4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-4974]

Advanced Manufacturing Technologies Designation Program; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Advanced Manufacturing Technologies Designation Program." FDA encourages the early adoption of advanced manufacturing technologies (AMTs) by the pharmaceutical industry, which can improve the reliability and robustness of the manufacturing process and can benefit patients by enhancing product quality and reducing drug development time or increasing or maintaining the supply of drugs that are life-supporting, life-sustaining, of critical importance to providing health care, or in shortage. This guidance provides recommendations to persons and organizations interested in participating in FDA's Advanced Manufacturing Technologies Designation Program, which facilitates the development of drugs manufactured using an AMT that has been designated as such under the program. The guidance finalizes the draft guidance of the same title issued on December 13, 2023.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-D-4974 for "Advanced Manufacturing Technologies Designation Program." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and

Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ranjani Prabhakara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6648, Silver Spring, MD 20993, 240-402-4652; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Advanced Manufacturing Technologies Designation Program." FDA's Advanced Manufacturing Technologies Designation Program, which is required under section 506L of the Federal Food, Drug, and Cosmetic Act (FD&C Act, 21 U.S.C. 356l), 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 a drug as an AMT. The program facilitates the development of drugs as described in section 506L(b) of the FD&C Act 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 (42 U.S.C. 262), and regulated by CDER or CBER. An application or supplemental application referencing a designated AMT can receive certain benefits under the program, such as FDA's early interaction with applicants regarding the development and manufacture of drugs using a designated AMT, as described in section 506L(c)(1) of the FD&C Act.

The guidance outlines the eligibility criteria for AMT designation, the submission and assessment process for requests, including data and information to be submitted, and the benefits

of receiving an AMT designation, among other information, and includes a questions and answers section to cover additional details about key concepts important for program utilization. The guidance finalizes the draft guidance of the same title issued on December 13, 2023 (88 FR 86333). FDA considered comments received on the draft guidance in finalizing the guidance. FDA made changes from the draft guidance to improve clarity about the AMT designation process, the content of AMT designation requests, the roles and responsibilities of different entities involved in the development and use of designated AMTs, and the relationship between the Advanced Manufacturing Technologies Designation Program and other FDA programs addressing emerging or advanced technologies.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Advanced Manufacturing Technologies Designation Program." 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.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. FDA is issuing this guidance, as final, in accordance with section 506L of the FD&C Act, which directs FDA to initiate a program and establish a process for AMT designation, including information collection provisions subject to review and approval by OMB under the PRA. Section 506L(e)(2) of the FD&C Act further directs FDA to issue program guidance. Before implementing the information collection provisions of the guidance, FDA will publish a notice in the *Federal Register* continuing to invite public comment on the proposed collections of information (see 88 FR 86333) and announce OMB's decision to approve, modify, or disapprove the collections of information, including the OMB control number(s).

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, or https://www.regulations.gov.

Dated: December 27, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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