

of the Secretary, institute a civil action to recover a civil money penalty in the amount and for any of the acts set forth in subsection (a) of this section. Such an action may be instituted separately from or in connection with any other claim, civil or criminal, initiated by the Attorney General under this chapter.

(2) Amount

In determining the amount of a civil penalty under paragraph (1), the Secretary or the court shall take into account the nature, circumstances, extent, and gravity of the act subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior, similar acts, and such other matters as justice may require.

(3) Limitation on actions

No action may be initiated under this section—

(A) with respect to any act described in subsection (a) of this section that occurred before May 13, 1992, or

(B) more than 6 years after the date when facts material to the act are known or reasonably should have been known by the Secretary but in no event more than 10 years after the date the act took place.

(c) Judicial review

Any person that is the subject of an adverse decision under subsection (b)(1)(A) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(d) Recovery of penalties

The Attorney General may recover any civil penalty (plus interest at the currently prevailing rates from the date the penalty became final) assessed under subsection (b)(1)(A) of this section in an action brought in the name of the United States. The amount of such penalty may be deducted, when the penalty has become final, from any sums then or later owing by the United States to the person against whom the penalty has been assessed. In an action brought under this subsection, the validity, amount, and appropriateness of the penalty shall not be subject to judicial review.

(e) Informants

The Secretary may award to any individual (other than an officer or employee of the Federal Government or a person who materially participated in any conduct described in subsection (a) of this section) who provides information leading to the imposition of a civil penalty under this section an amount not to exceed—

(1) \$250,000, or

(2) one-half of the penalty so imposed and collected,

whichever is less. The decision of the Secretary on such award shall not be reviewable.

(June 25, 1938, ch. 675, §307, as added Pub. L. 102-282, §3, May 13, 1992, 106 Stat. 159; amended Pub. L. 103-80, §3(g), Aug. 13, 1993, 107 Stat. 776.)

PRIOR PROVISIONS

A prior section 307 of act June 25, 1938, was renumbered section 310 and is classified to section 337 of this title.

AMENDMENTS

1993—Subsec. (b)(3)(A). Pub. L. 103-80 made technical amendment to reference to May 13, 1992, to reflect correction of corresponding provision of original act.

CONSTRUCTION

This section not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102-282, see section 7 of Pub. L. 102-282, set out as a note under section 335a of this title.

§ 335c. Authority to withdraw approval of abbreviated drug applications

(a) In general

The Secretary—

(1) shall withdraw approval of an abbreviated drug application if the Secretary finds that the approval was obtained, expedited, or otherwise facilitated through bribery, payment of an illegal gratuity, or fraud or material false statement, and

(2) may withdraw approval of an abbreviated drug application if the Secretary finds that the applicant has repeatedly demonstrated a lack of ability to produce the drug for which the application was submitted in accordance with the formulations or manufacturing practice set forth in the abbreviated drug application and has introduced, or attempted to introduce, such adulterated or misbranded drug into commerce.

(b) Procedure

The Secretary may not take any action under subsection (a) of this section with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(c) Applicability

Subsection (a) of this section shall apply with respect to offenses or acts regardless of when such offenses or acts occurred.

(d) Judicial review

Any person that is the subject of an adverse decision under subsection (a) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(June 25, 1938, ch. 675, §308, as added Pub. L. 102-282, §4, May 13, 1992, 106 Stat. 160.)

CONSTRUCTION

This section not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102-282, see section 7 of Pub. L. 102-282, set out as a note under section 335a of this title.

§ 336. Report of minor violations

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

(June 25, 1938, ch. 675, §309, formerly §306, 52 Stat. 1045; renumbered §309, Pub. L. 102-282, §2, May 13, 1992, 106 Stat. 150.)

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.

§ 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

(June 25, 1938, ch. 675, §310, formerly §307, 52 Stat. 1046; Sept. 3, 1954, ch. 1263, §37, 68 Stat.

1239; Pub. L. 101-535, §4, Nov. 8, 1990, 104 Stat. 2362; renumbered §310, Pub. L. 102-282, §2, May 13, 1992, 106 Stat. 150.)

AMENDMENTS

1990—Pub. L. 101-535 substituted “(a) Except as provided in subsection (b) of this section, all” for “All” and “any proceeding under this section” for “any such proceeding” and added subsec. (b).

1954—Act Sept. 3, 1954, struck out reference to section 654 of title 28.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective 24 months after Nov. 8, 1990, except that such amendment effective Dec. 31, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, see section 10(a)(1)(C) of Pub. L. 101-535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

§ 337a. Extraterritorial jurisdiction

There is extraterritorial jurisdiction over any violation of this chapter relating to any article regulated under this chapter if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

(June 25, 1938, ch. 675, §311, as added Pub. L. 112-144, title VII, §718, July 9, 2012, 126 Stat. 1077.)

SUBCHAPTER IV—FOOD

§ 341. Definitions and standards for food

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose