

**(d) Definitions**

For purposes of this title:<sup>1</sup>

(1) The term “priority countermeasure” has the meaning given such term in section 247d-6(h)(4)<sup>1</sup> 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.

FF of Pub. L. 117-328, set out as a note under section 350a-1 of this title.

### § 356a. Manufacturing changes

#### (a) In general

With respect to a drug for which there is in effect an approved application under section 355 or 360b of this title or a license under section 262 of title 42, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

(1) the holder of the approved application or license (referred to in this section as a “holder”) has validated the effects of the change in accordance with subsection (b); and

(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d).

#### (b) Validation of effects of changes

For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before distribution of the drug as so made, the holder involved validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

#### (c) Major manufacturing changes

##### (1) Requirement of supplemental application

For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

##### (2) Changes qualifying as major changes

For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug. Such a change includes a change that—

(A) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in subsection (a) for the drug (unless exempted by the Secretary by regulation or guidance from the requirements of this subsection);

(B) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

(C) is another type of change determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

#### (d) Other manufacturing changes

##### (1) In general

For purposes of subsection (a)(2)(B), the Secretary may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

(A) The Secretary may in accordance with paragraph (2) authorize holders to distribute such drugs without submitting a supplemental application for such changes.

(B) The Secretary may in accordance with paragraph (3) require that, prior to the distribution of such drugs, holders submit to the Secretary supplemental applications for such changes.

(C) The Secretary may establish categories of such changes and designate categories to which subparagraph (A) applies and categories to which subparagraph (B) applies.

##### (2) Changes not requiring supplemental application

###### (A) Submission of report

A holder making a manufacturing change to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which shall contain such information as the Secretary determines to be appropriate, and which shall include the information developed under subsection (b) by the holder in validating the effects of the change. The report shall be submitted by such date as the Secretary may specify.

###### (B) Authority regarding annual reports

In the case of a holder that during a single year makes more than one manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph (A) authorize the holder to comply with such subparagraph by submitting a single report for the year that provides the information required in such subparagraph for all the changes made by the holder during the year.

##### (3) Changes requiring supplemental application

###### (A) Submission of supplemental application

The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information as the Secretary determines to be appropriate, which shall include the information developed under subsection (b) by the holder in validating the effects of the change.

###### (B) Authority for distribution

In the case of a manufacturing change to which paragraph (1)(B) applies:

(i) The holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under such paragraph, unless the Secretary notifies the holder within such 30-day period that prior approval of the application is required before distribution may be commenced.