''(b) FINAL GUIDANCE.—Not later than 12 months after the close of the period for public comment on the draft guidance under subsection (a), the Secretary of Health and Human Services shall finalize such guidance.''

§ 356h. Competitive generic therapies

(a) In general

The Secretary may, at the request of an applicant of a drug that is designated as a competitive generic therapy pursuant to subsection (b), expedite the development and review of an abbreviated new drug application under section 355(j) of this title for such drug.

(b) Designation process

(1) Request

The applicant may request the Secretary to designate the drug as a competitive generic therapy.

(2) Timing

A request under paragraph (1) may be made concurrently with, or at any time prior to, the submission of an abbreviated new drug application for the drug under section 355(j) of this title.

(3) Criteria

A drug is eligible for designation as a competitive generic therapy under this section if the Secretary determines that there is inadequate generic competition.

(4) Designation

Not later than 60 calendar days after the receipt of a request under paragraph (1), the Secretary may—

(A) determine whether the drug that is the subject of the request meets the criteria described in paragraph (3); and

(B) if the Secretary finds that the drug meets such criteria, designate the drug as a competitive generic therapy.

(c) Actions

In expediting the development and review of an application under subsection (a), the Secretary may, as requested by the applicant, take actions including the following:

(1) Hold meetings with the applicant and the review team throughout the development of the drug prior to submission of the application for such drug under section 355(j) of this title.

(2) Provide timely advice to, and interactive communication with, the applicant regarding the development of the drug to ensure that the development program to gather the data necessary for approval is as efficient as practicable.

(3) Involve senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review of such application, including with respect to drug-device combination products and other complex products.

(4) Assign a cross-disciplinary project lead—

(A) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

(B) to serve as a scientific liaison between the review team and the applicant.

(d) Reporting requirement

Not later than one year after the date of the approval of an application under section 355(j) of this title with respect to a drug for which the development and review is expedited under this section, the sponsor of such drug shall report to the Secretary on whether the drug has been marketed in interstate commerce since the date of such approval.

(e) Definitions

In this section:

(1) The term ''generic drug'' means a drug that is approved pursuant to section 355(j) of this title.

(2) The term ''inadequate generic competition'' means, with respect to a drug, there is not more than one approved drugs[1] on the list of drugs described in section 355(j)(7)(A) of this title (not including drugs on the discontinued section of such list) that is—

(A) the reference listed drug; or

(B) a generic drug with the same reference listed drug as the drug for which designation as a competitive generic therapy is sought.

(3) The term ''reference listed drug'' means the listed drug (as such term is used in section 355(j) of this title) for the drug involved.

(June 25, 1938, ch. 675, § 506H, as added Pub. L. 115–52, title VIII, § 803(a), Aug. 18, 2017, 131 Stat. 1070.)

Statutory Notes and Related Subsidiaries

GUIDANCE; AMENDED REGULATIONS

Pub. L. 115–52, title VIII, § 803(b), Aug. 18, 2017, 131 Stat. 1071, provided that:

''(1) IN GENERAL.—

''(A) ISSUANCE.—The Secretary of Health and Human Services shall—

''(i) not later than 18 months after the date of enactment of this Act [Aug. 18, 2017], issue draft guidance on section 506H of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 356h], as added by subsection (a); and

''(ii) not later than 1 year after the close of the comment period for the draft guidance, issue final guidance on such section 506H.

''(B) CONTENTS.—The guidance issued under this paragraph shall—

''(i) specify the process and criteria by which the Secretary makes a designation under section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

''(ii) specify the actions the Secretary may take to expedite the development and review of a competitive generic therapy pursuant to such a designation; and

''(iii) include good review management practices for competitive generic therapies.

''(2) AMENDED REGULATIONS.—The Secretary of Health and Human Services shall issue or revise any regulations as may be necessary to carry out this section not later than 2 years after the date of enactment of this Act [Aug. 18, 2017].''

§ 356i. Prompt reports of marketing status

(a) Notification of withdrawal

The holder of an application approved under subsection (c) or (j) of section 355 of this title or subsection (a) or (k) of section 262 of title 42 shall notify the Secretary in writing 180 days prior to withdrawing the approved drug from sale, or if 180 days is not practicable as soon as

[1] So in original. Probably should be ''drug''.

practicable but not later than the date of withdrawal. The holder shall include with such notice the—

(1) National Drug Code;

(2) identity of the drug by established name (or, in the case of a biological product, the proper name) and by proprietary name, if any;

(3) new drug application number, abbreviated application number, or biologics license application number;

(4) strength of the drug;

(5) date on which the drug is expected to no longer be available for sale; and

(6) reason for withdrawal of the drug.

(b) Notification of drug not available for sale

The holder of an application approved under subsection (c) or (j) of section 355 of this title or subsection (a) or (k) of section 262 of title 42 shall notify the Secretary in writing within 180 calendar days of the date of approval of the drug if the drug will not be available for sale within 180 calendar days of such date of approval. The holder shall include with such notice the—

(1) identity of the drug by established name (or, in the case of a biological product, the proper name) and by proprietary name, if any;

(2) new drug application number, abbreviated application number, or biologics license application number;

(3) strength of the drug;

(4) date on which the drug will be available for sale, if known; and

(5) reason for not marketing the drug after approval.

(c) Additional one-time report

Within 180 days of December 29, 2022, all holders of applications approved under subsection (a) or (k) of section 262 of title 42 shall review the information in the list published under section 262(k)(9)(A) of title 42 and shall submit a written notice to the Secretary—

(1) stating that all of the application holder's biological products in the list published under such section 262(k)(9)(A) of title 42 that are not listed as discontinued are available for sale; or

(2) including the information required pursuant to subsection (a) or (b), as applicable, for each of the application holder's biological products that are in the list published under such section 262(k)(9)(A) of title 42 and not listed as discontinued, but have been discontinued from sale or never have been available for sale.

(d) Failure to meet requirements

If a holder of an approved application fails to submit the information required under subsection (a), (b), or (c), the Secretary may—

(1) move the application holder's drugs from the active section of the list published under section 355(j)(7)(A) of this title to the discontinued section of the list, except that the Secretary shall remove from the list in accordance with section 355(j)(7)(C) of this title drugs the Secretary determines have been withdrawn from sale for reasons of safety or effectiveness; and

(2) identify the application holder's biological products as discontinued in the list published under section 262(k)(9)(A) of title 42, except that the Secretary shall remove from the list in accordance with section 262(k)(9)(B) of such title biological products for which the license has been revoked or suspended for reasons of safety, purity, or potency.

(e) Updates

The Secretary shall update the list published under section 355(j)(7)(A) of this title based on the information provided under subsections (a), (b), and (c) by moving drugs that are not available for sale from the active section to the discontinued section of the list, except that drugs the Secretary determines have been withdrawn from sale for reasons of safety or effectiveness shall be removed from the list in accordance with section 355(j)(7)(C) of this title. The Secretary shall update the list published under section 262(k)(9)(A) of title 42 based on information provided under subsections (a), (b), and (c) by identifying as discontinued biological products that are not available for sale, except that biological products for which the license has been revoked or suspended for safety, purity, or potency reasons shall be removed from the list in accordance with section 262(k)(9)(B) of title 42. The Secretary shall make monthly updates to the lists referred to in the preceding sentences based on the information provided pursuant to subsections (a) and (b), and shall update such lists based on the information provided under subsection (c) as soon as practicable.

(f) Limitation on use of notices

Any notice submitted under this section shall not be made public by the Secretary and shall be used solely for the purpose of the updates described in subsection (e).

(June 25, 1938, ch. 675, § 506I, as added Pub. L. 115–52, title VIII, § 804, Aug. 18, 2017, 131 Stat. 1071; amended Pub. L. 117–328, div. FF, title III, § 3201, Dec. 29, 2022, 136 Stat. 5808.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, § 3201(a)(1)(A), substituted ''The holder of an application approved under subsection (c) or (j) of section 355 of this title or subsection (a) or (k) of section 262 of title 42'' for ''The holder of an application approved under subsection (c) or (j) of section 355 of this title'' in introductory provisions.

Subsec. (a)(2). Pub. L. 117–328, § 3201(a)(1)(B), substituted ''established name (or, in the case of a biological product, the proper name)'' for ''established name''.

Subsec. (a)(3). Pub. L. 117–328, § 3201(a)(1)(C), substituted '', abbreviated application number, or biologics license application number'' for ''or abbreviated application number''.

Subsec. (b). Pub. L. 117–328, § 3201(a)(2)(A), substituted ''The holder of an application approved under subsection (c) or (j) of section 355 of this title or subsection (a) or (k) of section 262 of title 42'' for ''The holder of an application approved under subsection (c) or (j)'' in introductory provisions.

Subsec. (b)(1). Pub. L. 117–328, § 3201(a)(2)(B), substituted ''established name (or, in the case of a biological product, the proper name)'' for ''established name''.

Subsec. (b)(2). Pub. L. 117–328, § 3201(a)(2)(C), substituted '', abbreviated application number, or biologics license application number'' for ''or abbreviated application number''.

Subsec. (c). Pub. L. 117–328, § 3201(b), amended subsec. (c) generally. Prior to amendment, subsec. (c) related to an additional one-time report to be done within 180 days of Aug. 18, 2017.

Subsec. (d). Pub. L. 117–328, § 3201(c)(1), added subsec. (d) and struck out former subsec. (d). Prior to amendment, text read as follows: ''If a holder of an approved application fails to submit the information required under subsection (a), (b), or (c), the Secretary may move the application holder's drugs from the active section of the list published under subsection 355(j)(7)(A) of this title to the discontinued section of the list, except that the Secretary shall remove from the list in accordance with subsection 355(j)(7)(C) of this title drugs the Secretary determines have been withdrawn from sale for reasons of safety of effectiveness.''

Subsec. (e). Pub. L. 117–328, § 3201(d), substituted ''section 355(j)(7)(A) of this title'' for ''subsection 355(j)(7)(A) of this title'' and ''section 355(j)(7)(C) of this title'' for ''subsection 355(j)(7)(C) of this title''.

Pub. L. 117–328, § 3201(c)(2), inserted ''The Secretary shall update the list published under section 262(k)(9)(A) of title 42 based on information provided under subsections (a), (b), and (c) by identifying as discontinued biological products that are not available for sale, except that biological products for which the license has been revoked or suspended for safety, purity, or potency reasons shall be removed from the list in accordance with section 262(k)(9)(B) of title 42.'' before ''The Secretary shall make monthly updates'' and substituted ''monthly updates to the lists referred to in the preceding sentences'' for ''monthly updates to the list'' and ''and shall update such lists based on'' for ''and shall update the list based on''.

§ 356j. Discontinuance or interruption in the production of medical devices

(a) In general

A manufacturer of a device that—

(1) is critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or

(2) for which the Secretary determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a public health emergency;

shall, during, or in advance of, a public health emergency declared by the Secretary under section 247d of title 42, notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the device (except for discontinuances as a result of an approved modification of the device) or an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States, and the reasons for such discontinuance or interruption.

(b) Timing

A notice required under subsection (a) shall be submitted to the Secretary—

(1) at least 6 months prior to the date of the discontinuance or interruption; or

(2) if compliance with paragraph (1) is not possible, as soon as practicable.

(c) Distribution

(1) Public availability

To the maximum extent practicable, subject to paragraph (2), the Secretary shall distribute, through such means as the Secretary determines appropriate, information on the discontinuance or interruption of the manufacture of devices reported under subsection (a) to appropriate organizations, including physician, health provider, patient organizations, and supply chain partners, as appropriate and applicable, as described in subsection (g).

(2) Public health exception

The Secretary may choose not to make information collected under this section publicly available pursuant to this section if the Secretary determines that disclosure of such information would adversely affect the public health, such as by increasing the possibility of unnecessary over purchase of product, component parts, or other disruption of the availability of medical products to patients.

(d) Confidentiality

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(e) Failure to meet requirements

If a person fails to submit information required under subsection (a) in accordance with subsection (b)—

(1) the Secretary shall issue a letter to such person informing such person of such failure;

(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person who receives such letter shall submit to the Secretary a written response to such letter setting forth the basis for noncompliance and providing information required under subsection (a); and

(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make such letter and any response to such letter under paragraph (2) available to the public on the internet website of the Food and Drug Administration, with appropriate redactions made to protect information described in subsection (d), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not notifying as required under subsection (a), the requirements of this paragraph shall not apply.

(f) Expedited inspections and reviews

If, based on notifications described in subsection (a) or (h) or any other relevant information, the Secretary concludes that there is, or is likely to be, a shortage of an[1] device, the Secretary shall, as appropriate—

(1) prioritize and expedite the review of a submission under section 360c(f)(2) of this title, 360e of this title, review of a notification under section 360(k) of this title, or 360j(m) of this title for a device that could help mitigate or prevent such shortage; or

(2) prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent such shortage.

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[1] So in original. Probably should be ''a''.