beling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(June 25, 1938, ch. 675, § 503A, as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328; amended Pub. L. 113–54, title I, § 106(a), Nov. 27, 2013, 127 Stat. 598.)

AMENDMENTS

2013—Subsec. (a). Pub. L. 113–54, § 106(a)(1), struck out ''unsolicited'' before ''receipt of a valid prescription'' in introductory provisions.

Subsec. (b)(1)(A)(i)(III). Pub. L. 113–54, § 106(a)(4), substituted ''subsection (c)'' for ''subsection (d)''.

Subsecs. (c) to (f). Pub. L. 113–54, § 106(a)(2), (3), redesignated subsecs. (d) to (f) as (c) to (e), respectively, and struck out former subsec. (c). Prior to amendment, subsec. (c) read as follows: ''A drug may be compounded under subsection (a) of this section only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.''

EFFECTIVE DATE

Pub. L. 105–115, title I, § 127(b), Nov. 21, 1997, 111 Stat. 2330, provided that: ''Section 503A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353a], added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act [Nov. 21, 1997].''

§ 353a–1. Enhanced communication

(a) Submissions from State boards of pharmacy

In a manner specified by the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), the Secretary shall receive submissions from State boards of pharmacy—

(1) describing actions taken against compounding pharmacies, as described in subsection (b); or

(2) expressing concerns that a compounding pharmacy may be acting contrary to section 353a of this title.

(b) Content of submissions from State boards of pharmacy

An action referred to in subsection (a)(1) is, with respect to a pharmacy that compounds drugs, any of the following:

(1) The issuance of a warning letter, or the imposition of sanctions or penalties, by a State for violations of a State's pharmacy regulations pertaining to compounding.

(2) The suspension or revocation of a State-issued pharmacy license or registration for violations of a State's pharmacy regulations pertaining to compounding.

(3) The recall of a compounded drug due to concerns relating to the quality or purity of such drug.

(c) Consultation

The Secretary shall implement subsection (a) in consultation with the National Association of Boards of Pharmacy.

(d) Notifying State boards of pharmacy

The Secretary shall immediately notify State boards of pharmacy when—

(1) the Secretary receives a submission under subsection (a)(1); or

(2) the Secretary makes a determination that a pharmacy is acting contrary to section 353a of this title.

(Pub. L. 113–54, title I, § 105, Nov. 27, 2013, 127 Stat. 597.)

CODIFICATION

Section was enacted as part of the Compounding Quality Act and also as part of the Drug Quality and Security Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 353b. Outsourcing facilities

(a) In general

Sections 352(f)(1), 355, and 360eee–1 of this title shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

(1) Registration and reporting

The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

(2) Bulk drug substances

The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

(A)(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(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 bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing;

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

(C) the bulk drug substances are each manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

(3) Ingredients (other than bulk drug substances)

If any ingredients (other than bulk drug substances) are used in compounding the drug,