

plement this title [enacting subpart 9 of part C of subchapter VII of this chapter and sections 353a-1 and 353b of this title, amending this section and sections 352, 353a, 352b, and 353c of this title, and enacting provisions set out as notes under section 301 of this title] (and the amendments made by this title), the Secretary of Health and Human Services shall—

“(1) issue a notice of proposed rulemaking that includes the proposed regulation;

“(2) provide a period of not less than 60 calendar days for comments on the proposed regulation; and

“(3) publish the final regulation not more than 18 months following publication of the proposed rule and not less than 30 calendar days before the effective date of such final regulation.”

Secretary of Health and Human Services to promulgate regulations to implement amendments made by section 401 of Pub. L. 105-115 not later than 1 year after Nov. 21, 1997, see section 401(c) of Pub. L. 105-115, set out as a note under section 360aaa of this title.

#### SAVINGS PROVISIONS

Pub. L. 113-54, title II, §208, Nov. 27, 2013, 127 Stat. 640, provided that: “Except as provided in the amendments made by paragraphs (1), (2), and (3) of section 204(a) [amending section 353 of this title] and by section 206(a) [amending this section], nothing in this title [enacting part H of subchapter V of this chapter, amending this section and sections 333, 352, 353, and 360eee-1 of this title, and enacting provisions set out as notes under sections 301, 333, and 353 of this title] (including the amendments made by this title) shall be construed as altering any authority of the Secretary of Health and Human Services with respect to a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) under any other provision of such Act [21 U.S.C. 301 et seq.] or the Public Health Service Act (42 U.S.C. 201 et seq.).”

Amendment by Pub. L. 91-513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91-513, set out as a note under section 321 of this title.

#### CONSTRUCTION OF 2015 AMENDMENT

Pub. L. 114-114, §2(d), Dec. 28, 2015, 129 Stat. 3130, provided that: “Nothing in this Act [amending this section and enacting provisions set out as notes under this section and section 301 of this title] (or the amendments made by this Act) shall be construed to apply with respect to drugs that are not also cosmetics (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)).”

#### CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendments by sections 103(e), 105(c), 106(d), 204(j)(1), 211(b), (c), and 301(b) of Pub. L. 111-353 to be construed to apply to certain alcohol-related facilities, see section 2206 of this title.

Nothing in amendments by Pub. L. 111-353 to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

#### CONSTRUCTION OF 2009 AMENDMENTS

Pub. L. 111-31, div. A, title I, §103(p), June 22, 2009, 123 Stat. 1838, provided that: “Nothing in this section [amending this section and sections 333, 334, 355, 360m, 372 to 374, 375, 379a, 381, 393, 399, and 679 of this title and enacting provisions set out as notes under sections 333 and 387c of this title] is intended or shall be construed to expand, contract, or otherwise modify or amend the

existing limitations on State government authority over tribal restricted fee or trust lands.”

#### CONSTRUCTION OF 2002 AMENDMENTS

Pub. L. 107-188, title III, §315, June 12, 2002, 116 Stat. 675, provided that: “Nothing in this title [enacting sections 350c, 350d, 398, 399, and 679c of this title, sections 3353, 3354, 8319, and 8320 of Title 7, Agriculture, and section 247b-20 of Title 42, The Public Health and Welfare, amending this section, sections 334, 335a, 342, 343, 360, 372, 374, and 381 of this title, and section 43 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under this section and sections 341, 350c, 350d, and 381 of this title], or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations.”

#### TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

#### PREEMPTION OF STATE LAWS

Pub. L. 114-114, §2(c), Dec. 28, 2015, 129 Stat. 3129, provided that: “No State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect restrictions with respect to the manufacture or introduction or delivery for introduction into interstate commerce of rinse-off cosmetics containing plastic microbeads (as defined in section 301(ddd) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)) that are not identical to the restrictions under such section 301(ddd) that have begun to apply under subsection (b) [set out as a note above].”

### § 332. Injunction proceedings

#### (a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown<sup>1</sup> to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

#### (b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

(June 25, 1938, ch. 675, §302, 52 Stat. 1043; Pub. L. 87-781, title I, §103(d), title II, §201(c), Oct. 10, 1962, 76 Stat. 784, 793; Pub. L. 103-80, §3(d), Aug. 13, 1993, 107 Stat. 775.)

#### AMENDMENTS

1993—Subsec. (a). Pub. L. 103-80, §3(d)(1), struck out “, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled ‘An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes’, approved October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 381),” after “for cause shown”.

Subsec. (b). Pub. L. 103-80, §3(d)(2), struck out at end “Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 387).”

<sup>1</sup> So in original. Probably should be followed by a comma.

1962—Subsec. (a). Pub. L. 87-781, §103(d), struck out “(e),” after “paragraphs”.

Pub. L. 87-781, §201(c), struck out “(f),” after “paragraphs”.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by section 103(c) of Pub. L. 87-781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87-781, set out as a note under section 321 of this title.

Pub. L. 87-781, title II, §203, Oct. 10, 1962, 76 Stat. 793, provided that: “The amendments made by this title [amending this section and section 374 of this title and enacting provisions set out as notes under sections 321 and 374 of this title] shall take effect on the date of enactment of this Act [Oct. 10, 1962].”

**§ 333. Penalties**

**(a) Violation of section 331 of this title; second violation; intent to defraud or mislead**

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section,<sup>1</sup> if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.

**(b) Prescription drug marketing violations**

(1) Notwithstanding subsection (a), any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(1) of this title,

shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than \$50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

<sup>1</sup> So in original. Words “of this section” probably should not appear.

(B) A civil penalty of not more than \$1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than \$100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 353(c)(1) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than \$125,000.

(6) Notwithstanding subsection (a), any person who is a manufacturer or importer of a prescription drug under section 384(b) of this title and knowingly fails to comply with a requirement of