

## 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.)

## 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), 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,