

physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

(3) Interim list

(A) In general

Before the effective date of the regulations finalized to implement subsection (a)(6), the Secretary may designate drugs, categories of drugs, or conditions as described such¹ subsection by—

- (i) publishing a notice of such substances, drugs, categories of drugs, or conditions proposed for designation, including the rationale for such designation, in the Federal Register;
- (ii) providing a period of not less than 60 calendar days for comment on the notice; and
- (iii) publishing a notice in the Federal Register designating such drugs, categories of drugs, or conditions.

(B) Sunset of notice

Any notice provided under subparagraph (A) shall not be effective after the earlier of—

- (i) the date that is 5 years after November 27, 2013; or
- (ii) the effective date of the final regulations issued to implement subsection (a)(6).

(4) Updates

The Secretary shall review, and update as necessary, the regulations containing the lists of drugs, categories of drugs, or conditions described in subsection (a)(6) regularly, but not less than once every 4 years. Nothing in the previous sentence prohibits submissions to the Secretary, before or during any 4-year period described in such sentence, requesting updates to such lists.

(d)² Definitions

In this section:

(1) The term “compounding” includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(2) The term “essentially a copy of an approved drug” means—

(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 353(b) of this title and not subject to approval in an application submitted under section 355 of this title, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing; or

(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 353(b) of this title and not subject to approval in an application submitted under section 355 of this title, unless there is a change that produces for an indi-

vidual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

(3) The term “approved drug” means a drug that is approved under section 355 of this title and does not appear on the list described in subsection (a)(4) of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

(4)(A) The term “outsourcing facility” means a facility at one geographic location or address that—

- (i) is engaged in the compounding of sterile drugs;
- (ii) has elected to register as an outsourcing facility; and
- (iii) complies with all of the requirements of this section.

(B) An outsourcing facility is not required to be a licensed pharmacy.

(C) An outsourcing facility may or may not obtain prescriptions for identified individual patients.

(5) The term “sterile drug” means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.

(d)² Obligation to pay fees

Payment of the fee under section 379j-62 of this title, as described in subsection (a)(9), shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees.

(June 25, 1938, ch. 675, §503B, as added Pub. L. 113-54, title I, §102(a)(2), Nov. 27, 2013, 127 Stat. 588.)

Editorial Notes

PRIOR PROVISIONS

A prior section 503B of act June 25, 1938, ch. 675, was renumbered section 503C by Pub. L. 113-54, §102(a)(1), Nov. 27, 2013, 127 Stat. 587, and transferred to section 353c of this title.

§ 353c. Prereview of television advertisements

(a) In general

The Secretary may require the submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement) to the Secretary for review under this section not later than 45 days before dissemination of the television advertisement.

(b) Review

In conducting a review of a television advertisement under this section, the Secretary may make recommendations with respect to information included in the label of the drug—

- (1) on changes that are—
 - (A) necessary to protect the consumer good and well-being; or
 - (B) consistent with prescribing information for the product under review; and

¹ So in original.

² So in original. Two subsecs. (d) have been enacted.

(2) if appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities.

(c) No authority to require changes

Except as provided by subsection (e), this section does not authorize the Secretary to make or direct changes in any material submitted pursuant to subsection (a).

(d) Elderly populations, children, racially and ethnically diverse communities

In formulating recommendations under subsection (b), the Secretary shall take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

(e) Specific disclosures

(1) Serious risk; safety protocol

In conducting a review of a television advertisement under this section, if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may require inclusion of such disclosure in the advertisement.

(2) Date of approval

In conducting a review of a television advertisement under this section, the Secretary may require the advertisement to include, for a period not to exceed 2 years from the date of the approval of the drug under section 355 of this title or section 262 of title 42, a specific disclosure of such date of approval if the Secretary determines that the advertisement would otherwise be false or misleading.

(f) Rule of construction

Nothing in this section may be construed as having any effect on requirements under section 352(n) of this title or on the authority of the Secretary under section 314.550, 314.640, 601.45, or 601.94 of title 21, Code of Federal Regulations (or successor regulations).

(June 25, 1938, ch. 675, § 503C, formerly § 503B, as added Pub. L. 110–85, title IX, § 901(d)(2), Sept. 27, 2007, 121 Stat. 939, renumbered § 503C, Pub. L. 113–54, title I, § 102(a)(1), Nov. 27, 2013, 127 Stat. 587.)

Editorial Notes

CODIFICATION

Section was formerly classified to section 353b of this title prior to renumbering by Pub. L. 113–54.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as an Effective Date of 2007 Amendment note under section 331 of this title.

§ 353d. Process to update labeling for certain generic drugs

(a) Definitions

For purposes of this section:

(1) The term “covered drug” means a drug approved under section 355(c) of this title—

(A) for which there are no unexpired patents included in the list under section 355(j)(7) of this title and no unexpired period of exclusivity;

(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and

(C) for which—

(i)(I) there is new scientific evidence available pertaining to new or existing conditions of use that is not reflected in the approved labeling;

(II) the approved labeling does not reflect current legal and regulatory requirements for content or format; or

(III) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; and

(ii) updating the approved labeling would benefit the public health.

(2) The term “period of exclusivity”, with respect to a drug approved under section 355(c) of this title, means any period of exclusivity under clause (ii), (iii), or (iv) of section 355(c)(3)(E) of this title, clause (ii), (iii), or (iv) of section 355(j)(5)(F) of this title, or section 355a, 355f, or 360cc of this title.

(3) The term “generic version” means a drug approved under section 355(j) of this title whose reference listed drug is a covered drug.

(4) The term “relevant accepted use” means a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary to meet the standards for approval under section 355 of this title.

(5) The term “selected drug” means a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.

(b) Identification of covered drugs

The Secretary may identify covered drugs for which labeling updates would provide a public health benefit. To assist in identifying covered drugs, the Secretary may do one or both of the following:

(1) Enter into cooperative agreements or contracts with public or private entities to review the available scientific evidence concerning such drugs.

(2) Seek public input concerning such drugs, including input on whether there is a relevant accepted use in clinical practice that is not reflected in the approved labeling of such drugs or whether new scientific evidence is available regarding the conditions of use for such drug, by—

(A) holding one or more public meetings;

(B) opening a public docket for the submission of public comments; or

(C) other means, as the Secretary determines appropriate.

(c) Selection of drugs for updating

If the Secretary determines, with respect to a covered drug, that the available scientific evidence meets the standards under section 355 of this title for adding or modifying information to the labeling or providing supplemental informa-