Report to Congress

Advanced Manufacturing Technologies Designation Program

Section 506L of the Federal Food, Drug, and Cosmetic Act
CY 2025 Report

Food and Drug Administration

Executive Summary

On December 29, 2022, the Food and Drug Omnibus Reform Act of 2022 (FDORA) was signed into law as part of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 (2022). Section 3213 of FDORA established FDA's Advanced Manufacturing Technologies (AMT) Designation Program by amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 506L (21 U.S.C. 356l). Section 506L(e)(3) of the FD&C Act requires FDA to submit a report on the AMT Designation Program not later than three years after enactment and annually thereafter. Such report shall include the following information:

- The number of persons that have requested designations and that have been granted designations.
- The number of methods of manufacturing that have been the subject of designation requests and that have been granted designations.
- The average number of calendar days for completion of evaluations under section 506L(c)(2).
- An analysis of the factors in data submissions that result in determinations to designate and not to designate after evaluation under section 506L(c)(2).
- The number of applications received under section 505 of the FD&C Act or section 351 of the Public Health Service Act (PHS Act) including supplemental applications, that have included an advanced manufacturing technology designated under section 506L, and the number of such applications approved.

This report fulfills the statutory mandate for FDA to submit, within three years of enactment of section 506L, and annually thereafter, a report containing a description and evaluation of the AMT Designation Program, including the types of innovative manufacturing approaches supported under such Program.

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Acronym List

AMT	Advanced Manufacturing Technologies
ANDA	Abbreviated New Drug Application
BLA	Biologics License Application
CATT	CBER's Advanced Technologies Team
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
ETT	CDER's Emerging Technology Team
FDA	Food and Drug Administration
FDORA	Food and Drug Omnibus Reform Act of 2022
FD&C Act	Federal Food, Drug, and Cosmetic Act
NDA	New Drug Application
PHS Act	Public Health Service Act

I. Background

On December 29, 2022, the Food and Drug Omnibus Reform Act of 2022 (FDORA) was signed into law as part of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 (2022). Section 3213 of FDORA established FDA's Advanced Manufacturing Technologies (AMT) Designation Program by amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 506L (21 U.S.C. 356l). The AMT Designation Program 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, including a biological product, and active pharmaceutical ingredients of such drugs[1] as an AMT if such method or combination of methods incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially improve the manufacturing process while maintaining equivalent, or providing superior, drug quality. 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 (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).

In connection with section 506L(e)(1) of the FD&C Act, FDA held a public meeting on June 8, 2023, to discuss and obtain input and recommendations from relevant external partners regarding:

- the goals and scope of the AMT Designation Program, and the framework, procedures, and requirements suitable for the Program; and

- ways in which FDA will support the use of advanced manufacturing technologies and other innovative manufacturing approaches for drugs.

Subsequently, in connection with section 506L(e)(2) of the FD&C Act, FDA issued a draft guidance on December 13, 2023 (88 FR 86333), regarding the goals and implementation of the AMT Designation Program. A 90-day public comment period followed issuance of the draft guidance. On December 31, 2024, FDA issued a final guidance (90 FR 110) that finalized the draft guidance of the same title. 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 AMT Designation Program and other FDA programs addressing emerging or advanced technologies.

[1] For purposes of this report, hereafter the term *drugs* will be used to collectively refer to "drugs, including biological products, and active pharmaceutical ingredients of such drugs."

Section 506L(e)(3) of the FD&C Act requires FDA to publish on its website and submit to Congress a report, not later than 3 years after the date of enactment of this section and annually thereafter, containing a description and evaluation of the AMT Designation Program being conducted under section 506L, including the types of innovative manufacturing approaches supported under the program. The statutory requirement in section 506L(e)(3) is as follows:

> *(3) REPORT.—Not later than 3 years after the date of enactment of this section and annually thereafter, the Secretary shall publish on the website of the Food and Drug Administration and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing a description and evaluation of the program being conducted under this section, including the types of innovative manufacturing approaches supported under the program. Such report shall include the following:*
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> > *(A) The number of persons that have requested designations and that have been granted designations.*
> >
> > *(B) The number of methods of manufacturing that have been the subject of designation requests and that have been granted designations.*
> >
> > *(C) The average number of calendar days for completion of evaluations under subsection (c)(2).*
> >
> > *(D) An analysis of the factors in data submissions that result in determinations to designate and not to designate after evaluation under subsection (c)(2).*
> >
> > *(E) The number of applications received under section 505 of [the FD&C Act] or section 351 of the [PHS Act], including supplemental applications, that have included an advanced manufacturing technology designated under this section, and the number of such applications approved.*

II. Requested Information

AMT designations are limited to those methods of manufacturing that meet the criteria described in section 506L of the FD&C Act. To determine eligibility, a team of FDA experts from the center (CBER, CDER, or both) with jurisdiction over the type of drug that would incorporate the proposed AMT reviews the request.

As of October 16, 2025, FDA has received 18 designation requests and granted 3 designations, with 9 requests currently under active review. Below we discuss the designation requests, granted designations, and the other requested information more specifically within the context of the product center, CBER and CDER, that evaluated the designation request. To date, no designation requests have required both CBER and CDER evaluation.

A. Center for Biologics Evaluation and Research

As of October 16, 2025, since enactment of section 506L of the FD&C Act, CBER has received 13 designation requests from 13 separate entities, and granted 3 designations with 6 requests under active review. The types of manufacturing methods granted AMT designation include those that enable automated manufacturing of cell-based therapies.

For all the requests for which CBER has made designation determinations, CBER issued AMT designation determination letters within the 180-day statutory timeframe for completion of evaluation under section 506L(c)(2), with an average completion time of 157 calendar days.

Consistent with the criteria for AMT designation under section 506L(b), factors in data submissions that resulted in determinations to designate methods of manufacturing as AMTs included:

- Novelty, appropriate selection of comparators (e.g., industry standards).
- Robust demonstration of equivalent or superior drug quality using the proposed AMT versus comparator.
- Reduction in drug development time or improvement of the existing manufacturing process, and/or increase in or maintaining critical drug supplies.

Common reasons for designation denial included:

- Incomplete or insufficient data packages that lacked critical quality attributes or at-scale quality data.
- Unsubstantiated claims of manufacturing process or drug supply improvement.
- Lack of novelty relative to regulatory assessment and inspection experience or industry standards.

CBER has not received any original applications or efficacy supplements to an approved application under section 505 of the FD&C Act or section 351 of the PHS Act that have included an AMT designated under section 506L of the FD&C Act.

B. Center for Drug Evaluation and Research

As of October 16, 2025, since enactment of section 506L of the FD&C Act, CDER has received 5 designation requests from 5 separate entities, and granted 0 designations, with 3 requests under active review.

For both of the requests for which CDER has made a designation determination, CDER issued AMT designation determination letters within the 180-day statutory timeframe for completion of evaluation under section 506L(c)(2), with an average completion time of 179 calendar days.

Consistent with the criteria for AMT designation under section 506L(b), factors in data submissions that resulted in determinations to not designate methods of manufacturing as AMTs included:

- Absence of information describing the potential of the technology to reduce drug development time or improve the existing manufacturing process, and/or increase or maintain critical drug supplies.
- Absence of information to describe how the technology meets the criteria for a particular context of use.
- A lack of demonstration that the proposed technology reflects a novel method of manufacturing.

CDER has not received any applications under section 505 of the FD&C Act or section 351 of the PHS Act that have included an AMT designated under section 506L of the FD&C Act.

III. Conclusion

This report fulfills the statutory mandate, under section 506L(e)(3) of the FD&C Act, for the first report containing a description and evaluation of the AMT Designation Program, including the types of innovative manufacturing approaches supported under the Program. Per section 506L of the FD&C Act, FDA will continue to submit annual reports containing this information.

This report was prepared by FDA's Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research. For information on obtaining additional copies, please contact:

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This report is available on FDA's home page at https://www.fda.gov/.