

sonably 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) 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) 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)) 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.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

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) 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) 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) 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.)

Statutory Notes and Related Subsidiaries

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.)