data, methods, and tools, and to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

''(2) SENSE OF CONGRESS.—It is the sense of Congress that the Food and Drug Administration should apply the accelerated approval and fast track provisions set forth in section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by this section, to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments.''

GUIDANCE; AMENDED REGULATIONS

Pub. L. 112–144, title IX, § 901(c), July 9, 2012, 126 Stat. 1085, provided that:

''(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act [July 9, 2012], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall issue draft guidance to implement the amendments made by this section [amending this section]. In developing such guidance, the Secretary shall specifically consider issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 356], as amended by subsection (b), for drugs designated for a rare disease or condition under section 526 of such Act (21 U.S.C. 360bb) and shall also consider any unique issues associated with very rare diseases.

''(2) FINAL GUIDANCE.—Not later than 1 year after the issuance of draft guidance under paragraph (1), and after an opportunity for public comment, the Secretary shall—

''(A) issue final guidance; and

''(B) amend the regulations governing accelerated approval in parts 314 and 601 of title 21, Code of Federal Regulations, as necessary to conform such regulations with the amendment made by subsection (b).

''(3) CONSIDERATION.—In developing the guidance under paragraphs (1) and (2)(A) and the amendments under paragraph (2)(B), the Secretary shall consider how to incorporate novel approaches to the review of surrogate endpoints based on pathophysiologic and pharmacologic evidence in such guidance, especially in instances where the low prevalence of a disease renders the existence or collection of other types of data unlikely or impractical.

''(4) CONFORMING CHANGES.—The Secretary shall issue, as necessary, conforming amendments to the applicable regulations under title 21, Code of Federal Regulations, governing accelerated approval.

''(5) NO EFFECT OF INACTION ON REQUESTS.—The issuance (or nonissuance) of guidance or conforming regulations implementing the amendment made by subsection (b) shall not preclude the review of, or action on, a request for designation or an application for approval submitted pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 356], as amended by subsection (b).''

Pub. L. 112–144, title IX, § 902(b), July 9, 2012, 126 Stat. 1087, provided that:

''(1) IN GENERAL.—

''(A) GUIDANCE.—Not later than 18 months after the date of enactment of this Act [July 9, 2012], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall issue draft guidance on implementing the requirements with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), as amended by this section. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

''(B) AMENDED REGULATIONS.—

''(i) IN GENERAL.—If the Secretary determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations in order to implement the amendments made by this section to section 506(a) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall amend such regulations not later than 2 years after the date of enactment of this Act.

''(ii) PROCEDURE.—In amending regulations under clause (i), the Secretary shall—

''(I) issue a notice of proposed rulemaking that includes the proposed regulation;

''(II) provide a period of not less than 60 days for comments on the proposed regulation; and

''(III) publish the final regulation not less than 30 days before the effective date of the regulation.

''(iii) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing the amendments made by this section only as described in clause (ii).

''(2) REQUIREMENTS.—Guidance issued under this section shall—

''(A) specify the process and criteria by which the Secretary makes a designation under section 506(a)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 356(a)(3)]; and

''(B) specify the actions the Secretary shall take to expedite the development and review of a breakthrough therapy pursuant to such designation under such section 506(a)(3), including updating good review management practices to reflect breakthrough therapies.''

Pub. L. 105–115, title I, § 112(b), Nov. 21, 1997, 111 Stat. 2310, provided that: ''Within 1 year after the date of enactment of this Act [Nov. 21, 1997], the Secretary of Health and Human Services shall issue guidance for fast track products (as defined in [former] section 506(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 356(a)(1)]) that describes the policies and procedures that pertain to section 506 of such Act.''

§ 356–1. Accelerated approval of priority countermeasures

(a) In general

The Secretary of Health and Human Services may designate a priority countermeasure as a fast-track product pursuant to section 356 of this title or as a device granted review priority pursuant to section 360e(d)(5)[1] of this title. Such a designation may be made prior to the submission of—

(1) a request for designation by the sponsor or applicant; or

(2) an application for the investigation of the drug under section 355(i) of this title or section 262(a)(3) of title 42.

Nothing in this subsection shall be construed to prohibit a sponsor or applicant from declining such a designation.

(b) Use of animal trials

A drug for which approval is sought under section 355(b) of this title or section 262 of title 42 on the basis of evidence of effectiveness that is derived from animal studies pursuant to section 123[1] may be designated as a fast track product for purposes of this section.

(c) Priority review of drugs and biological products

A priority countermeasure that is a drug or biological product shall be considered a priority drug or biological product for purposes of performance goals for priority drugs or biological products agreed to by the Commissioner of Food and Drugs.

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[1] See References in Text note below.

(d) Definitions

For purposes of this title: [1]

(1) The term ''priority countermeasure'' has the meaning given such term in section 247d–6(h)(4) [1] of title 42.

(2) The term ''priority drugs or biological products'' means a drug or biological product that is the subject of a drug or biologics application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997.

(Pub. L. 107–188, title I, § 122, June 12, 2002, 116 Stat. 613.)

Editorial Notes

REFERENCES IN TEXT

Section 360e(d)(5) of this title, referred to in subsec. (a), was struck out and former subsec. (d)(6) redesignated subsec. (d)(5) of section 360e by Pub. L. 114–255, div. A, title III, § 3051(c)(1), Dec. 13, 2016, 130 Stat. 1124. Section 360e(d)(5) no longer relates to grants of review priority.

Section 123, referred to in subsec. (b), is section 123 of Pub. L. 107–188, title I, June 12, 2002, 116 Stat. 613, which is not classified to the Code.

This title, referred to in subsec. (d), is title I of Pub. L. 107–188, June 12, 2002, 116 Stat. 596, which enacted this section, section 669a of Title 29, Labor, and sections 244, 245, 247d–3a, 247d–3b, 247d–7a to 247d–7d, 300hh, 300hh–11 to 300hh–13, 1320b–5, and 7257d of Title 42, The Public Health and Welfare, amended sections 247d to 247d–6, 264, 266, 290hh–1, and 5196b of Title 42, and enacted provisions set out as notes preceding section 8101 of Title 38, Veterans' Benefits, and under sections 201, 244, 247d, 247d–6, 300hh, 300hh–12, and 1320b–5 of Title 42. For complete classification of this title to the Code, see Tables.

Section 247d–6(h)(4) of title 42, referred to in subsec. (d)(1), was redesignated section 247d–6(e)(4) by Pub. L. 109–417, title III, § 304(3), Dec. 19, 2006, 120 Stat. 2861.

Section 101(4) of the Food and Drug Administration Modernization Act of 1997, referred to in subsec. (d)(2), is section 101(4) of Pub. L. 105–115, which is set out as a note under section 379g of this title.

CODIFICATION

Section was enacted as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 356–2. Accelerated approval Council

(1) In general

Not later than 1 year after December 29, 2022, the Secretary shall establish an intra-agency coordinating council (referred to in this subsection as the ''Council'') within the Food and Drug Administration to ensure the consistent and appropriate use of accelerated approval across the Food and Drug Administration, pursuant to section 356(c) of this title.

(2) Membership

The members of the Council shall consist of the following senior officials, or a designee of such official, from the Food and Drug Administration and relevant Centers:

(A) The Director of the Center for Drug Evaluation and Research.

(B) The Director of the Center for Biologics Evaluation and Research.

(C) The Director of the Oncology Center of Excellence.

(D) The Director of the Office of New Drugs.

(E) The Director of the Office of Orphan Products Development.

(F) The Director of the Office of Tissues and Advanced Therapies.

(G) The Director of the Office of Medical Policy.

(H) At least 3 directors of review divisions or offices overseeing products approved under accelerated approval, including at least one director within the Office of Neuroscience.

(3) Duties of the Council

(A) Meetings

The Council shall convene not fewer than 3 times per calendar year to discuss issues related to accelerated approval, including any relevant cross-disciplinary approaches related to product review with respect to accelerated approval.

(B) Policy development

The Council shall directly engage with product review teams to support the consistent and appropriate use of accelerated approval across the Food and Drug Administration. Such engagement may include—

(i) developing guidance for Food and Drug Administration staff and best practices for, and across, product review teams, including with respect to communication between sponsors and the Food and Drug Administration and the review of products under accelerated approval;

(ii) providing training for product review teams; and

(iii) advising review divisions on best practices with respect to product-specific development, review, and withdrawal of products under accelerated approval.

(4) Publication of a report

Not later than 1 year after December 29, 2022, and annually thereafter, the Council shall publish on the public website of the Food and Drug Administration a report on the activities of the Council.

(Pub. L. 117–328, div. FF, title III, § 3210(e), Dec. 29, 2022, 136 Stat. 5824.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Food and Drug Omnibus Reform Act of 2022, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Nothing in section 3210(e) of Pub. L. 117–328, which enacted this section, to be construed to affect ongoing withdrawal proceedings for products approved pursuant to section 356(c) of this title for which a notice of proposed withdrawal has been published in the Federal Register prior to Dec. 29, 2022, see section 3210(f) of Pub. L. 117–328, set out as a Construction of 2022 Amendment note under section 356 of this title.

DEFINITION OF ''SECRETARY''

Secretary as used in this section means the Secretary of Health and Human Services, see section 3002 of div.