Subsec. (b). Pub. L. 89–74, § 6(b)(1), inserted ''equipment, or other thing proceeded against'' after ''article'' in first sentence.

Subsec. (d). Pub. L. 89–74, § 6(b)(2), designated existing provisions as par. (1), redesignated cls. (1) and (2) of the second sentence thereof as (A) and (B), and added pars. (2) and (3).

1957—Subsec. (d). Pub. L. 85–250 permitted, under certain circumstances, reexportation of articles condemned at places other than original port of entry.

1953—Subsec. (c). Act Aug. 7, 1953, provided that a true copy of the analysis in any case shall be furnished the owner.

1948—Subsec. (a). Act June 24, 1948, inserted ''or while held for sale (whether or not the first sale) after shipment in interstate commerce'' to make this subsection coextensive with section 331(k) of this title.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2012 AMENDMENT

Pub. L. 112–144, title VII, § 709(c), July 9, 2012, 126 Stat. 1070, provided that: ''The amendments made by subsection (a) [amending this section] shall not take effect until the Secretary has issued a final regulation under subsection (b) [amending this section and enacting provisions set out as a note under this section].''

[Final regulation issued May 29, 2014, effective June 30, 2014. See 79 F.R. 30716.]

EFFECTIVE DATE OF 2011 AMENDMENT

Pub. L. 111–353, title II, § 207(c), Jan. 4, 2011, 124 Stat. 3944, provided that: ''The amendment made by this section [amending this section] shall take effect 180 days after the date of enactment of this Act [Jan. 4, 2011].''

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Pub. L. 94–278, title V, § 502(c), Apr. 22, 1976, 90 Stat. 413, provided that: ''The amendments made by subsection (a) [amending this section and sections 321, 333, and 343 of this title] shall take effect 180 days after the date of the enactment of this Act [Apr. 22, 1976].''

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90–639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–74 effective Feb. 1, 1966, see section 11 of Pub. L. 89–74, set out as a note under section 321 of this title.

REGULATIONS

Pub. L. 112–144, title VII, § 709(b)(1), July 9, 2012, 126 Stat. 1069, provided that: ''Not later than 2 years after the date of the enactment of this Act [July 9, 2012], the Secretary of Health and Human Services shall promulgate regulations in accordance with section 304(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 334(i)], as added by paragraph (2) of this subsection, to implement administrative detention authority with respect to drugs, as authorized by the amendments made by subsection (a) [amending this section]. Before promulgating such regulations, the Secretary shall consult with stakeholders, including manufacturers of drugs.''

Pub. L. 111–353, title II, § 207(b), Jan. 4, 2011, 124 Stat. 3944, provided that: ''Not later than 120 days after the date of enactment of this Act [Jan. 4, 2011], the Secretary shall issue an interim final rule amending subpart K of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section [amending this section].''

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for any 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 2011 AMENDMENT

Nothing in amendment 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.

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.

§ 335. Hearing before report of criminal violation

Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

(June 25, 1938, ch. 675, § 305, 52 Stat. 1045.)

Statutory Notes and Related Subsidiaries

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.

§ 335a. Debarment, temporary denial of approval, and suspension

(a) Mandatory debarment; certain drug applications

(1) Corporations, partnerships, and associations

If the Secretary finds that a person other than an individual has been convicted, after May 13, 1992, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

(2) Individuals

If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct—

(A) relating to the development or approval, including the process for development or approval, of any drug product, or

(B) otherwise relating to the regulation of any drug product under this chapter,

the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

(b) Permissive debarment; certain drug applications; food imports

(1) In general

The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (2) or (3), debar—

(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application;

(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application;

(C) a person from importing an article of food or offering such an article for import into the United States; or

(D) a person from importing or offering for import into the United States a drug.

(2) Persons subject to permissive debarment; certain drug applications

The following persons are subject to debarment under subparagraph (A) or (B) of paragraph (1):

(A) Corporations, partnerships, and associations

Any person other than an individual that the Secretary finds has been convicted—

(i) for conduct that—

(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

(II) is a felony under Federal law (if the person was convicted before May 13, 1992), a misdemeanor under Federal law, or a felony under State law, or

(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(B) Individuals

(i) Any individual whom the Secretary finds has been convicted of—

(I) a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this chapter, or

(II) a conspiracy to commit, or aiding or abetting, such criminal offense or a felony described in subsection (a)(2),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(ii) Any individual whom the Secretary finds has been convicted of—

(I) a felony which is not described in subsection (a)(2) or clause (i) of this subparagraph and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or

(II) a conspiracy to commit, or aiding or abetting, such felony,

if the Secretary finds, on the basis of the conviction of such individual and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this chapter relating to drug products.

(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of such participation and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this chapter relating to drug products.

(iv) Any high managerial agent whom the Secretary finds—

(I) worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment under subsection (a)(2), or clause (i), of such other individual,

(II) had actual knowledge of the actions described in subclause (I) of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge,

(III) knew that the actions described in subclause (I) were violative of law, and

(IV) did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions,

if the Secretary finds that the type of conduct which served as the basis for such other individual's conviction undermines the process for the regulation of drugs.

(3) Persons subject to permissive debarment; food or drug importation

A person is subject to debarment under paragraph (1)(C) if—

(A) the person has been convicted of a felony for conduct relating to the importation into the United States of any food;

(B) the person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals;

(C) the person has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance (as defined in section 802 of this title);

(D) the person has engaged in a pattern of importing or offering for import—

(i) controlled substances that are prohibited from importation under section 1401(m) of title 19; or

(ii) adulterated or misbranded drugs that are—

(I) not designated in an authorized electronic data interchange system as a product that is regulated by the Secretary; or

(II) knowingly or intentionally falsely designated in an authorized electronic data interchange system as a product that is regulated by the Secretary.

(4) Stay of certain orders

An order of the Secretary under clause (iii) or (iv) of paragraph (2)(B) shall not take effect until 30 days after the order has been issued.

(5) Definition

For purposes of paragraph (3)(D), the term ''pattern of importing or offering for import'' means importing or offering for import a drug described in clause (i) or (ii) of paragraph (3)(D) in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer.

(c) Debarment period and considerations

(1) Effect of debarment

The Secretary—

(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) during the period such person is debarred,

(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B), debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from such individual, and

(C) shall, if the Secretary makes the finding described in paragraph (6) or (7) of section 335b(a) of this title, assess a civil penalty in accordance with section 335b of this title.

(2) Debarment periods

(A) In general

The Secretary shall debar a person under subsection (a) or (b) for the following periods:

(i) The period of debarment of a person (other than an individual) under subsection (a)(1) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under subsection (a) occurs within 10 years after such person has been debarred under subsection (a)(1), the period of debarment shall be permanent.

(ii) The debarment of an individual under subsection (a)(2) shall be permanent.

(iii) The period of debarment of any person under paragraph (2) or (3) of subsection (b) shall not be more than 5 years.

The Secretary may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses.

(B) Notification

Upon a conviction for an offense described in subsection (a) or (b) or upon execution of an agreement with the United States to plead guilty to such an offense, the person involved may notify the Secretary that the person acquiesces to debarment and such person's debarment shall commence upon such notification.

(3) Considerations

In determining the appropriateness and the period of a debarment of a person under subsection (b) and any period of debarment beyond the minimum specified in subparagraph (A)(i) of paragraph (2), the Secretary shall consider where applicable—

(A) the nature and seriousness of any offense involved,

(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this chapter or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

(d) Termination of debarment

(1) Application

Any person that is debarred under subsection (a) (other than a person permanently debarred) or any person that is debarred under subsection (b) may apply to the Secretary for termination of the debarment under this subsection. Any information submitted to the Secretary under this paragraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(2) Deadline

The Secretary shall grant or deny any application respecting a debarment which is submitted under paragraph (1) within 180 days of the date the application is submitted.

(3) Action by the Secretary

(A) Corporations

(i) Conviction reversal

If the conviction which served as the basis for the debarment of a person under subsection (a)(1) or paragraph (2)(A) or (3) of subsection (b) is reversed, the Secretary shall withdraw the order of debarment.

(ii) Application

Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of a person if the Secretary finds that—

(I) changes in ownership, management, or operations have fully corrected the causes of the offense involved and provide reasonable assurances that the offense will not occur in the future, and

(II) in applicable cases, sufficient audits, conducted by the Food and Drug Administration or by independent experts acceptable to the Food and Drug Administration, demonstrate that pending applications and the development of drugs being tested before the submission of an application are free of fraud or material false statements.

In the case of persons debarred under subsection (a)(1), such termination shall take effect no earlier than the expiration of one year from the date of the debarment.

(B) Individuals

(i) Conviction reversal

If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) or clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B) or subsection (b)(3) is reversed, the Secretary shall withdraw the order of debarment.

(ii) Application

Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of an individual who has been debarred under subsection (b)(2)(B) or subsection (b)(3) if such termination serves the interests of justice and adequately protects the integrity of the drug approval process or the food importation process, as the case may be.

(4) Special termination

(A) Application

Any person that is debarred under subsection (a)(1) (other than a person permanently debarred under subsection (c)(2)(A)(i)) or any individual who is debarred under subsection (a)(2) may apply to the Secretary for special termination of debarment under this subsection. Any information submitted to the Secretary under this subparagraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(B) Corporations

Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that—

(i) the person making the application under subparagraph (A) has demonstrated that the felony conviction which was the basis for such person's debarment involved the commission of an offense which was not authorized, requested, commanded, performed, or recklessly tolerated by the board of directors or by a high managerial agent acting on behalf of the person within the scope of the board's or agent's office or employment,

(ii) all individuals who were involved in the commission of the offense or who knew or should have known of the offense have been removed from employment involving the development or approval of any drug subject to sections[1] 355 of this title,

(iii) the person fully cooperated with all investigations and promptly disclosed all wrongdoing to the appropriate authorities, and

(iv) the person acted to mitigate any impact on the public of any offense involved, including the recall, or the discontinuation of the distribution, of any drug with respect to which the Secretary requested a recall or discontinuation of distribution due to concerns about the safety or efficacy of the drug.

(C) Individuals

Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that such individual has provided substantial assistance in the investigations or prosecutions of offenses which are described in subsection (a) or (b) or which relate to any matter under the jurisdiction of the Food and Drug Administration.

(D) Secretarial action

The action referred to in subparagraphs (B) and (C) is—

[1] So in original. Probably should be ''section''.

(i) in the case of a person other than an individual—

(I) terminating the debarment immediately, or

(II) limiting the period of debarment to less than one year, and

(ii) in the case of an individual, limiting the period of debarment to less than permanent but to no less than 1 year,

whichever best serves the interest of justice and protects the integrity of the drug approval process.

(e) Publication and list of debarred persons

The Secretary shall publish in the Federal Register the name of any person debarred under subsection (a) or (b), the effective date of the debarment, and the period of the debarment. The Secretary shall also maintain and make available to the public a list, updated no less often than quarterly, of such persons, of the effective dates and minimum periods of such debarments, and of the termination of debarments.

(f) Temporary denial of approval

(1) In general

The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (3), refuse by order, for the period prescribed by paragraph (2), to approve any abbreviated drug application submitted by any person—

(A) if such person is under an active Federal criminal investigation in connection with an action described in subparagraph (B),

(B) if the Secretary finds that such person—

(i) has bribed or attempted to bribe, has paid or attempted to pay an illegal gratuity, or has induced or attempted to induce another person to bribe or pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services or to any other Federal, State, or local official in connection with any abbreviated drug application, or has conspired to commit, or aided or abetted, such actions, or

(ii) has knowingly made or caused to be made a pattern or practice of false statements or misrepresentations with respect to material facts relating to any abbreviated drug application, or the production of any drug subject to an abbreviated drug application, to any officer, employee, or agent of the Department of Health and Human Services, or has conspired to commit, or aided or abetted, such actions, and

(C) if a significant question has been raised regarding—

(i) the integrity of the approval process with respect to such abbreviated drug application, or

(ii) the reliability of data in or concerning such person's abbreviated drug application.

Such an order may be modified or terminated at any time.

(2) Applicable period

(A) In general

Except as provided in subparagraph (B), a denial of approval of an application of a person under paragraph (1) shall be in effect for a period determined by the Secretary but not to exceed 18 months beginning on the date the Secretary finds that the conditions described in subparagraphs (A), (B), and (C) of paragraph (1) exist. The Secretary shall terminate such denial—

(i) if the investigation with respect to which the finding was made does not result in a criminal charge against such person, if criminal charges have been brought and the charges have been dismissed, or if a judgment of acquittal has been entered, or

(ii) if the Secretary determines that such finding was in error.

(B) Extension

If, at the end of the period described in subparagraph (A), the Secretary determines that a person has been criminally charged for an action described in subparagraph (B) of paragraph (1), the Secretary may extend the period of denial of approval of an application for a period not to exceed 18 months. The Secretary shall terminate such extension if the charges have been dismissed, if a judgment of acquittal has been entered, or if the Secretary determines that the finding described in subparagraph (A) was in error.

(3) Informal hearing

Within 10 days of the date an order is issued under paragraph (1), the Secretary shall provide such person with an opportunity for an informal hearing, to be held within such 10 days, on the decision of the Secretary to refuse approval of an abbreviated drug application. Within 60 days of the date on which such hearing is held, the Secretary shall notify the person given such hearing whether the Secretary's refusal of approval will be continued, terminated, or otherwise modified. Such notification shall be final agency action.

(g) Suspension authority

(1) In general

If—

(A) the Secretary finds—

(i) that a person has engaged in conduct described in subparagraph (B) of subsection (f)(1) in connection with 2 or more drugs under abbreviated drug applications, or

(ii) that a person has engaged in flagrant and repeated, material violations of good manufacturing practice or good laboratory practice in connection with the development, manufacturing, or distribution of one or more drugs approved under an abbreviated drug application during a 2-year period, and—

(I) such violations may undermine the safety and efficacy of such drugs, and

(II) the causes of such violations have not been corrected within a reasonable period of time following notice of such violations by the Secretary, and

(B) such person is under an active investigation by a Federal authority in connection with a civil or criminal action involving conduct described in subparagraph (A),

the Secretary shall issue an order suspending the distribution of all drugs the development or approval of which was related to such conduct described in subparagraph (A) or suspending the distribution of all drugs approved under abbreviated drug applications of such person if the Secretary finds that such conduct may have affected the development or approval of a significant number of drugs which the Secretary is unable to identify. The Secretary shall exclude a drug from such order if the Secretary determines that such conduct was not likely to have influenced the safety or efficacy of such drug.

(2) Public health waiver

The Secretary shall, on the Secretary's own initiative or in response to a petition, waive the suspension under paragraph (1) (involving an action described in paragraph (1)(A)(i)) with respect to any drug if the Secretary finds that such waiver is necessary to protect the public health because sufficient quantities of the drug would not otherwise be available. The Secretary shall act on any petition seeking action under this paragraph within 180 days of the date the petition is submitted to the Secretary.

(h) Termination of suspension

The Secretary shall withdraw an order of suspension of the distribution of a drug under subsection (g) if the person with respect to whom the order was issued demonstrates in a petition to the Secretary—

(1)(A) on the basis of an audit by the Food and Drug Administration or by experts acceptable to the Food and Drug Administration, or on the basis of other information, that the development, approval, manufacturing, and distribution of such drug is in substantial compliance with the applicable requirements of this chapter, and

(B) changes in ownership, management, or operations—

(i) fully remedy the patterns or practices with respect to which the order was issued, and

(ii) provide reasonable assurances that such actions will not occur in the future, or

(2) the initial determination was in error.

The Secretary shall act on a submission of a petition under this subsection within 180 days of the date of its submission and the Secretary may consider the petition concurrently with the suspension proceeding. Any information submitted to the Secretary under this subsection does not constitute an amendment or supplement to a pending or approved abbreviated drug application.

(i) Procedure

The Secretary may not take any action under subsection (a), (b), (c), (d)(3), (g), or (h) 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.

(j) Judicial review

(1) In general

Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) 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.

(2) Exception

Any person that is the subject of an adverse decision under clause (iii) or (iv) of subsection (b)(2)(B) may obtain a review of such decision by the United States District Court for the District of Columbia or a district court of the United States for the district in which the person resides, by filing in such court (within 30 days following the date the person is notified of the Secretary's decision) a complaint requesting that the decision be modified or set aside. In such an action, the court shall determine the matter de novo.

(k) Certification

Any application for approval of a drug product shall include—

(1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b), in connection with such application, and

(2) if such application is an abbreviated drug application, a list of all convictions, described in subsections (a) and (b) which occurred within the previous 5 years, of the applicant and affiliated persons responsible for the development or submission of such application.

***(l)* Applicability**

(1) Conviction

For purposes of this section, a person is considered to have been convicted of a criminal offense—

(A) when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending,

(B) when a plea of guilty or nolo contendere by the person has been accepted by a Federal or State court, or

(C) when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program where judgment of conviction has been withheld.

(2) Effective dates

Subsection (a), subparagraph (A) of subsection (b)(2), clauses (i) and (ii) of subsection

(b)(2)(B), and subsection (b)(3)(A) shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a) or (b). Clauses (iii) and (iv) of subsection (b)(2)(B), subsection (b)(3)(B), and subsections (f) and (g) shall not apply to an act or action which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (b), (f), or (g). Clause (iv) of subsection (b)(2)(B) shall not apply to an action which occurred before June 1, 1992. Subsection (k) shall not apply to applications submitted to the Secretary before June 1, 1992.

(m) Devices; mandatory debarment regarding third-party inspections and reviews

(1) In general

If the Secretary finds that a person has been convicted of a felony under section 331(gg) of this title, the Secretary shall debar such person from being accredited under section 360m(b) or 374(g)(2) of this title and from carrying out activities under an agreement described in section 383(b) of this title.

(2) Debarment period

The Secretary shall debar a person under paragraph (1) for the following periods:

(A) The period of debarment of a person (other than an individual) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under such paragraph occurs within 10 years after such person has been debarred under such paragraph, the period of debarment shall be permanent.

(B) The debarment of an individual shall be permanent.

(3) Termination of debarment; judicial review; other matters

Subsections (c)(3), (d), (e), (i), (j), and (*l*)(1) apply with respect to a person (other than an individual) or an individual who is debarred under paragraph (1) to the same extent and in the same manner as such subsections apply with respect to a person who is debarred under subsection (a)(1), or an individual who is debarred under subsection (a)(2), respectively.

(June 25, 1938, ch. 675, §306, as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 150; amended Pub. L. 105–115, title I, §125(b)(2)(C), Nov. 21, 1997, 111 Stat. 2325; Pub. L. 107–188, title III, §304(a)–(c), June 12, 2002, 116 Stat. 665, 666; Pub. L. 107–250, title II, §203, Oct. 26, 2002, 116 Stat. 1610; Pub. L. 115–271, title III, §3022(b)(2), Oct. 24, 2018, 132 Stat. 3938.)

Editorial Notes

PRIOR PROVISIONS

A prior section 306 of act June 25, 1938, was renumbered section 309 and is classified to section 336 of this title.

AMENDMENTS

2018—Subsec. (b)(1). Pub. L. 115–271, §3022(b)(2)(A)(i), inserted ''or (3)'' after ''paragraph (2)'' in introductory provisions.

Subsec. (b)(1)(D). Pub. L. 115–271, §3022(b)(2)(A)(ii)–(v), added subpar. (D).

Subsec. (b)(3). Pub. L. 115–271, §3022(b)(2)(B)(i), inserted ''or drug'' after ''food'' in heading.

Subsec. (b)(3)(C), (D). Pub. L. 115–271, §3022(b)(2)(B)(ii)–(iv), added subpars. (C) and (D).

Subsec. (b)(5). Pub. L. 115–271, §3022(b)(2)(C), added par. (5).

2002—Subsec. (a). Pub. L. 107–188, §304(b)(1), substituted ''Mandatory debarment; certain drug applications'' for ''Mandatory debarment'' in heading.

Subsec. (b). Pub. L. 107–188, §304(b)(2)(A), substituted ''Permissive debarment; certain drug applications; food imports'' for ''Permissive debarment'' in heading.

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) 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),'' and inserted '', and subsection (b)(3)(A)'' after ''subsection (b)(2)(B)'' and in second sentence inserted '', subsection (b)(3)(B),'' after ''subsection (b)(2)(B)''.

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''.

Statutory Notes and Related Subsidiaries

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—