include the following information:
  - A proposed agenda outlining how the 60-minute time frame allotted for the EMCRM should be apportioned for discussing each agenda item.

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<sup>72</sup> The applicant should notify their FDA POC immediately if the list of participants from the applicant's organization and consultants changes. In this situation, FDA may reschedule the teleconference if the revised list of teleconference participants requires additional FDA personnel. In the event this teleconference is ultimately rescheduled outside the 30-day window, FDA will consider the GDUFA III goal of conducting the teleconference within 30 days of the date the applicant submits the request met.

<sup>73</sup> As stated in section III.B of this guidance, FDA will not provide substantive assessment of the data or information provided by the applicant at the meeting.

<sup>74</sup> For applicants that meet the criteria in the GDUFA III commitment letter for an EMCRM, FDA will generally grant the applicant's requested meeting format. If FDA, in its discretion, provides the opportunity for an EMCRM to an ANDA applicant that does not meet the criteria in the GDUFA III commitment letter, FDA has the discretion to provide a teleconference or written response only instead of a meeting.

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- Suggested dates and times (e.g., morning or afternoon) for the meeting that are within the time frame of an EMCRM. Nonavailability dates and times should also be included.
- A list of all individuals, with their titles and affiliations, who will participate in the requested meeting from the applicant's organization, including consultants and interpreters.<sup>75</sup>
- A list of specific assessment disciplines asked to participate in the requested meeting or teleconference based on the questions to be discussed. FDA has discretion to determine which assessment disciplines attend the meeting. FDA will have appropriate staff participate in the meeting or teleconference to respond to the applicant's questions, which may be from different disciplines than the disciplines that the applicant requested to participate.

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

For post-CRL scientific meetings, in addition to the information in subsection 1 – General Meeting Package Content, meeting packages should generally also include:

1. A brief statement indicating how the product meets the criteria for a complex product (see section II).
2. The specific approaches to address deficiencies identified in the CRL, grouped by discipline, with data to support discussion. The meeting package must discuss one or more of the following: (1) a new equivalence study needed to address the deficiencies identified in the CRL; (2) an approach that is different from that submitted in the ANDA, e.g., a change in study type from in vivo to in vitro; (3) a new comparative use human factors study; or (4) a new approach to demonstrating sameness of a complex active ingredient.
3. The requested format<sup>76</sup> – face-to-face, videoconference, teleconference, or written response only. For requested formats other than written response only, the meeting request package should also include the following information:

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<sup>75</sup> The applicant should notify their FDA POC immediately if the list of meeting participants from the applicant's organization and consultants changes. In this situation, FDA may reschedule the meeting if the revised list of meeting participants requires additional FDA personnel. In the event this meeting is ultimately rescheduled outside the 90-day window, FDA will consider the GDUFA III goal of conducting the meeting within 90 days after issuance of the last mid-cycle DRL met.

<sup>76</sup> For ANDA applicants that meet the criteria in the GDUFA III commitment letter for a post-CRL scientific meeting, FDA will generally grant the applicant's requested format. If FDA, in its discretion, provides the opportunity for a post-CRL scientific meeting to an ANDA applicant that does not meet the criteria in the GDUFA III commitment letter, FDA has the discretion to provide a teleconference or written response only instead of a meeting or direct the ANDA applicant to utilize the controlled correspondence pathway.

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- A proposed agenda and discussion topics, outlining how the 60-minute time frame allotted for the post-CRL scientific meeting should be apportioned for discussing each agenda item.
- Suggested dates and times (e.g., morning or afternoon) for the meeting that are within the time frame for a post-CRL scientific meeting. Nonavailability dates and times should also be included.
- A list of all individuals, with their titles and affiliations, who will participate in the requested meeting from the applicant's organization, including consultants and interpreters.<sup>77</sup>
- A list of specific assessment disciplines asked to participate in the requested meeting or teleconference based on the questions to be discussed. FDA has discretion to determine which assessment disciplines attend the meeting. FDA will have appropriate staff participate in the meeting or teleconference to respond to the applicant's questions, which may be from different disciplines than the disciplines that the applicant requested to participate.

## **IX. PRE-MEETING COMMUNICATIONS WITH APPLICANTS**

For a product development meeting, if FDA is not providing a written response to the prospective ANDA applicant, FDA agreed to provide preliminary written comments to the prospective ANDA applicant's point of contact and FDA intends to provide such comments 5 calendar days before the meeting.<sup>78</sup> For a pre-submission meeting, FDA agreed to provide preliminary written comments to the prospective ANDA applicant's point of contact 5 calendar days before the meeting.<sup>79</sup>

In general, FDA does not intend to provide preliminary written comments in advance of an MCRM. For EMCRMs, FDA intends to provide preliminary written comments to the ANDA applicant's point of contact no later than 3 calendar days before the meeting.

For post-CRL scientific meetings, FDA intends to provide preliminary written comments to the ANDA applicant's point of contact no later than 5 calendar days before the meeting.

Communications before the meeting between applicants and FDA, including preliminary written comments, can serve as a foundation for discussion or as the final meeting responses. Nevertheless, preliminary written comments should not be construed as final unless there is

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<sup>77</sup> The applicant should notify their POC immediately if the list of meeting participants from the applicant's organization and consultants changes. In this situation, FDA may reschedule the meeting if the revised list of meeting participants requires additional FDA personnel. In the event this meeting is ultimately scheduled outside the 90-day window, FDA will consider the GDUFA III goal of conducting the meeting within 90 days of granting the meeting request met.

<sup>78</sup> GDUFA III commitment letter at 26.

<sup>79</sup> *Ibid.* at 27.

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agreement between the applicant and FDA that additional discussion is not necessary for any question (i.e., when the meeting is canceled because the applicant is satisfied with FDA's preliminary written comments), or the applicant and FDA agree a particular question is considered resolved, allowing extra time for discussion of other questions during the meeting. After receiving the preliminary written comments, the applicant should provide an updated agenda with its list of questions for discussion in order of priority, no later than 48 hours before the scheduled meeting. Preliminary written comments communicated by FDA should not generate the submission of new questions, and new questions will not be entertained at the meeting.

### **X. PROCEDURES FOR CONDUCT OF MEETINGS**

#### **A. Introductions and Agenda**

Product development and pre-submission meetings for complex products will be chaired by an FDA staff member and will begin with introductions<sup>80</sup> and a statement of the agenda.

In general, for product development meetings, the meeting participants will discuss the questions posed and the data provided by the prospective ANDA applicant to assist its complex product development program.

In general, for pre-submission meetings, the prospective ANDA applicant will present the unique or novel data or information that will be included in the ANDA submission.

The Regulatory Project Manager assigned to the ANDA will manage the MCRM or the EMCRM. In general, for MCRMs, the meeting participants will discuss the questions posed about the rationale for any deficiency identified in the mid-cycle DRL, and/or questions related to the FDA's assessment of the data or information in the ANDA. In general, for EMCRMs, the meeting participants will discuss the questions related to a proposed scientific path to address possible deficiencies in the mid-cycle DRL(s).

Post-CRL scientific meetings for complex products will be chaired by an FDA staff member and will begin with introductions<sup>81</sup> and a statement of the agenda. In general, the meeting participants will discuss scientific advice on possible approaches to address deficiencies identified in the CRL related to establishing equivalence.

#### **B. End of Meeting Summary**

Before the end of the meeting, FDA attendees and the applicant attendees should summarize the important discussion points, agreements, clarifications, and action items. Generally, the applicant will be asked to present the summary to ensure that there is mutual understanding of

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<sup>80</sup> In general, FDA attendees may include, as applicable, additional staff from CDER's OGD, Office of Pharmaceutical Quality (OPQ), Office of Surveillance and Epidemiology, and Office of New Drugs. Center for Devices and Radiological Health staff may also attend if the complex product has a device component.

<sup>81</sup> See footnote 80.

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meeting outcomes and action items. FDA staff can add or further clarify any important points not covered in the summary, and these items can be added to the meeting minutes. The summary can be done at the end of the meeting or after the discussion of each question.

### **C. Presentations**

Presentations by applicants are not generally needed for meetings, except for pre-submission meetings, because the information necessary for review and discussion should be part of the meeting package. If an applicant plans to make a presentation, the presentation should be discussed ahead of time with the FDA point of contact to ensure that FDA has the presentation materials ahead of the meeting, if possible. All presentations should be kept brief to maximize the time available for discussion.

The length of the meeting will not be increased to accommodate a presentation. If a presentation contains more than a small amount of content distinct from clarifications or explanations of previous data, or contains data that were not included in the original meeting package submitted to FDA for review, FDA staff may not be able to provide comments on the new information.

FDA does not expect that the ANDA applicant attendees of the MCRMs will provide any presentations.

## **XI. DOCUMENTATION AND MEETING MINUTES**

Documentation of meeting outcomes, agreements and disagreements, issues for further discussion, and action items is critical to ensuring that this information is preserved for meeting attendees and for future reference. FDA minutes are the official record of the meeting. FDA agreed to issue the official, finalized minutes to the prospective ANDA applicant within 30 days after the product development or pre-submission meeting.<sup>82</sup> FDA intends to issue the official, finalized minutes to the ANDA applicant for the MCRM, EMCRM, or post-CRL scientific meeting within 30 days after the meeting.

## **XII. RESOLUTION OF DISPUTE ABOUT MEETING MINUTES**

On occasion, there may be disputes regarding the accuracy and sufficiency of the minutes of a product development meeting, pre-submission meeting, MCRM, EMCRM, or post-CRL scientific meeting. An applicant requesting additional clarification of the meeting minutes issued by FDA should contact the assigned FDA point of contact. FDA recommends that the applicant submit its concerns about the meeting minutes in writing to FDA within 10 calendar days of receipt of the official meeting minutes. This process addresses issues with the meeting minutes only.

If a prospective ANDA applicant needs to discuss additional issues that were not addressed at the product development or pre-submission meeting, the prospective ANDA applicant should submit

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<sup>82</sup> GDUFA III commitment letter at 26 and 27.

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a controlled correspondence or a new meeting request. If an ANDA applicant needs to discuss additional issues that were not addressed at the MCRM or EMCRM, the ANDA applicant should contact the Regulatory Project Manager.<sup>83</sup> If an ANDA applicant needs to discuss additional issues that were not addressed at the post-CRL scientific meeting, the ANDA applicant should submit a controlled correspondence or a request for another post-CRL scientific meeting.

If, after following up as described above, there are still significant differences in the applicant's and FDA's understanding of the content of the official meeting minutes, the applicant should notify FDA in writing with respect to specific disagreements. The applicant should submit the correspondence to its application or, if there is no application, submit a letter to the division director of the division that chaired the meeting, with a copy to the FDA point of contact describing the concern.

The applicant's concerns will be taken under consideration by the assessment division and senior management, if senior management was present at the meeting. If the minutes are determined to accurately and sufficiently reflect the meeting discussion, the point of contact will convey this decision to the applicant, and the minutes will stand as the official documentation of the meeting. If, after discussions with the applicant, FDA deems it necessary to change the official minutes, the changes will be documented in an addendum to the official minutes. The addendum will also document any continued objections.<sup>84</sup>

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<sup>83</sup> The applicant should not submit a request for another MCRM or EMCRM. FDA will deny such a request.

<sup>84</sup> Any addendum will be shared with the applicant by FDA.

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**XIII. APPENDICES**

**A. Summary of Scope and Criteria for Meetings for Complex Products Under GDUFA III**

<b>Meeting Type</b>	<b>Purpose/Scope</b>	<b>Criteria</b>	<b>Additional Considerations</b>
Product Development	(a) Development of a complex product for which FDA has not issued product-specific guidance	<ul style="list-style-type: none"> <li>• Meets the purpose/scope</li> <li>• Prospective ANDA applicant submits a complete meeting package</li> <li>• Controlled correspondence response would not adequately address the prospective applicant's questions</li> <li>• Product development meeting would significantly improve ANDA assessment efficiency</li> </ul>	
	(b) Alternative equivalence evaluation for a complex product for which FDA has issued a product-specific guidance	<ul style="list-style-type: none"> <li>• Meets the purpose/scope</li> <li>• Prospective ANDA applicant submits a complete meeting package</li> <li>• Controlled correspondence response would not adequately address the prospective applicant's questions</li> <li>• Product development meeting would significantly improve ANDA assessment efficiency</li> </ul>	
	(c) Complex product development issues other than those described in (a) and (b) above	<ul style="list-style-type: none"> <li>• Meets the purpose/scope</li> <li>• Prospective ANDA applicant submits a complete meeting package</li> <li>• Controlled correspondence response would not adequately address the prospective applicant's questions</li> <li>• Product development meeting would significantly improve ANDA assessment efficiency</li> </ul>	<ul style="list-style-type: none"> <li>• Granting of meeting is dependent on available resources</li> </ul>

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<b>Meeting Type</b>	<b>Purpose/Scope</b>	<b>Criteria</b>	<b>Additional Considerations</b>
Pre-Submission	<ul style="list-style-type: none"> <li>• Opportunity for prospective ANDA applicants 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</li> </ul>	<ul style="list-style-type: none"> <li>• Prospective ANDA applicant that was granted a product development meeting for the same complex generic product</li> <li>• FDA agreed to grant a pre-submission meeting to a prospective ANDA applicant of a complex product that did not have a product development meeting if FDA believes in its sole discretion that the pre-submission meeting would improve assessment efficiency</li> </ul>	<ul style="list-style-type: none"> <li>• Meeting request should be submitted approximately 6 to 8 months before submission of the ANDA</li> <li>• Prospective ANDA applicant that was granted a product development meeting, had a product development meeting, or received a written response only is not obligated to request a pre-submission meeting</li> </ul>
Mid-Cycle Review	<ul style="list-style-type: none"> <li>• Opportunity for the applicant to ask for rationale for any deficiency(ies) 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</li> </ul>	<ul style="list-style-type: none"> <li>• Held during the first review cycle with ANDA applicants of complex products that were granted a prior product development meeting for the same product</li> <li>• ANDA applicants of complex products that have participated only in a pre-submission meeting may be eligible to request an MCRM at Agency discretion and will be notified in the ANDA Filing Acknowledgement letter if they are eligible to request an MCRM</li> <li>• Applicants of CGT-designated ANDAs that have not had a product development meeting will be notified in either the ANDA Filing Acknowledgement letter or CGT Designation Grant letter if they are eligible to request an MCRM</li> </ul>	<ul style="list-style-type: none"> <li>• MCRMs are requested by the ANDA applicant. The applicant will submit a meeting package and proposed agenda</li> <li>• An applicant cannot present any new data or information at this meeting</li> </ul>



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<b>Meeting Type</b>	<b>Purpose/Scope</b>	<b>Criteria</b>	<b>Additional Considerations</b>
Enhanced Mid-Cycle Review	<ul style="list-style-type: none"> <li>• Opportunity for the ANDA 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)</li> </ul>	<ul style="list-style-type: none"> <li>• Held during the first review cycle with ANDA applicants of complex products that have were granted a prior product development meeting for the same product</li> <li>• ANDA applicants of complex products that have participated only in a pre-submission meeting may be eligible to request an EMCRM at Agency discretion and will be notified in the ANDA Filing Acknowledgement letter if they are eligible to request an EMCRM</li> </ul>	<ul style="list-style-type: none"> <li>• EMCRMs are requested by the ANDA applicant. The applicant will submit a meeting package and agenda</li> <li>• FDA will discuss the data and information but will not provide substantive assessment of data or information provided by the applicant at the meeting</li> <li>• If an applicant requests and FDA grants an EMCRM, FDA will extend the goal date and the response due date for the relevant DRL(s) as described on page 28 of the GDUFA III commitment letter and in section III.C above</li> </ul>
Post-CRL Scientific	<ul style="list-style-type: none"> <li>• Opportunity for ANDA applicants to seek scientific advice from FDA on possible approaches to address deficiencies identified in a CRL related to establishing equivalence</li> </ul>	<ul style="list-style-type: none"> <li>• 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</li> <li>• An applicant’s post-CRL scientific meeting request must discuss one or more of the four categories described on pages 28-29 of the GDUFA III commitment letter and in section III.D above</li> </ul>	<ul style="list-style-type: none"> <li>• An applicant can have a post-CRL teleconference described on page 16 of the GDUFA III commitment letter prior to requesting this meeting</li> <li>• Applicants are eligible to request a post-CRL scientific meeting even if they have not had a product development meeting</li> </ul>

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### **B. Pre-Submission Meeting Presentation Outline Template for Prospective ANDA Applicants**

The pre-submission meeting presentation outline template provided below is intended to assist prospective ANDA applicants in preparing pre-submission meeting presentations, and it includes suggested items from the Agency for prospective ANDA applicants to present at the pre-submission meetings to help orient the discussion. Suggested items for the pre-submission meeting presentation include, but are not limited to: (1) formulation; (2) new analytical methods; (3) new statistical methods; (4) novel in vitro drug release testing methods; (5) alternative bioequivalence study design to the recommendations in the product-specific guidance with justification for the alternative study design; (6) regulatory history; and (7) summary of generic development.

Prospective ANDA applicants should address the suggested items, as applicable, and provide responses/information as appropriate in a concise and clear manner.

Note that the information included below is not an exhaustive list of the information that prospective ANDA applicants should consider including in their pre-submission meeting presentation. There may be additional items that should be included in the pre-submission meeting presentation.

#### Presentation Outline Template:

1. Pre-Submission Meeting Request Summary
  - a. Applicant name
  - b. Anticipated ANDA submission date
  - c. Reference Listed Drug (RLD)
    - i. Information on drug substance, dosage form, route of administration
    - ii. RLD information (RLD number, approval date, application holder)
    - iii. Indication(s)
    - iv. Dose and route of administration
  - d. Reference Standard
    - i. Indicate if the Reference Standard is the same as the RLD
    - ii. When the Reference Standard is different from the RLD, include the Reference Standard information (application number, approval date, application holder)
  - e. Complex drug as defined by the GDUFA III commitment letter (indicate all that apply)
    - i. Complex active ingredient
    - ii. Complex formulation
    - iii. Complex route of delivery
    - iv. Complex dosage form
    - v. Complex drug-device combination
    - vi. Other complexity

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2. Justification for the Request (indicate all that apply)
  - a. Complex drug product
  - b. ANDA to be submitted within 6 to 8 months of pre-submission meeting request
  - c. Previous product development meeting
  - d. Other justification
  
3. Regulatory History
  - a. Previous communications with FDA, including but not limited to:
    - i. Controlled correspondence
    - ii. Pre-ANDA meeting requests
    - iii. Suitability petitions
    - iv. PSG teleconference
    - v. Pre-submission PSG meeting requests
    - vi. Competitive generic therapy (CGT) designation requests
  
4. Summary of Generic Drug Development
  - a. Provide a brief summary of the status of the generic drug product development program, including but not limited to:
    - i. Formulation development
    - ii. Stability
    - iii. Status of bioequivalence evaluation
  
5. Formulation Composition
  - a. Inactive ingredients exceeding the maximum potency per unit dose and/or maximum daily exposure specified in the inactive ingredient database
    - i. No
    - ii. Yes, with justification
  - b. Formulation composition assessment
    - i. Yes, per regulation (e.g., qualitative (Q1) and quantitative (Q2) sameness)
    - ii. Yes, per PSG recommendations (e.g., Q1/Q2 or “no significant difference”)
    - iii. No
  - c. Formulation composition table
  
6. Filing
  - a. Waiver requests, if any
  - b. Noteworthy items related to filing
  
7. Labeling
  - a. Unique or novel labeling differences
  - b. Labeling differences due to proposed differences in device design
  
8. Bioequivalence
  - a. Product-specific guidance (PSG) available
    - i. No
    - ii. Yes

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- b. Deviation from recommendations in PSG
    - i. No
    - ii. Yes, with minor deviation (e.g., study design, study population, etc.)
    - iii. Yes, with major deviation (e.g., an alternative bioequivalence approach, different statistical analysis, etc.)
  - c. A brief description of the deviation (if applicable)
  - d. Failed bioequivalence study with the same or different test formulation
  - e. In vitro dissolution test conducted for supporting bioequivalence:
    - i. No
    - ii. Yes, to request biowaiver for additional strength(s)
    - iii. Yes, as a pivotal in vitro bioequivalence study
  - f. Novel bioanalytical methods used in the in vivo bioequivalence study or novel analytical methods used for in vitro bioequivalence study with justification
  - g. Novel statistical analysis used for supporting bioequivalence with justification
  - h. Other novel scientific approaches with justification
9. User Interface Assessment (if applicable)
- a. FDA recommends that applicants use and follow the draft guidance for industry *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA* for the user interface of the proposed product.
  - b. If there are design differences identified in the user interface of the proposed product as compared to the RLD, identify the proposed formulation and/or data you propose to submit (e.g., in vitro data, comparative human factor study).
  - c. Applicants are encouraged to include specific considerations for their proposed product as compared to the RLD with regard to the user interface.
  - d. Other noteworthy items for user interface assessment.
10. Chemistry Manufacturing Control (CMC)
- a. Complex active pharmaceutical ingredient (API)
    - i. No
    - ii. Yes
  - b. Comparative tests for supporting API sameness (if applicable)
  - c. Novel or unique approaches used in development, manufacture, and control strategy of the drug product
  - d. Comparative tests for supporting Q1 sameness/similarity of complex functional excipients (if applicable)
  - e. Other noteworthy items for CMC (e.g., complex device and related quality considerations)
11. Supplemental Materials
- a. A list of supplemental materials, if any