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# 21 U.S. Code § 335a

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## Debarment, temporary denial of approval, and suspension

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### **(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

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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.

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