''(b) FINAL GUIDANCE.—Not later than 12 months after the close of the period for public comment on the draft guidance under subsection (a), the Secretary of Health and Human Services shall finalize such guidance.''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