

Subsec. (b)(1)(C). Pub. L. 107-188, §304(a)(1), added subpar. (C).

Subsec. (b)(2). Pub. L. 107-188, §304(b)(2)(B), substituted “permissive debarment; certain drug applications” for “permissive debarment” in heading.

Pub. L. 107-188, §304(a)(2)(A), inserted “subparagraph (A) or (B) of” before “paragraph (1)” in introductory provisions.

Subsec. (b)(3), (4). Pub. L. 107-188, §304(a)(2)(B), (C), added par. (3) and redesignated former par. (3) as (4).

Subsec. (c)(2)(A)(iii). Pub. L. 107-188, §304(b)(3), substituted “paragraph (2) or (3) of subsection (b)” for “subsection (b)(2)”.

Subsec. (d)(3)(A)(i). Pub. L. 107-188, §304(b)(4)(A), substituted “subsection (a)(1) of this section or paragraph (2)(A) or (3) of subsection (b)” for “subsection (a)(1) or (b)(2)(A)”.

Subsec. (d)(3)(A)(ii)(II). Pub. L. 107-188, §304(b)(4)(B), inserted “in applicable cases,” before “sufficient audits”.

Subsec. (d)(3)(B)(i). Pub. L. 107-188, §304(b)(4)(C), inserted “or subsection (b)(3)” after “subsection (b)(2)(B)”.

Subsec. (d)(3)(B)(ii). Pub. L. 107-188, §304(b)(4)(C), (D), inserted “or subsection (b)(3)” after “subsection (b)(2)(B)” and “or the food importation process, as the case may be” before period.

Subsec. (l)(2). Pub. L. 107-188, §304(c), in first sentence struck out “and” after “subsection (b)(2) of this section,” and inserted “, and subsection (b)(3)(A) of this section” after “subsection (b)(2)(B) of this section” and in second sentence inserted “, subsection (b)(3)(B) of this section,” after “subsection (b)(2)(B) of this section”.

Subsec. (m). Pub. L. 107-250 added subsec. (m).

1997—Subsec. (d)(4)(B)(ii). Pub. L. 105-115 struck out “or 357” after “355”.

#### CONSTRUCTION

Pub. L. 102-282, §7, May 13, 1992, 106 Stat. 162, provided that: “No amendment made by this Act [enacting this section and sections 335b and 335c of this title and amending sections 321, 336, 337, and 355 of this title] shall 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 this Act.”

#### CONGRESSIONAL FINDINGS

Pub. L. 102-282, §1(c), May 13, 1992, 106 Stat. 149, provided that: “The Congress finds that—

“(1) there is substantial evidence that significant corruption occurred in the Food and Drug Administration’s process of approving drugs under abbreviated drug applications,

“(2) there is a need to establish procedures designed to restore and to ensure the integrity of the abbreviated drug application approval process and to protect the public health, and

“(3) there is a need to establish procedures to bar individuals who have been convicted of crimes pertaining to the regulation of drug products from working for companies that manufacture or distribute such products.”

### § 335b. Civil penalties

#### (a) In general

Any person that the Secretary finds—

(1) knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a material fact in connection with an abbreviated drug application,

(2) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any of-

ficer, employee, or agent of the Department of Health and Human Services in connection with an abbreviated drug application,

(3) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department’s discharge of its responsibilities in connection with an abbreviated drug application,

(4) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which such person had an obligation to disclose relating to any drug subject to an abbreviated drug application,

(5) knowingly obstructed an investigation of the Department of Health and Human Services into any drug subject to an abbreviated drug application,

(6) is a person that has an approved or pending drug product application and has knowingly—

(A) employed or retained as a consultant or contractor, or

(B) otherwise used in any capacity the services of,

a person who was debarred under section 335a of this title, or

(7) is an individual debarred under section 335a of this title and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application,

shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed \$250,000 in the case of an individual and \$1,000,000 in the case of any other person.

#### (b) Procedure

##### (1) In general

###### (A) Action by the Secretary

A civil penalty under subsection (a) of this section shall be assessed by the Secretary on a person by an order made on the record after an opportunity for an agency hearing on disputed issues of material fact and the amount of the penalty. In the course of any investigation or hearing under this subparagraph, 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.

###### (B) Action by the Attorney General

In lieu of a proceeding under subparagraph (A), the Attorney General may, upon request 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.