

eral 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.

#### SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 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 evi-

dence 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.

#### SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 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 note set out under section 41 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.

### 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 of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

(June 25, 1938, ch. 675, §401, 52 Stat. 1046; Apr. 15, 1954, ch. 143, §1, 68 Stat. 54; Aug. 1, 1956, ch. 861, §1, 70 Stat. 919; Pub. L. 103-80, §3(h), Aug. 13, 1993, 107 Stat. 776.)

#### AMENDMENTS

1993—Pub. L. 103-80 substituted “or reasonable standards of fill of container. No definition” for “and/or reasonable standards of fill of container: *Provided*, That no definition”.

1956—Act Aug. 1, 1956, designated provisions constituting subsec. (a) as entire section and repealed subsec. (b) which provided the procedure for establishment of regulations and is covered by section 371(e) of this title.

1954—Act Apr. 15, 1954, designated existing provisions as subsec. (a) and added subsec. (b).

#### SAVINGS PROVISION

Section 3 of act Aug. 1, 1956, provided that: “In any case in which, prior to the enactment of this Act [Aug. 1, 1956], a public hearing has been begun in accordance with section 401 of the Federal Food, Drug, and Cosmetic Act [341 of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by such section, or has been begun in accordance with section 701(e) of such Act [section 371(e) of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by section 403(j), 404(a), 406(a) or (b), 501(b), 502(d), 502(h), 504 or 604 of such Act [section 343(j), 344(a), 346(a) or (b), 351(b), 352(d), 352(h), 354, or 364 of this title], the provisions of such section 401 or 701(e), as the case may be, as in force immediately prior to the date of the enactment of this Act [Aug. 1, 1956], shall be applicable as though this Act [amending this section and section 371(e) of this title] had not been enacted.”

#### 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 note set out under section 41 of this title.

#### EX. ORD. NO. 13100. PRESIDENT'S COUNCIL ON FOOD SAFETY

Ex. Ord. No. 13100, Aug. 25, 1998, 63 F.R. 45661, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs, it is hereby ordered as follows:

SECTION 1. *Establishment of President's Council on Food Safety.* (a) There is established the President's Council on Food Safety (“Council”). The Council shall comprise the Secretaries of Agriculture, Commerce, Health and Human Services, the Director of the Office of Management and Budget (OMB), the Administrator of the En-