

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.)

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§ 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), 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, or

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

(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) of this section,

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) of this section,

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) of this section 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.