
CENTER DIRECTOR

**SPECIAL TERMINATION OF MANDATORY DEBARMENT
OF AN INDIVIDUAL**

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PURPOSE This MAPP is intended to assist Food and Drug Administration (FDA) personnel and presiding officers in making recommendations or determinations concerning special termination of mandatory, permanent debarment of individuals under section 306(d)(4) of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Generic Drug Enforcement Act of 1992 (GDEA).

BACKGROUND

The GDEA provides FDA with strong, remedial authorities to deal with criminal conduct. The statute, signed by President Bush on May 13, 1992, was created by Congress in response to the generic drug scandal of the 1980's to provide safeguards against fraudulent data associated with drug applications. This law authorizes FDA to debar individuals and firms, and to take other enforcement actions.

REFERENCES

- The Generic Drug Enforcement Act of 1992, section 306 (21 U.S.C. 335a)
- The Federal Food, Drug, and Cosmetic Act, section 201(x) (21 U.S.C. 321(x)).

- 21 CFR Part 16 (1995).
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DEFINITIONS

- **Presiding Officer.** The person designated by the Deputy Commissioner for Operations to conduct the informal hearing and who has authority to make the final decision to grant or deny the application for termination of debarment under section 306(d)(4) of the act. (For information pertaining to delegation of authority to make decisions concerning termination, see *RESPONSIBILITIES* section of this guide.)
 - **Substantial Assistance.** To be eligible for special termination, the debarred individual must have provided substantial assistance in an investigation or prosecution of illegal activity of at least one other person. The illegal activity must either be described in section 306(a) or (b) or relate to any matter under the jurisdiction of FDA.
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POLICY **Informal Hearing**

The provisions of 21 CFR Part 16 (1995) govern the hearing process for special termination of debarment.

Requirements for Special Termination of Debarment

The agency may terminate the debarment, or limit the period of debarment, of an individual permanently debarred under section 306(a)(2) of the act (21 U.S.C. 335a(a)(2)) if the agency finds, after an informal hearing, that:

- The debarred individual has provided substantial assistance in the investigation or prosecution of an offense that is eligible for debarment under the act or that relates to any matter under the jurisdiction of FDA (see section 306(d)(4)(C)); and
- Special termination serves the interest of justice; and
- Special termination does not threaten the integrity of the drug approval process; and
- There is no additional basis under section 306(a) or (b) of the act for continuation of the debarment.

Burden of Proof; Evidence; Record as Basis of Decision; Standard of Proof

- The individual applying for special termination has the burden of proof.
- Any oral or documentary evidence may be received, but the agency as a matter of policy may exclude irrelevant, immaterial, or unduly repetitious evidence.
- A final determination or order may not be issued except on consideration of the whole record or parts thereof relied upon by a party and supported by reliable, probative, and adequate evidence.¹

Factors to Consider Regarding Special Termination

- **Substantial Assistance.** To be eligible for special termination, the debarred individual must have provided substantial assistance as defined in this guide.

Any determination made by the Department of Justice (DOJ) (e.g., in the sentencing transcript or by motion to the court) concerning the substantial assistance of the debarred individual should be regarded as conclusive in most cases, unless contrary information becomes known after the date of sentencing and before a decision is made regarding the special termination application.

- **Serves the Interest of Justice and Protects the Integrity of the Drug Approval Process.** In determining whether and to what extent the debarment period should be limited, the interest of justice and the integrity of the drug approval process should be considered. To that end, the following are relevant factors:²

1. **Nature and Seriousness of the Offense Involved:**

- a. **The conduct underlying the conviction should be considered an unfavorable factor if it--**

¹"Adequate evidence" has been retained as an appropriate standard for termination-type proceedings (suspension); it is defined as a *reasonable* belief that the act or omission has occurred. (See Office of Management and Budget (OMB) Government-wide Debarment Policy Letter, 47 FR 28854, 28856 Comments (d), (i), (July 1, 1982)).

² Any determination by the Department of Justice (DOJ) or the court made in the presentence report or sentencing transcript, or any information agreed to in a plea agreement should be considered conclusive in most cases insofar as the determination or information concerns the favorable and unfavorable factors listed under the *POLICY/Factors to Consider Regarding Special Termination/Serves the Interest of Justice and Protects the Integrity of the Drug Approval Process* section of this guide.

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- i. Created a risk of injury to consumers; or
 - ii. Potentially undermined the safety, effectiveness, or quality of any drug; or
 - iii. Otherwise undermined the integrity of the drug approval or regulatory processes.
 - b. **The conduct underlying the conviction should be considered an extremely unfavorable factor if it--**
 - i. Potentially undermined the safety or effectiveness of a drug used for a life-threatening or serious condition; or
 - ii. Resulted in physical harm to a consumer.
 2. **Culpability for conduct underlying conviction:**
 - a. **Extent to which the individual participated in offense.**
 - i. The extent to which the individual participated in the offense should be considered a favorable factor if information submitted under the *PROCEDURES/Contents* section of this guide supports the reasonable belief that the debarred individual did not actively participate in, plan, or assist in the planning of the conduct underlying the conviction and/or acted at the direction of a superior.
 - ii. The extent to which the individual participated in the offense should be considered an unfavorable factor if information submitted under the *PROCEDURES/Contents* section of this guide supports the reasonable belief that the debarred individual--
 - (a) Planned or participated in the planning of, directed, or initiated the conduct underlying the conviction; or
 - (b) Was in a position of authority or possessed special skills that he or she used to permit, perform, or cause the conduct underlying the

conviction.

- iii. The severity of the sentence imposed by the court may be an indication of the extent to which the individual participated in the offense.

b. Motive or state of mind.

- i. The motive or state of mind of the individual should be considered a favorable factor if information submitted under the *PROCEDURES/Contents* section of this guide demonstrates that the individual's conduct underlying the conviction resulted from force, intimidation, or, especially, from threats of personal injury or substantial damage to property.
- ii. The motive or state of mind of the individual should be considered an unfavorable factor if information submitted under the *PROCEDURES/Contents* section of this guide demonstrates that the individual's conduct underlying the conviction was performed in exchange for financial or other personal gain.
- iii. The motive or state of mind of the individual should be considered an extremely unfavorable factor if information submitted under the *PROCEDURES/Contents* section of this guide demonstrates that the debarred individual displayed a wanton disregard for the public health or the drug regulatory process.

c. Frequency of illegal conduct.

- i. The frequency of the illegal conduct should be considered a favorable factor if the illegal conduct was a first offense or consisted of only a few similar violations that occurred within a short period of time.
- ii. The frequency of the illegal conduct should be considered an unfavorable factor if it:
 - a. Involved different types of illegal acts even if they occurred over a short period of time; or

b. Suggests a pattern or practice of illegal conduct.

d. **Medical circumstances.**

The medical circumstances of the individual should be considered a favorable factor if:

- i. The record in the criminal proceeding, including sentencing documents, demonstrates that the court determined that the individual had a mental or emotional condition before or during the commission of the offense that reduced the individual's culpability; and
- ii. The individual has undergone treatment for the condition and shows signs of rehabilitation.

3. **History of other wrongful conduct:**

a. **Prior or subsequent offenses.**

If prior or subsequent to the conviction underlying the debarment, the individual was subject to a criminal, civil, or administrative sanction in connection with a violation of any Federal or State law, or a violation of any regulation of a Federal or State agency, then such prior or subsequent offense should be considered an unfavorable factor if such offense:

- i. Relates to the development, approval, or regulation of any drug product; or
- ii. Involves bribery, payment of an illegal gratuity, 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 or civil offense; or
- iii. Involves conspiracy to commit, or aiding or abetting, any of the offenses listed in subsection i. or ii. of this section;
- iv. Otherwise indicates corrupt behavior.

b. **Ongoing criminal investigation.**

An ongoing criminal investigation should be considered an unfavorable factor if the debarred individual is currently under criminal investigation for violation of any Federal or State law that involves any offense described under 3. a. of this section.

c. **Other wrongful conduct.**

- i. If there is adequate evidence to support the belief that the debarred individual engaged in wrongful conduct other than the specific conduct upon which the conviction was based, and such other wrongful conduct involves a violation of the act or a violation listed under 3. a. of this section, then such other wrongful conduct should be considered an unfavorable factor.
- ii. The statute of limitations governing debarment proceedings should not limit consideration of any prior wrongful conduct.

4. **Character and rehabilitation of individual:**

a. **Character of individual.**

- i. The character of the individual should be considered a favorable factor if:
 - (a) The individual shows significant signs of remorse, regret, an understanding of the wrongfulness of the criminal behavior, and rehabilitation (e.g., if there is credible evidence of responsible behavior subsequent to the illegal conduct for a significant period of time); and
 - (b) Based on information submitted under the *PROCEDURES/Contents* section of this guide, there is adequate evidence to support the belief that the particular conduct giving rise to the debarment will not recur and that the individual currently will not otherwise pose a threat to the integrity of the drug approval process. (For example, the conduct underlying the conviction

was an aberration from the individual's normal behavior. Additionally, the presiding officer may consider restitution, rehabilitation, time served in prison, and payment of all fines, as well as all the adverse consequences experienced by the debarred person as a result of the conviction including incarceration, debarment, conviction, financial hardship, fine.)

- ii. Substantial assistance, defined in the *POLICY/Factors to Consider Regarding Special Termination* section of this guide, may be considered as an indication of remorse, if the assistance was offered before or promptly after the violation was discovered.

b. **Judgment of court.**

- i. The judgment imposed should be considered a favorable factor if the sentence imposed by the court has been served and all fines and debts due to the court or agency by the debarred individual have been paid, or satisfactory arrangements have been made to fulfill these obligations.
- ii. The judgment imposed should be considered an unfavorable factor if the sentence imposed by the court has not yet been served or all fines and debts due to the court or agency by the debarred individual have not been paid, or satisfactory arrangements have not been made to fulfill these obligations.

5. **Other matters as justice may require:**

The favorable and unfavorable factors listed in this section are not exhaustive. Other matters may be considered as justice may require.

Factors to Consider Regarding the New Debarment Period

If the agency decides to grant the application for special termination, the following factors are relevant in determining the extent to which the debarment period may be limited:

- The period of limitation that best serves the interest of justice;

- The period of limitation that best protects the integrity of the drug approval process; and
- Whether the 1-year minimum period of debarment has expired on or before the effective date of termination (see section 306(d)(4)(D)(ii)).

General Guide

In determining whether or not to terminate debarment or to limit the period of debarment, all presiding officers should weigh the significance of all favorable and unfavorable factors in light of the remedial, public health-related purposes underlying debarment. Termination should not be granted unless, balancing favorable and unfavorable information, there are reasonable assurances that the conduct that formed the basis for the debarment has not recurred and will not recur, and that the individual will not otherwise pose a threat to the integrity of the drug approval process.

If there are substantial or several favorable factors to justify special termination, the period of debarment may be set at a length sufficiently below permanent (close to or at the 1-year minimum required by section 306(c)(2)(A)(ii) of the act) to reflect that fact. If substantial assistance, as defined in the *POLICY/Factors to Consider Regarding Special Termination* section of this guide, is established, but there are one substantial or several unfavorable factors, the period of debarment may be set at a length sufficiently close to or at permanent (the maximum permitted by section 306(c)(2)(A)(ii) of the act) to reflect that fact.

RESPONSIBILITIES

- **The Administrative Adjudications Group, Regulatory Policy Staff, is responsible for:**
 1. Conducting an initial evaluation of the application for termination, including obtaining any other necessary information, and making a recommendation [to be signed by the Director or a Deputy Director, CDER] to the Deputy Commissioner for Operations as to whether termination should be granted or denied or whether an informal hearing should be granted.
 2. Drafting orders refusing to terminate debarment or granting termination under section 306(d)(4) of the act.
 3. Drafting notices granting or denying an opportunity for an informal

hearing under section 306(d)(4) of the act.

- **The Deputy Commissioner for Operations is responsible for:**
 1. Issuing notices granting or denying an informal hearing under section 306(d)(4) of the act.
 2. Issuing final orders terminating debarment or refusing to terminate debarment under section 306(d)(4) of the act.
 3. Designating a person to serve as presiding officer.

The Commissioner has delegated to the Deputy Commissioner for Operations, among others, the authority to appoint a person to serve as presiding officer. Under 21 C.F.R. section 16.42(a), “an employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.” Under 21 C.F.R. 5.20(b), the Associate Commissioner for Regulatory Affairs and the Deputy Commissioners are authorized to perform all of the functions of the Commissioner of Food and Drugs. Given the past role of the Deputy Commissioner for Operations in debarment matters, it is appropriate for the Deputy Commissioner of Operations to designate a person to serve as presiding officer.

- **The presiding officer is responsible for:**
 1. Conducting a hearing pursuant to the provisions of part 16.
 2. Preparing a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.
 3. Rendering a written decision granting or denying termination and stating the reasons for the action and the basis for the decision in the administrative record. This decision will be published in the form of a final order issued by the Deputy Commissioner for Operations.

PROCEDURES

Timing, Method, and Contents of Request for Special Termination

- **Timing.** An individual debarred under section 306(a)(2) of the act may submit a written application for termination to the agency after publication of the individual's final debarment order in the Federal Register.
- **Method.** An application for special termination should be identified with the docket number of the debarment order and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Four copies of each application should be submitted. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.
- **Contents.**
 1. **The application should include as much of the following information as is relevant and practicable:**
 - a. A written statement specifically requesting special termination;
 - b. A written description of the conduct underlying the conviction that resulted in the individual's debarment, together with a description of the individual's motive and circumstances that gave rise to the conduct; a description of the specific facts showing that the applicant has provided substantial assistance as defined in the *POLICY/Factors to Consider Regarding Special Termination/Serves the Interest of Justice and Protects the Integrity of the Drug Approval Process* section of this guide; and information demonstrating that the conduct will not recur, and that the interests of justice and the integrity of the drug approval process will not be compromised by a grant of special termination;
 - c. The presentence report;³

³ The presentence report generated by DOJ and the U.S. District Court may determine whether the offense is indicative of or an aberration from the individual's normal behavior and whether the individual is remorseful. It usually contains prior criminal records, personal and family data, including mental/emotional condition, financial condition, and education of the individual.

- d. The sentencing transcript;⁴
- e. Letter(s) of reference from a previous employer or a current employer, or both, describing the character and job responsibilities of the individual, or letter(s) of reference from other persons with personal knowledge of the character of the individual;
- f. If the individual was or is currently a party to any other criminal or civil proceeding, information identifying the parties to the proceeding, describing the basis for the proceeding, and stating the verdict or current status of the proceeding; and
- g. Any other written documentation supporting the individual's request for special termination under 21 U.S.C. 335a(d)(4). Documentation from DOJ or the court should be considered the most convincing, reliable, and probative evidence that the individual has provided substantial assistance as defined in the *POLICY/Factors to Consider Regarding Special Termination* section of this guide.

Internal Procedures for Processing Special Termination Applications

- Upon receipt of the application for termination, the Administrative Adjudications Group, CDER, will seek a determination from DOJ as to whether the applicant has met the threshold burden of providing substantial assistance.
- If the Administrative Adjudications Group, CDER, finds that substantial assistance was not provided by the applicant, the Center will forward the application and all relevant information to the Deputy Commissioner for Operations with a recommendation to deny special termination on the basis of failure to provide substantial assistance.

The Deputy Commissioner for Operations may then issue an order refusing to terminate debarment under section 306(d)(4) of the act and denying an opportunity for an informal hearing.

- If the Administrative Adjudications Group, CDER, determines that the applicant provided substantial assistance, the Administrative Adjudications

⁴The sentencing transcript generated by the court may include findings similar to those in the presentence report (n.3) in addition to other findings pertaining to substantial assistance and aggravating and mitigating evidence.

Group, CDER, will thoroughly evaluate the application to determine whether the other requirements for special termination have been met.

- The Administrative Adjudications Group, CDER, may request in writing that the debarred individual submit additional information or authorization to obtain additional information from the court, probation officers, professional associates, investigative agencies, and others, as necessary, to determine whether the other requirements for special termination have been met.
- If the Administrative Adjudications Group, CDER, determines that the requirements for special termination have been met, the Center will forward the application and all relevant information to the Deputy Commissioner for Operations with a recommendation that termination be granted. The Deputy Commissioner for Operations will then review the application, all relevant information, and the CDER recommendation to determine whether termination should be granted.
- If the Administrative Adjudications Group, CDER, determines that the requirements for special termination have not been met, the Center will forward the application and all relevant information to the Deputy Commissioner for Operations with a recommendation that termination be denied. The Deputy Commissioner for Operations will then review the application, all relevant information, and the CDER recommendation to determine whether termination should be denied.
- If the Administrative Adjudications Group, CDER, is unable to determine whether termination is warranted, the Center will forward the application and all relevant information to the Deputy Commissioner for Operations with a statement to the effect that, based upon information available, the Center is unable to determine the applicant's eligibility for termination, and a recommendation for an informal hearing under Part 16. The Deputy Commissioner for Operations will then review the application, all relevant information and the CDER recommendation to determine whether termination and/or a hearing is warranted.
- If the Deputy Commissioner for Operations determines that termination is warranted, the Deputy Commissioner for Operations will issue an order granting termination under section 306(d)(4) of the act.
- If the Deputy Commissioner for Operations determines that termination is not warranted, the Deputy Commissioner for Operations will issue an order denying a hearing and refusing to terminate debarment under section 306(d)(4) of the

act.

- If the Deputy Commissioner for Operations is unable to determine whether termination is warranted, the Deputy Commissioner for Operations will issue a notice of opportunity for an informal hearing under part 16.

After the informal hearing, the Deputy Commissioner for Operations will issue a written order, based upon the written decision of the presiding officer, granting or denying special termination of debarment under section 306(d)(4) of the act, as appropriate.

Settlement

Nothing in this guide limits the authority of FDA to settle any issues or case.

Presiding Officer's Consideration of Previous Findings of Agencies of the U.S. Government

In making a recommendation or decision on special termination, the presiding officer should consider conclusory any previous relevant findings of another agency of the U. S. Government, absent contrary and probative information that becomes known after the date of such finding [and before a decision is made regarding the special termination application].

Denial of Hearing

- Failure to allege with specificity all material facts necessary to make a determination under 306 shall result in the denial of a hearing and the continuation of debarment. (See 21 CFR 16.26 (1995).) Hearings will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions.
- Failure to show that the individual has provided substantial assistance as defined in the *POLICY/Factors to Consider Regarding Special Termination* section of this guide shall result in the denial of a hearing and the continuation of debarment.

Denial of Application

Failure to submit information supporting the individual's application for special termination; failure to submit any requested information or authorization; or knowingly furnishing false information in the application for termination shall result in the denial of

the application for special termination and the continuation of debarment.

EFFECTIVE DATE

This MAPP is effective upon date of publication.