

interruption in the manufacture of a device for which such notification is received. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.”

GUIDANCE ON DEVICE SHORTAGE NOTIFICATION
REQUIREMENT

Pub. L. 117-328, div. FF, title II, §2514(c), Dec. 29, 2022, 136 Stat. 5806, provided that: “Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary shall issue or revise draft guidance regarding requirements under section 506J of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j). Such guidance shall include a list of each device product code for which a manufacturer of such device is required to notify the Secretary in accordance with section 506J.”

§ 356k. Platform technologies

(a) In general

The Secretary shall establish a program for the designation of platform technologies that meet the criteria described in subsection (b).

(b) Criteria

A platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology under this section if—

(1) the platform technology is incorporated in, or utilized by, a drug approved under section 355 of this title or a biological product licensed under section 351 of the Public Health Service Act [42 U.S.C. 262];

(2) preliminary evidence submitted by the sponsor of the approved or licensed drug described in paragraph (1), or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and

(3) data or information submitted by the applicable person under paragraph (2) indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process.

(c) Request for designation

A person may request the Secretary designate a platform technology as a designated platform technology concurrently with, or at any time after, submission 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)] for the investigation of a drug that incorporates or utilizes the platform technology that is the subject of the request.

(d) Designation

(1) In general

Not later than 90 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the platform technology that is the subject of the request meets the criteria described in subsection (b).

(2) Designation

If the Secretary determines that the platform technology meets the criteria described

in subsection (b), the Secretary shall designate the platform technology as a designated platform technology and may expedite the development and review of any subsequent application submitted under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for a drug that uses or incorporates the platform technology pursuant to subsection (e), as appropriate.

(3) Determination not to designate

If the Secretary determines that the platform technology does not meet the criteria under subsection (b), the Secretary shall include with the determination not to designate the technology a written description of the rationale for such determination.

(4) Revocation of designation

The Secretary may revoke a designation made under paragraph (2), if the Secretary determines that the designated platform technology no longer meets the criteria described in subsection (b). The Secretary shall communicate the determination to revoke a designation to the requesting sponsor in writing, including a description of the rationale for such determination.

(5) Applicability

Nothing in this section shall prevent a product that uses or incorporates a designated platform technology from being eligible for expedited approval pathways if it is otherwise eligible under this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.].

(e) Actions

The Secretary may take actions to expedite the development and review of an application for a drug that incorporates or utilizes a designated platform technology, including—

(1) engaging in early interactions with the sponsor to discuss the use of the designated platform technology and what is known about such technology, including data previously submitted that is relevant to establishing, as applicable, safety or efficacy under section 355(b) of this title or safety, purity, or potency under section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)];

(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug that proposes to use the designated platform technology to ensure that the development program designed to gather data necessary for approval or licensure is as efficient as practicable, which may include holding meetings with the sponsor and the review team throughout the development of the drug; and

(3) considering inspectional findings, including prior findings, related to the manufacture of a drug that incorporates or utilizes the designated platform technology.

(f) Leveraging data from designated platform technologies

The Secretary shall, consistent with applicable standards for approval, authorization, or licensure under this chapter and section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)], allow the sponsor of an application under sec-

tion 355(b) of this title or section 351(a) of the Public Health Service Act or a request for emergency use authorization under section 360bbb-3 of this title, in order to support approval, licensure, or authorization, to reference or rely upon data and information within an application or request for a drug or biological product that incorporates or utilizes the same platform technology designated under subsection (d), provided that—

(1) such data and information was submitted by the same sponsor, pursuant to the application 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.”

§ 356I. 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