(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 a drug development tool, the requestor involved shall, on request, be granted a meeting with the Secretary to discuss the basis of the Secretary's decision to rescind or modify the determination before the effective date of the rescission or modification.

(c) Transparency

(1) In general

Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a biannual basis, on the Internet website of the Food and Drug Administration the following:

(A) Information with respect to each qualification submission under the qualification process under subsection (a), including—

(i) the stage of the review process applicable to the submission;

(ii) the date of the most recent change in stage status;

(iii) whether external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package; and

(iv) submissions from requestors under the qualification process under subsection (a), including any data and evidence contained in such submissions, and any updates to such submissions.

(B) The Secretary's formal written determinations in response to such qualification submissions.

(C) Any rescissions or modifications under subsection (b)(3) of a determination to qualify a drug development tool.

(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (a).

(E) A comprehensive list of—

(i) all drug development tools qualified under subsection (a); and

(ii) all surrogate endpoints which were the basis of 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].

(2) Relation to Trade Secrets Act

Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18.

(3) Applicability

(A) In general

Nothing in this section shall be construed as authorizing or directing the Secretary to disclose—

(i) any information contained in an application submitted under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] that is confidential commercial or trade secret information subject to section 552(b)(4) of title 5 or section 1905 of title 18; or

(ii) in the case of a drug development tool that may be used to support the development of a qualified countermeasure, security countermeasure, or qualified pandemic or epidemic product, as defined in sections 319F–1, 319F–2, and 319F–3, respectively, of the Public Health Service Act [42 U.S.C. 247d–6a, 247d–6b, 247d–6d], any information that the Secretary determines has a significant potential to affect national security.

(B) Public acknowledgment

In the case that the Secretary, pursuant to subparagraph (A)(ii), does not make information publicly available, the Secretary shall provide on the internet website of the Food and Drug Administration an acknowledgment of the information that has not been disclosed, pursuant to subparagraph (A)(ii).

(d) Rule of construction

Nothing in this section shall be construed—

(1) to alter the standards of evidence under subsection (c) or (d) of section 355 of this title,

including the substantial evidence standard in such subsection (d), or under section 351 of the Public Health Service Act [42 U.S.C. 262] (as applicable); or

(2) to limit the authority of the Secretary to approve or license products under this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], as applicable (as in effect before December 13, 2016).

(e) Definitions

In this section:

(1) Biomarker

The term ''biomarker''—

(A) means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention; and

(B) includes a surrogate endpoint.

(2) Biomedical research consortia

The term ''biomedical research consortia'' means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 1001(a) of title 20), patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.

(3) Clinical outcome assessment

The term ''clinical outcome assessment'' means—

(A) a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and

(B) includes a patient-reported outcome.

(4) Context of use

The term ''context of use'' means, with respect to a drug development tool, the circumstances under which the drug development tool is to be used in drug development and regulatory review.

(5) Drug development tool

The term ''drug development tool'' includes—

(A) a biomarker;

(B) a clinical outcome assessment; and

(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.

(6) Patient-reported outcome

The term ''patient-reported outcome'' means a measurement based on a report from a patient regarding the status of the patient's health condition without amendment or interpretation of the patient's report by a clinician or any other person.

(7) Qualification

The terms ''qualification'' and ''qualified'' mean a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this chapter.

(8) Requestor

The term ''requestor'' means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.

(9) Surrogate endpoint

The term ''surrogate endpoint'' means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and—

(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or

(B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product in accordance with section 356(c) of this title.

(June 25, 1938, ch. 675, § 507, as added Pub. L. 114–255, div. A, title III, § 3011(a), Dec. 13, 2016, 130 Stat. 1086; amended Pub. L. 116–22, title VII, § 705(e), June 24, 2019, 133 Stat. 964.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (d)(2), 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.

PRIOR PROVISIONS

A prior section 357, act June 25, 1938, ch. 675, § 507, as added July 6, 1945, ch. 281, § 3, 59 Stat. 463; amended Mar. 10, 1947, ch. 16, § 3, 61 Stat. 12; July 13, 1949, ch. 305, § 2, 63 Stat. 409; Aug. 5, 1953, ch. 334, § 2, 67 Stat. 389; Pub. L. 87–781, title I, §§ 105(a), (b), (d)–(f), 106(a), (b), Oct. 10, 1962, 76 Stat. 785, 786, 787; Pub. L. 90–399, § 105(b), July 13, 1968, 82 Stat. 352; Pub. L. 102–300, § 6(b)(2), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, § 3(p), Aug. 13, 1993, 107 Stat. 777, related to certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, prior to repeal by Pub. L. 105–115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

AMENDMENTS

2019—Subsec. (c)(3). Pub. L. 116–22 designated existing provisions as subpar. (A), inserted heading and ''or directing'' after ''authorizing'' in text, substituted ''disclose—'' for ''disclose'', designated remainder of existing provisions as cl. (i) of subpar. (A), substituted '';or'' for period at end, and added cl. (ii) of subpar. (A) and subpar. (B).

Statutory Notes and Related Subsidiaries

GUIDANCE

Pub. L. 114–255, div. A, title III, § 3011(b), Dec. 13, 2016, 130 Stat. 1089, provided that:

''(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section [this note] as the 'Secretary') shall, in consultation with biomedical research consortia (as defined in subsection (e) of section 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 357] (as added by subsection (a)) and other interested parties through a collaborative public

process, issue guidance to implement such section 507 that—

''(A) provides a conceptual framework describing appropriate standards and scientific approaches to support the development of biomarkers delineated under the taxonomy established under paragraph (3);

''(B) with respect to the qualification process under such section 507—

''(i) describes the requirements that entities seeking to qualify a drug development tool under such section shall observe when engaging in such process;

''(ii) outlines reasonable timeframes for the Secretary's review of letters, qualification plans, or full qualification packages submitted under such process; and

''(iii) establishes a process by which such entities or the Secretary may consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the Secretary in the review of qualification plans and full qualification submissions under such section; and

''(C) includes such other information as the Secretary determines appropriate.

''(2) TIMING.—Not later than 3 years after the date of the enactment of this Act [Dec. 13, 2016], the Secretary shall issue draft guidance under paragraph (1) on the implementation of section 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 357] (as added by subsection (a)). The Secretary shall issue final guidance on the implementation of such section not later than 6 months after the date on which the comment period for the draft guidance closes.

''(3) TAXONOMY.—

''(A) IN GENERAL.—For purposes of informing guidance under this subsection, the Secretary shall, in consultation with biomedical research consortia and other interested parties through a collaborative public process, establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.

''(B) PUBLIC AVAILABILITY.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall make such taxonomy publicly available in draft form for public comment. The Secretary shall finalize the taxonomy not later than 1 year after the close of the public comment period.''

§ 358. Authority to designate official names

(a) Necessity or desirability; use in official compendiums; infringement of trademarks

The Secretary may designate an official name for any drug or device if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any drug or device shall be the only official name of that drug or device used in any official compendium published after such name has been prescribed or for any other purpose of this chapter. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

(b) Review of names in official compendiums

Within a reasonable time after October 10, 1962, and at such other times as he may deem necessary, the Secretary shall cause a review to be made of the official names by which drugs are identified in the official United States Pharmacopoeia, the official Homoeopathic Pharmacopoeia of the United States, and the official National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto) to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

(c) Determinations of complexity, usefulness, multiplicity, or lack of name; designation by Secretary

Whenever he determines after any such review that (1) any such official name is unduly complex or is not useful for any other reason, (2) two or more official names have been applied to a single drug or device, or to two or more drugs which are identical in chemical structure and pharmacological action and which are substantially identical in strength, quality, and purity, or to two or more devices which are substantially equivalent in design and purpose or (3) no official name has been applied to a medically useful drug or device, he shall transmit in writing to the compiler of each official compendium in which that drug or drugs or device are identified and recognized his request for the recommendation of a single official name for such drug or drugs or device which will have usefulness and simplicity. Whenever such a single official name has not been recommended within one hundred and eighty days after such request, or the Secretary determines that any name so recommended is not useful for any reason, he shall designate a single official name for such drug or drugs or device. Whenever he determines that the name so recommended is useful, he shall designate that name as the official name of such drug or drugs or device. Such designation shall be made as a regulation upon public notice and in accordance with the procedure set forth in section 553 of title 5.

(d) Revised official names; compilation, publication, and public distribution of listings

After each such review, and at such other times as the Secretary may determine to be necessary or desirable, the Secretary shall cause to be compiled, published, and publicly distributed a list which shall list all revised official names of drugs or devices designated under this section and shall contain such descriptive and explanatory matter as the Secretary may determine to be required for the effective use of those names.

(e) Request by compiler of official compendium for designation of name

Upon a request in writing by any compiler of an official compendium that the Secretary exercise the authority granted to him under subsection (a), he shall upon public notice and in accordance with the procedure set forth in section 553 of title 5 designate the official name of the drug or device for which the request is made.

(June 25, 1938, ch. 675, § 508, as added Pub. L. 87–781, title I, § 111(a), Oct. 10, 1962, 76 Stat. 789; amended Pub. L. 94–295, § 5(b), May 28, 1976, 90 Stat. 581; Pub. L. 103–80, § 3(q), Aug. 13, 1993, 107 Stat. 777.)

Editorial Notes

AMENDMENTS

1993—Subsecs. (c), (e). Pub. L. 103–80 substituted reference to section 553 of title 5 for ''section 4 of the Administrative Procedure Act (5 U.S.C. 1003)''.