tion for the drug with respect to which designation of the designated platform technology under subsection (d) was granted; or

(2) the sponsor relying on such data and information received a right of reference to such data and information from the sponsor described in paragraph (1).

(g) Changes to a designated platform technology

A sponsor of more than one application approved under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for drugs that incorporate or utilize a designated platform technology may submit a single supplemental application for proposed changes to the designated platform technology that may be applicable to more than one such drug that incorporates or utilizes the same designated platform technology. Such supplemental application may cross-reference data and information submitted in other applications and may include one or more comparability protocols regarding how such changes to the platform technology would be made for each applicable drug or biological product.

(h) Definitions

For purposes of this section:

(1) The term ''platform technology'' means a well-understood and reproducible technology, which may include a nucleic acid sequence, molecular structure, mechanism of action, delivery method, vector, or a combination of any such technologies that the Secretary determines to be appropriate, that the sponsor demonstrates—

(A) is incorporated in or utilized by a drug or biological product and is essential to the structure or function of such drug or biological product;

(B) can be adapted for, incorporated into, or utilized by, more than one drug or biological product sharing common structural elements; and

(C) facilitates the manufacture or development of more than one drug or biological product through a standardized production or manufacturing process or processes.

(2) The term ''designated platform technology'' means a platform technology that is designated as a platform technology under subsection (d).

(i) Rule of construction

Nothing in this section shall be construed to—

(1) alter the authority of the Secretary to approve drugs pursuant to section 505 of this Act [21 U.S.C. 355] or license biological products pursuant to section 351 of the Public Health Service Act [42 U.S.C. 262], including standards of evidence and applicable conditions for approval or licensure under the applicable Act; or

(2) confer any new rights with respect to the permissibility of a sponsor of an application for a drug product or biological product referencing information contained in another application submitted by the holder of an approved application under section 355(c) of this title or of a license under section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)].

(June 25, 1938, ch. 675, § 506K, as added Pub. L. 117–328, div. FF, title II, § 2503(a), Dec. 29, 2022, 136 Stat. 5798.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (d)(5), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Statutory Notes and Related Subsidiaries

GUIDANCE

Pub. L. 117–328, div. FF, title II, § 2503(b), Dec. 29, 2022, 136 Stat. 5801, provided that: ''Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall issue draft guidance on the implementation of this section. Such guidance shall include examples of drugs that can be manufactured using platform technologies, including drugs that contain or consist of vectors and nucleic acids, information about the Secretary's review of platform technologies, information regarding submitting for designation, considerations for persons submitting a request for designation who have been granted a right of reference, the implementation of the designated platform technology designation program, efficiencies that may be achieved in the development and review of products that incorporate or utilize designated platform technologies, and recommendations and requirements for making and reporting manufacturing changes to a designated platform technology in accordance with section 506K(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 356k(g)] (as added by subsection (a)) and section 506A of such Act (21 U.S.C. 356a), as applicable.''

§ 356*l*. Advanced manufacturing technologies designation program

(a) In general

Not later than 1 year after December 29, 2022, the Secretary shall initiate a program under which persons may request designation of an advanced manufacturing technology as described in subsection (b).

(b) Designation process

The Secretary shall establish a process for the designation under this section of methods of manufacturing drugs, including biological products, and active pharmaceutical ingredients of such drugs, as advanced manufacturing technologies. A method of manufacturing, or a combination of manufacturing methods, is eligible for designation as an advanced manufacturing technology 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 for a drug while maintaining equivalent, or providing superior, drug quality, including by—

(1) reducing development time for a drug using the designated manufacturing method; or

(2) increasing or maintaining the supply of—

(A) a drug that is life-supporting, life-sustaining, or of critical importance to providing health care; or

(B) a drug that is on the drug shortage list under section 356e of this title.

(c) Evaluation and designation of an advanced manufacturing technology

(1) Submission

A person who requests designation of a method of manufacturing as an advanced manufacturing technology under this section shall submit to the Secretary data or information demonstrating that the method of manufacturing meets the criteria described in subsection (b) in a particular context of use. The Secretary may facilitate the development and review of such data or information by—

(A) providing timely advice to, and interactive communication with, such person regarding the development of the method of manufacturing; and

(B) involving senior managers and experienced staff of the Food and Drug Administration, as appropriate, in a collaborative, cross-disciplinary review of the method of manufacturing, as applicable.

(2) Evaluation and designation

Not later than 180 calendar days after the receipt of a request under paragraph (1), the Secretary shall determine whether to designate such method of manufacturing as an advanced manufacturing technology, in a particular context of use, based on the data and information submitted under paragraph (1) and the criteria described in subsection (b).

(d) Review of advanced manufacturing technologies

If the Secretary designates a method of manufacturing as an advanced manufacturing technology, the Secretary shall—

(1) expedite the development and review of an application submitted under section 355 of this title or section 262 of title 42, including supplemental applications, for drugs that are manufactured using a designated advanced manufacturing technology; and

(2) allow the holder of an advanced technology designation, or a person authorized by the advanced manufacturing technology designation holder, to reference or rely upon, in an application submitted under section 355 of this title or section 262 of title 42, including a supplemental application, data and information about the designated advanced manufacturing technology for use in manufacturing drugs in the same context of use for which the designation was granted.

(e) Implementation and evaluation of advanced manufacturing technologies program

(1) Public meeting

The Secretary shall publish in the Federal Register a notice of a public meeting, to be held not later than 180 days after December 29, 2022, to discuss, and obtain input and recommendations from relevant stakeholders regarding—

(A) the goals and scope of the program under this section, and the framework, procedures, and requirements suitable for such program; and

(B) ways in which the Food and Drug Administration will support the use of advanced manufacturing technologies and other innovative manufacturing approaches for drugs.

(2) Program guidance

(A) In general

The Secretary shall—

(i) not later than 180 days after the public meeting under paragraph (1), issue draft guidance regarding the goals and implementation of the program under this section; and

(ii) not later than 2 years after December 29, 2022, issue final guidance regarding the implementation of such program.

(B) Content

The guidance described in subparagraph (A) shall address—

(i) the process by which a person may request a designation under subsection (b);

(ii) the data and information that a person requesting such a designation is required to submit under subsection (c), and how the Secretary intends to evaluate such submissions;

(iii) the process to expedite the development and review of applications under subsection (d); and

(iv) the criteria described in subsection (b) for eligibility for such a designation.

(3) Report

Not later than 3 years after December 29, 2022, 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:

(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 355 of this title or section 262 of title 42, including supplemental applications, that have included an advanced manufacturing technology designated under this section, and the number of such applications approved.

(f) Sunset

The Secretary—

(1) may not consider any requests for designation submitted under subsection (c) after October 1, 2032; and

(2) may continue all activities under this section with respect to advanced manufacturing technologies that were designated pursuant to subsection (b) prior to such date, if the Secretary determines such activities are in the interest of the public health.

(June 25, 1938, ch. 675, § 506L, as added Pub. L. 117–328, div. FF, title III, § 3213, Dec. 29, 2022, 136 Stat. 5826.)

§ 357. Qualification of drug development tools

(a) Process for qualification

(1) In general

The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use under which—

(A)(i) a requestor initiates such process by submitting a letter of intent to the Secretary; and

(ii) the Secretary accepts or declines to accept such letter of intent;

(B)(i) if the Secretary accepts the letter of intent, a requestor submits a qualification plan to the Secretary; and

(ii) the Secretary accepts or declines to accept the qualification plan; and

(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

(ii) the Secretary determines whether to accept such qualification package for review; and

(iii) if the Secretary accepts such qualification package for review, the Secretary conducts such review in accordance with this section.

(2) Acceptance and review of submissions

(A) In general

Subparagraphs (B), (C), and (D) shall apply with respect to the treatment of a letter of intent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as ''qualification submissions'').

(B) Acceptance factors; nonacceptance

The Secretary shall determine whether to accept a qualification submission based on factors which may include the scientific merit of the qualification submission. A determination not to accept a submission under paragraph (1) shall not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

(C) Prioritization of qualification review

The Secretary may prioritize the review of a full qualification package submitted under paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

(i) as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug development tool and the availability or lack of alternative treatments for such disease or condition; and

(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of such a drug development tool and its proposed context of use as a public health priority.

(D) Engagement of external experts

The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of such consortia with respect to the review of any qualification plan submitted under paragraph (1) or the review of any full qualification package under paragraph (3).

(3) Review of full qualification package

The Secretary shall—

(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

(4) Qualification

The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on the scientific merit of a full qualification package reviewed under paragraph (3).

(b) Effect of qualification

(1) In general

A drug development tool determined to be qualified under subsection (a)(4) for a proposed context of use specified by the requestor may be used by any person in such context of use for the purposes described in paragraph (2).

(2) Use of a drug development tool

Subject to paragraph (3), a drug development tool qualified under this section may be used for—

(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 356(c) of this title) under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262]; or

(B) supporting the investigational use of a drug or biological product under section 355(i) of this title or section 351(a)(3) of the Public Health Service Act [42 U.S.C. 262(a)(3)].

(3) Rescission or modification

(A) In general

The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. Such a determination may be based on new information that calls into question the basis for such qualification.

(B) Meeting for review

If the Secretary rescinds or modifies under subparagraph (A) a determination to qualify