Advanced Manufacturing Technologies Designation Program

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Ranjani Prabhakara 240-402-4652, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

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Advanced Manufacturing Technologies Designation Program

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Office of Communications, Division of Drug Information
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Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
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Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
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Advanced Manufacturing Technologies Designation Program Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

Advanced manufacturing is a term for an innovative pharmaceutical manufacturing technology or approach that has the potential to improve the reliability and robustness of the manufacturing process and supply chain and increase timely access to quality medicines for the American public. Advanced manufacturing can integrate novel technological approaches, use established techniques in an innovative way, or apply production methods in a new domain where there are no defined best practices or experience. Advanced manufacturing can potentially be used for new or currently marketed small molecule drugs or biological products.

FDA encourages the early adoption of advanced manufacturing technologies (AMTs) that have the potential to benefit patients by improving manufacturing and supply dependability and optimizing development time of drug and biological products. These technologies can be integral to ensuring quality and supporting a robust supply of drugs that are life-supporting, life-sustaining, of critical importance to providing health care, or in shortage. AMTs can directly improve product quality (e.g., through better manufacturing controls and fewer human interventions).

This guidance provides recommendations to persons and organizations interested in participating in FDA's Advanced Manufacturing Technologies Designation Program, which is intended to facilitate the development of drugs, including biological products, manufactured using an AMT that has been designated as such under the program (hereinafter *designated AMT*). The guidance outlines the eligibility criteria for AMT designation, the submission and assessment process for requests, and the benefits of receiving an AMT designation and includes a questions and answers section to cover additional details about key concepts important for program utilization. Specifically, the guidance describes:

[1] This guidance has been prepared by the Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research at the Food and Drug Administration.

- The process for submitting an AMT designation request, including a description of eligibility criteria and the data and other information to be included.

- When and how FDA will communicate receipt of and provide advice on an AMT designation request.

- When and how FDA will assess AMT designation requests.

- The process by which FDA will engage with holders of designated AMTs and applicants for drugs manufactured using, referencing, or relying upon a designated AMT.[2]

- Potential benefits related to drug development and application assessment.[3]

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 guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

FDA's Advanced Manufacturing Technologies Designation Program, which is required under section 506L of the Federal Food, Drug, and Cosmetic Act (FD&C Act),[4] offers a framework for persons or organizations (e.g., applicants, contract manufacturers, technology developers) to request designation of a method or combination of methods of manufacturing[5] a drug[6] as an AMT. The program is intended to facilitate the development of drugs that are manufactured using a designated AMT, submitted in an application under section 505 of the FD&C Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (PHS Act, 42 U.S.C. 262), and regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). The holder of the AMT designation or another authorized party may reference or rely upon data or information about the designated AMT in an application in the same context of use for which the designation was granted.[7] FDA will expedite

[2] In this guidance, the term *applicant* also refers to sponsors of investigational new drug applications.

[3] In this guidance, the term *assessment* also means *review*. *Assessment* is the term that the Center for Drug Evaluation and Research's Office of Pharmaceutical Quality and Office of Generic Drugs will generally use in place of *review*. *Assessment* means the process of both evaluating and analyzing submitted data and information to determine whether the application meets the requirements for approval and documenting that determination.

[4] Section 3213 of the Food and Drug Omnibus Reform Act of 2022 (FDORA) amended the FD&C Act, in part, to add section 506L, codified at 21 U.S.C. § 356l.

[5] In this guidance, the term *manufacturing* includes the steps outlined in the definition of *manufacture* in 21 CFR 207.1.

[6] In this guidance, the term *drug* refers to human drug products and biological products, and components of such products including active pharmaceutical ingredients, unless otherwise specified.

[7] See section 506L(c)(1) of the FD&C Act. In this guidance, *context of use* refers to the purpose and manner of use for a designated AMT that will be used in drug development and manufacturing.

development and assessment of an application, including supplements, for drugs that are manufactured using a designated AMT as described in section 506L(d)(1) of the FD&C Act.

Use of designated AMTs can provide greater assurance of quality, shorten drug development time, assist stakeholders in more efficiently meeting regulatory requirements for commercial manufacturing, and strengthen regulatory predictability for products that use a designated AMT. To encourage the adoption of designated AMTs, FDA offers early engagement opportunities, before application submission, with persons or organizations seeking designation of a method of manufacturing as an AMT (hereinafter *requestors*), designated AMT holders, and applicants to advise on designated AMTs and their implementation in drug manufacturing.

III. AMT DESIGNATION REQUESTS

Requestors should familiarize themselves with the data requirements described in section 506L of the FD&C Act, the recommendations outlined in this guidance, and other publicly available sources of product development information[8] before submitting an AMT designation request.

AMT designation requests are made independently of application submissions. Therefore, there is no predetermined stage of product development or specific application assessment cycle during which AMT designation requests can be submitted to FDA. Rather, requestors should submit their request when they have sufficient knowledge to support justification for AMT designation.

FDA strongly recommends that requestors engage with CDER's Emerging Technology Team (ETT) or CBER's Advanced Technologies Team (CATT), where appropriate, *before* submitting an AMT designation request. The ETT manages CDER's Emerging Technology Program and the CATT manages CBER's Advanced Technologies Program. Both programs assist companies interested in implementing emerging or advanced technologies in drug development and are suitable for less mature technologies, such as proof-of-concept or prototype systems or hypothetical processes that have not yet been developed.[9] Early engagement with the ETT or CATT provides an initial opportunity to discuss a technology before it has reached a maturity level appropriate for AMT designation.

A. Criteria

Per the criteria described in section 506L(b) of the FD&C Act, a method of manufacturing or combination of methods is eligible for AMT designation if it incorporates a novel[10] technology or uses an established technique or technology in a novel way that will substantially improve the

[8] See, e.g., International Council for Harmonisation guidance for industry *Q8(R2) Pharmaceutical Development* (November 2009). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[9] For information about ETT and CATT and how they differ from the Advanced Manufacturing Technologies Designation Program and these two other programs, see section V, Q5, in this guidance.

[10] For an explanation of how FDA interprets the term *novel* in the context of a technology or a use of that technology being considered for AMT designation, see section V, Q1.

manufacturing process for a drug while maintaining equivalent, or providing superior, drug quality, including by:

- Reducing development time for a drug using the designated manufacturing method; or

- Increasing or maintaining the supply of a drug that is life-supporting, life-sustaining, or of critical importance to providing health care, or a drug that is on the drug shortage list under section 506E of the FD&C Act (21 U.S.C. 356e).

Because FDA strongly recommends that requestors engage with the ETT or CATT before submitting an AMT designation request, the AMT for which they are seeking designation (hereinafter *proposed AMT*) should also generally meet the eligibility criteria described in CDER's Emerging Technology Program and CBER's Advanced Technologies Program.[11]

B. Content of the Request

An AMT designation request must include data or information demonstrating that the method of manufacturing meets the statutory criteria in a particular context of use.[12] In addition, the request must demonstrate the ability of the proposed AMT to substantially improve the manufacturing process for a drug while maintaining or improving upon its quality, including by reducing drug development time or increasing or maintaining the supply of a drug that is life-supporting, life-sustaining, of critical importance to providing health care, or in shortage.[13] The robustness of the data and information should be commensurate with the level of risk inherent to the process and potential product, such that the data and information can be later leveraged in a marketing application.

Specifically, an AMT designation request should include the following information:

- A brief description of the method of manufacturing or combination of methods and why it should be considered for AMT designation, including a brief explanation of how the method, in part or in whole, incorporates a novel technology or uses an established technique or technology in a novel way.

- A detailed description of how the method of manufacturing or combination of methods meets the eligibility criteria described in section 506L(b) of the FD&C Act in a particular context of use. This description should include:

  - An outline of the steps of the proposed AMT, including information about where in the overall manufacturing process the proposed AMT is intended to be used.

[11] For the Emerging Technology Program's eligibility criteria, see https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/how-participate-etp. For the scope of the Advanced Technologies Program, see https://www.fda.gov/vaccines-blood-biologics/industry-biologics/cber-advanced-technologies-team-catt.

[12] Section 506L(c)(1) of the FD&C Act.

[13] Section 506L(b) of the FD&C Act.

- A description of proposed process controls, quality information, and, if applicable, proposed controls of critical steps, intended to ensure equivalent or superior drug quality.

- Developmental data and information for the proposed AMT that evaluates and justifies the context of use.

- The context of use under which the proposed AMT will be used in drug development, including information (e.g., dosage form, class of drug) about a model (i.e., representative) drug used to generate data submitted in the request.

- Perceived regulatory, technical, or other challenges to implementation of the proposed AMT.

- The timeline, as applicable and if known at the time of the AMT designation request, for drug development activities that incorporate the proposed AMT, including the planned submission of any applications that would use, reference, or rely upon data and information about the proposed AMT in the same context of use.

- If applicable, information about previous engagement with ETT/CATT.

- For a proposed AMT that is intended for use in manufacturing an existing drug that meets the criteria in section 506L(b)(2)(A) or (B) of the FD&C Act:

  - A cross-reference to the existing application.

  - Data demonstrating that the proposed AMT will increase or maintain the supply of the drug and will maintain equivalent or provide superior drug quality.

FDA acknowledges that requestors who are not also applicants may not have data about a specific drug to include in their AMT designation request. In these cases, FDA recommends that requestors include data generated using a model drug to provide the Agency with a clear understanding of the proposed AMT's parameters, limitations, and context of use.

C. Submission Process

Requestors should submit their AMT designation request electronically to AMT_designation_requests@fda.hhs.gov.[14] The subject line should be REQUEST FOR AMT DESIGNATION in uppercase letters. In addition to the data and information described in section III.B of this guidance, the email should include the requestor's contact information—including the

[14] If the request includes confidential commercial information, it is the responsibility of the company to ensure it is submitted using one of FDA's secure messaging partners. Requestors can ask to be added to the list of FDA's secure messaging partners by emailing SecureEmail@fda.hhs.gov. Confidential commercial or trade secret information should be clearly marked as such in accordance with 21 CFR 20.61(d).

name, address, email address, and telephone number for their main point of contact–and indicate if the request is specific to CDER, CBER, or both.

Upon receipt of the AMT designation request, FDA intends to acknowledge receipt and begin an evaluation to determine whether to designate the proposed AMT.

D. Designation Determination

AMT designations will generally be limited to those methods of manufacturing that meet the criteria described in section 506L(b) of the FD&C Act and section III.A of this guidance. To determine eligibility, a team of FDA experts from the center with jurisdiction over the type of drug intended for development will review the request. This team, including members of the ETT or CATT, where applicable, will evaluate the data and information submitted in the request, including information relating to the context of use, and will seek input from subject matter experts, as needed, to determine if the proposed AMT meets the designation criteria and should therefore be granted AMT designation. For proposed AMTs that have potential cross-center impact, a cross-disciplinary team, including members from CDER and CBER, will evaluate the requests.[15]

The team will include a designated lead with demonstrated expertise in the manufacturing process, product type, or other elements specific to the proposed AMT to serve as the primary subject matter expert for the request. The designated lead may facilitate contact with the requestor to obtain additional information about the AMT designation request or to coordinate discussions with the team concerning specific aspects of the proposed AMT during the designation determination process.[16] As appropriate, the designated lead will facilitate the involvement of senior FDA managers and other experienced FDA staff in a collaborative, cross-disciplinary review of the proposed AMT.[17]

Section 506L(e)(2) of the FD&C Act requires FDA to complete AMT designation determinations regarding designation for a particular context of use and acceptance into the program in writing within 180 calendar days of FDA's receipt of the request.[18] Submission of an AMT designation request does not guarantee designation or acceptance into the program. FDA expects to deny requests that are incomplete or submitted for methods of manufacturing that do not meet the criteria described in 506L(b) of the FD&C Act.

E. Lifecycle

Designated AMT holders should communicate proposed changes to designated AMTs by emailing AMT_designation_requests@fda.hhs.gov. The subject line should be PROPOSED CHANGE FOR DESIGNATED AMT in uppercase letters. In addition to the requestor's contact information described in section III.C of this guidance, the email should include the name of the

[15] See section 506L(c)(1) (B) of the FD&C Act.

[16] See section 506L(c)(1)(A) of the FD&C Act.

[17] See section 506L(c)(1)(B) of the FD&C Act.

[18] See section 506L(c)(2) of the FD&C Act.

designated lead on the original AMT designation request and the product center that reviewed the request (CDER, CBER, or both), a brief description of the proposed change, and a list of persons or entities who have been given a right of reference to the designated AMT. The email should also address the potential impact of the proposed change on:

- Whether the designated AMT continues to meet the criteria for designation.
- The particular context of use for which the AMT was designated, as defined at the time of initial designation.
- Approved applications for products using, referencing, or relying upon the designated AMT.

FDA intends to assess the proposed changes, including data to support such changes, to confirm that the designated AMT continues to meet criteria for designation and to evaluate any potential impact on the particular context of use for which the AMT was designated. Applicants with approved applications that use, reference, or rely upon a designated AMT should evaluate the potential impact of the change on the finished product that is the subject of the application to determine whether a postapproval submission is required as described in 21 CFR 314.70 or 601.12.[19]

Once FDA has gained significant experience assessing a designated AMT and the designated AMT has been used in multiple approved regulatory applications, FDA may decide to graduate the technology and transfer the review of future applications that use, reference, or rely upon that AMT—including supplements to an original application that had previously been granted the designation—to the standard quality assessment process (rather than an expedited process). Doing so would allow FDA to focus resources on new AMTs that continue to meet the program's goal of encouraging adoption of novel technologies to shorten drug development times for critical medicines while maintaining or improving product quality.

IV. POTENTIAL BENEFITS OF AMT DESIGNATION

A key benefit of the Advanced Manufacturing Technologies Designation Program is FDA's early interaction with requestors and applicants regarding the development of drugs that may be manufactured using a designated AMT.[20] As resources permit, FDA intends to provide timely advice and to engage in additional communication, in the form of written correspondence or meetings, with requestors, designated AMT holders, and applicants for a drug manufactured using a designated AMT. Such communication may take place during both early drug development and subsequent application assessment and will be used to address proposed or designated AMT-related questions and issues, including AMT design or development issues, submission content related to a designated AMT, and other AMT-related topics. When

[19] To facilitate this evaluation, FDA recommends that entities that obtain a right of reference to reference or rely upon a designated AMT ensure the agreement includes mechanisms for communication regarding future changes.

[20] See sections 506L(c) and (d) of the FD&C Act.

appropriate, this process may include coordination with the appropriate FDA quality assessment team.

FDA expects to prioritize applicant interactions that are intended to discuss the use of a designated AMT in drug development or commercial manufacturing, with higher priority being given to drug development activities and applications using a designated AMT with the potential to significantly improve product quality, address known quality issues for a drug or class of drugs, or increase or maintain the supply of drugs that are currently in shortage or imminently at risk of being in shortage. Consideration for prioritization may also be given to drug development activities and applications that are accepted into other expedited programs (e.g., fast track, breakthrough therapy). For NDAs, BLAs, and ANDAs involving complex generic drugs, these interactions typically occur under the appropriate user fee meeting type[21] and are generally facilitated through the designated lead for the AMT request, in consultation with the application quality assessment team. Applicants should determine the frequency and timing of the meeting requests based on the stage of development of their drug. For ANDAs not involving complex generic drugs, these interactions would typically take place through controlled correspondence.[22] However, applicants with a designated AMT—whether the ANDA involves a complex product or a non-complex product—can also request product development and presubmission meetings.[23] Any additional interaction deemed necessary by FDA will be communicated and facilitated by the designated lead for the AMT request.

Using existing tools and resources, the designated lead will communicate to the applicant advice and information relevant to product quality to support the successful adoption of a designated AMT. As needed, the designated lead will also connect applicants with other FDA disciplines outside the scope of product quality when an applicant requires expertise or advice from these other disciplines.

It is the applicant's responsibility to demonstrate, through the required technical data submitted in the chemistry, manufacturing, and controls (CMC) section,[24] that a designated AMT is suitable for inclusion in their application.

[21] See draft guidances for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products,* Revision 1 (September 2023) and *Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products,* Revision 1 (August 2023). When final, these guidances will represent FDA's current thinking on these topics. See also guidances for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA,* Revision 1 (October 2022) and *Expedited Programs for Regenerative Medicine Therapies for Serious Conditions* (February 2019).

[22] See draft guidance for industry *Controlled Correspondence Related to Generic Drug Development* (December 2022). When final, this guidance will represent the FDA's current thinking on this topic.

[23] Applicants should submit requests for a product development meeting in an appropriate format, such as the format described in the guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA,* Revision 1. In addition to the applicable information identified in sections V and VIII of the Formal Meetings guidance, applicants should provide documentation of the AMT designation.

[24] See 21 CFR 314.50(d)(1), 21 CFR 314.94(a)(9), and 21 CFR 601.2.

A. Drug Development

Applicants are encouraged to take advantage of the benefits afforded under the program to engage with the team that designated the AMT to discuss, early in the development process, how the designated AMT can be used to shorten or otherwise optimize drug development time.[25] The designated lead will work to:

- Ensure that meetings with the applicant are collaborative and productive.
- Answer applicant questions about the information appropriate to be included in their application.
- Discuss the quality assessment of future applications that plan to use, reference, or rely upon a designated AMT.

B. Application Assessment

The designated lead will facilitate the quality assessment of an application for a drug manufactured using the designated AMT with the aim of making the assessment process more efficient than the process for applications using manufacturing methods not designated under the program. FDA intends to use this approach to support applicants while they are developing the CMC section of their applications such that the incorporation of a designated AMT will not increase the time or number of assessment cycles required to arrive at a quality-related decision and, as a result, will not increase the time required to arrive at a decision regarding overall application approval. When a designated AMT is used across multiple drugs, the knowledge and familiarity gained by FDA during assessment of the first application should streamline the assessment of subsequent applications that use the same designated AMT.

When a designated AMT no longer meets the eligibility criteria, as described in section III.E of this guidance, appropriate steps will be followed to transfer information about the previously designated AMT to the appropriate assessment team for applications that used, referenced, or relied upon the previously designated AMT. New applications received after the transfer occurs will be eligible for the standard level of FDA communication and interaction that the application would otherwise receive.

V. QUESTIONS AND ANSWERS

Q1. What does FDA consider a novel technology or use of an established technique or technology in a novel way?

For purposes of evaluating eligibility for AMT designation, FDA generally considers a novel technology to be one that has not been used in a previously approved application and for which FDA therefore has limited assessment or inspectional experience. Similarly, FDA generally

[25] See section V, Q7, in this guidance for information about requesting engagement.

considers an established technique or technology to be novel if it is used in a way that has not been described in a previously approved application. It is important to note that certain technologies or their uses may be considered novel but play such a limited role in the development or manufacture of a particular drug that their incorporation would not qualify the method of manufacturing for AMT designation. In such cases, the method of manufacturing would not meet the eligibility criteria for designation because, given its limited role, the novel technology or novel use that is incorporated would not be considered to substantially improve the manufacturing process for a drug.

Q2. How is context of use considered when determining AMT designation and assessing applications for other products (i.e., not the model drug used for the AMT designation request)?

Consistent with section 506L(c) of the FD&C Act, AMT designation applies to a method of manufacturing within a particular context of use rather than to a specific application. Nevertheless, the data and information necessary to support an AMT designation request should, at a minimum, be specific to a particular class of drugs and, as described in section III of this guidance, should include development data, including batch analysis data generated using either a developmental candidate molecule or a model drug.

Requestors should fully and clearly describe the context of use within which they are requesting the AMT be designated, including how it will be used to develop and manufacture a specific type or range of drugs. Requestors can contact their designated lead to request an update to the context of use for a designated AMT when additional supportive data become available (e.g., additional batch analysis data from additional products). FDA will determine on a case-by-case basis whether to update the context of use (e.g., the scope of drugs to be manufactured using the designated AMT) for the designated AMT as proposed by the requestor or if additional data are necessary to support the expanded designation request.

Whether the use of a designated AMT for manufacturing a specific drug that is the subject of an application would be considered to be the same context of use for which the AMT was designated can be discussed in presubmission meetings and will be determined during the application assessment process.

Q3. How can an applicant reference or rely upon a designated AMT in an application?

When an applicant and designated AMT holder are different entities, the designated AMT holder can authorize the applicant to incorporate by reference data and information about the designated AMT in their application. In some cases, the designated AMT holder may also be the holder of a drug master file (DMF) that contains the designated AMT.[26] In those circumstances, an applicant submitting an NDA or ANDA can, to support their application and with an appropriate right of reference, generally reference a DMF. However, when a DMF holder is also the holder of a designated AMT, information specifically describing the designated AMT should be shared with the NDA or ANDA applicant. An application that references or relies upon a designated AMT

[26] See 21 CFR 314.420.

can receive the benefits provided by the AMT designation with the appropriate authorization if the referenced AMT is used to manufacture a drug in the same context of use for which the designation was granted as described above.

Although multiple applications can reference the same designated AMT, each application referencing a particular designated AMT will be assessed on its own merits. When referencing or relying upon a designated AMT in an application, applicants should explain how the designated AMT will be used to manufacture the drug that is the subject of the application and why that context of use is consistent with the context of use for which the AMT received designation.

Q4. How can designated AMTs be used, referenced, or relied upon in a BLA as compared to an NDA or ANDA?

Because AMT designation is granted outside the context of a specific application, a designated AMT can support a small molecule drug or biological product. Because a BLA holder is expected to have knowledge of and control over the manufacturing process for the biological product for which it has a license, FDA generally expects such information to be submitted directly to the BLA.[27] For this reason, the BLA applicant should have access to the supportive data and information for drug substance, drug substance intermediate, and drug product manufacturing relevant to the AMT and should not incorporate by reference a designated AMT, including by referencing a DMF that contains a designated AMT.

Q5. How does the Advanced Manufacturing Technologies Designation Program differ from CDER's Emerging Technology Program and CBER's Advanced Technologies Program?

All three programs focus on early engagement between FDA and prospective developers of CDER- or CBER-regulated products to discuss potential regulatory challenges and clarify related questions. CDER's Emerging Technology Program allows potential applicants, before application submission, to submit questions and proposals about the use of a specific emerging technology to the ETT, a group that serves as the primary point of contact for companies interested in implementing an emerging technology into their products regulated by CDER. CBER's Advanced Technologies Program promotes dialogue, education, and input between CBER and prospective developers of advanced manufacturing and testing technologies. The CATT facilitates such communications to promote the implementation of these technologies in the development of products regulated by CBER.[28]

As discussed earlier, engaging with the ETT or CATT is highly encouraged before requesting AMT designation. FDA recommends not requesting AMT designation at the same time as

[27] See 21 CFR 601.2 and draft guidance for industry *Drug Master Files* (October 2019). When final, this guidance will represent the FDA's current thinking on this topic.

[28] For more information about CDER's Emerging Technology Program, see guidance for industry *Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization* (September 2017) and https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/emerging-technology-program. For more information about CBER's Advanced Technologies Program, see https://www.fda.gov/vaccines-blood-biologics/industry-biologics/cber-advanced-technologies-program.

ETT/CATT engagement because ETT and CATT discussions generally occur earlier in the drug development process and are intended for less mature methods and technologies compared to AMT designation, which is intended for more mature methods and technologies (e.g., for which model drug-specific data are available).

In some cases, a particular technology that is not accepted into CDER's Emerging Technology Program or CBER's Advanced Technologies Program could nevertheless be eligible for AMT designation. For example, a method of manufacturing could already be at a stage where it is ready for commercial-scale production. The opposite could also be the case. For example, as noted in section III, it is possible that the data and information necessary for AMT designation might not yet be available for a technology granted acceptance into CDER's Emerging Technology Program or CBER's Advanced Technologies Program.

There are several differences between the three programs. For example, CDER's Emerging Technology Program and CBER's Advanced Technologies Program can involve activities outside the scope of AMT designation, such as training of FDA staff. AMT designation requests are also limited to manufacturing methods, whereas discussions with external stakeholders through ETT and CATT can involve other elements, such as novel dosage forms or drug delivery systems.

As discussed elsewhere in this guidance, a requestor or designated AMT holder may not necessarily be the same entity as the applicant who ultimately uses a designated AMT in an application. Although a participant in CDER's Emerging Technology Program can also engage with the ETT without a specific product in development yet, the Emerging Technology Program is primarily designed for companies that intend to eventually incorporate an emerging technology into the CMC section of their application. For CBER's Advanced Technologies Program, the CATT is limited to early engagement before regulatory submission. Therefore, any meetings regarding the use of a designated AMT that take place after application submission would generally occur through the Advanced Manufacturing Technologies Designation Program.

Q6. How does the Advanced Manufacturing Technologies Designation Program differ from the Platform Technology Designation Program?

Both the Advanced Manufacturing Technologies Designation Program and the Platform Technology Designation Program[29] aim to increase the efficiency of drug development and manufacturing. However, the two programs generally serve different purposes and apply to different types of technologies.

Regarding program purpose, one of the distinguishing criteria for a method of manufacturing or combination of methods being proposed for AMT designation is that it must incorporate a novel technology or an established technique or technology used in a novel way.[30] In contrast, one of the distinguishing criteria of a designated platform technology is that it is a well-understood and

[29] See section 506K of the FD&C Act (21 U.S.C. 356k), added by section 2503 of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act of 2022).

[30] See section 505L(b) of the FD&C Act.

reproducible technology that is incorporated in or utilized by an approved drug or licensed biological product.[31] For this reason, FDA expects to have previous assessment or inspectional experience with a designated platform technology.

Regarding eligible methods of manufacturing, a designated AMT is limited to a method or combination of methods of manufacturing a drug. In contrast, a broader range of technologies (e.g., nucleic acid sequences, molecular structures, mechanisms of action, delivery methods) is eligible for platform technology designation, and applicants must demonstrate, among other criteria,[32] that the platform technology is incorporated in or utilized by a drug and is essential to the structure or function of such drug to receive designation.[33]

Because of these differences between the two programs, FDA strongly recommends requesting only the designation that is appropriate for the particular method or technology in question. There should be no expectation that requesting both designations simultaneously would offer additional benefits.

Q7. How should an applicant request engagement with FDA regarding the use of a designated AMT?

Applicants can request a meeting with FDA to have a preliminary discussion about using a designated AMT and request subsequent meetings throughout the drug development process. As described in section IV of this guidance, such meeting requests will typically occur under the appropriate user fee meeting type and should be made in accordance with the electronic submission guidance[34] and other guidances related to formal meetings between FDA and applicants.[35] Although applicants can request such a meeting at any milestone during the application assessment process, FDA encourages earlier engagement to enable prompt resolution of regulatory challenges and more efficient application assessment. Any such submissions should be clearly identified as a **REQUEST FOR A MEETING UNDER THE ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PROGRAM** in bold, uppercase letters. In addition to the content recommended in relevant guidances,[36] the meeting background package should include the timing for application submission and a summary of how the designated AMT will be used to manufacture the drug.

[31] See section 506K(b)(1) of the FD&C Act.

[32] See section 506K(h)(1) of the FD&C Act.

[33] See section 506K(h)(1)(A) of the FD&C Act.

[34] See guidance for industry *Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (February 2020).

[35] See footnote 21.

[36] Ibid.