SMG 7712

FDA Staff Manual Guides, Volume IV – Agency Program Directives

Compliance Activities

Debarment Proceedings

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1. Purpose

The purpose of this Staff Manual Guide (SMG) is to provide general procedures for FDA staff to follow for debarment actions, and related proceedings, under section 306 of the Federal Food, Drug, and Cosmetic Act (the Act). When followed in conjunction with the procedures for formal evidentiary hearings and informal hearings in 21 CFR parts 12 and 16, the procedures described in this document will ensure that debarment actions are processed consistently and efficiently.[1]

2. Policy

- FDA is committed to initiating and resolving all proceedings relating to debarment in a timely manner.

- All timeframe references are to calendar days, unless stated otherwise.

- The Commissioner has redelegated the authority under section 306 of the Act to other agency officials, as indicated in SMGs 1410.21 and 1410.35.

[1] This SMG is not intended to supersede any of the procedures or requirements in the Act or FDA's regulations. This SMG outlines the general procedures to be followed by FDA personnel for mandatory and permissive debarments, including applications for termination and special termination of debarment. Other components within FDA may adopt additional procedures consistent with this SMG for implementing the responsibilities assigned to them in this document. This SMG is intended to be read in combination with any such procedures and the applicable regulations, particularly those found in 21 CFR parts 12 and 16.

3. Definitions

A. Center(s). One or more of FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM), Human Foods Program (HFP), and Center for Devices and Radiological Health (CDRH), the agency components with primary responsibility for regulating drugs, devices, and foods under the Act.

B. Commissioner. The Commissioner of Food and Drugs or another FDA official with the delegated authority to act on the Commissioner's behalf.

C. Company. A corporation, partnership, or association.

D. Debaree. A person who is the subject of debarment proceedings.

E. Debarment. An action taken by FDA, on the basis of a criminal conviction or conduct, as identified in section 306 of the Act, to prohibit an individual, corporation, partnership, or association:

- from submitting, or assisting in the submission of, certain drug applications or, in the case of individuals only, providing services in any capacity to the sponsor of an approved or pending drug application;
- from importing or offering for import an article of food into the United States;
- from importing or offering for import a drug article into the United States; or
- from being accredited to perform certain functions related to devices through programs administered by FDA, by other government agencies, or by other qualified non-government organizations and from carrying out activities under agreements with foreign countries to facilitate commerce in devices.

F. Final Debarment Order. The order published in the Federal Register, in accordance with section 306(e) of the Act, that announces the debarment, the effective date of the debarment, and the period of debarment.

G. The Office of the Chief Counsel or OCC. The Office of the General Counsel for the Department of Health and Human Services, Food and Drug Division.

H. The Office of Inspections and Investigations (OII). FDA's lead office for all agency field activities.

- **Office of Criminal Investigations (OCI).** OII Office responsible for conducting criminal investigations.

- **Office of Import Operations (OIO).** OII office responsible for FDA admissibility review of import articles regulated by the Agency.

- **The Division of Inspectorate Recall Operations (DIRO).** The division in OII responsible for initiating debarment notices and facilitating the final order process when the debaree candidate fails to respond or declines an opportunity for a hearing in response to a proposal to debar or acquiesces to debarment.

J. The Office of Scientific Integrity, Office of the Chief Scientist. The office within the FDA that has been delegated the authority to issue final debarment orders when the debaree candidate requests a hearing.

K. Person. An individual, corporation, partnership, or association (see section 201(e)).

L. Presiding Officer. An FDA employee to whom the Commissioner delegates authority to conduct a regulatory hearing under 21 CFR part 12 or 16 or an administrative law judge to whom such authority is delegated (21 CFR 12.60, 16.42(a)).

M. Proposal to Debar. The notice of an opportunity for hearing served on the debaree in order to initiate debarment proceedings that provides the debaree thirty (30) days in which to request a hearing and sixty (60) days to provide evidence or other information to justify a hearing.

4. Background

- Under section 306 of the Act, as a remedial measure, FDA has the authority to prohibit persons from participating in certain aspects of FDA-regulated activities through its debarment process.

- The triggering event for debarment is ordinarily a criminal conviction (section 306(a), (b), (m)). Depending on the nature of the conduct underlying the conviction, debarment may be triggered by a felony or misdemeanor conviction under Federal law or a felony conviction under State law (id.). An individual may be subject to debarment even if he or she was not the person convicted (section 306(b)(2)(B)(iii)-(iv)). 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 may also trigger debarment (section 306(b)(3)(B)). Additionally, a person can be debarred for a pattern of importing or offering for import controlled substances as defined in 19 U.S.C.1401(m) that are prohibited from importation. A pattern of importing or offering for import adulterated or misbranded drugs may also trigger debarment provided that those articles are

not designated in an authorized electronic data interchange system as a product that is regulated by FDA or are knowingly or intentionally falsely designated in an authorized electronic data interchange system as a product that is regulated by FDA (section 306(b)(3)(D)). For debarment to be based on a pattern of drug importation, the amount, frequency or dosage must be inconsistent with personal or household use by the importer.

- Depending on the nature of the criminal conviction or the conduct, debarment may be mandatory or permissive (section 306(a), (b), (m)). Both types of debarment, however, require that FDA make a finding that the debaree was convicted of a qualifying offense or engaged in conduct triggering debarment (id.). Permissive debarment also requires FDA to make additional findings and to consider additional factors regarding the appropriateness of debarment (section 306(b)). FDA may begin debarment proceedings at the agency's own initiative or in response to a petition (section 306(b)(1)).

- The applicable period of debarment depends on whether the debaree is an individual or company, whether the debarment was mandatory or permissive, and, if the debaree is not an individual, whether the debarment is its first or second (section 306(c)(2), (m)(2)). When debarment is not required to be permanent, FDA has some discretion in setting the period of debarment within the statutory range and must consider certain factors in exercising that discretion (section 306(c)(3), (m)(3)). FDA may determine whether multiple debarment periods, imposed for multiple offenses, will run concurrently or consecutively (section 306(c)(2)). Debarred persons may apply for termination or special termination of debarment, and FDA grants those applications under certain circumstances (section 306(d), (m)(3)). FDA must grant or deny any application for termination of debarment within 180 days of the date of submission (section 306(d)(2)).

- Under section 307(a)(6), any person with an approved or pending drug application who knowingly engages the services of a debarred person is liable for civil penalties. Under 307(a)(7), debarred individuals are subject to civil penalties for providing services to a person with an approved or pending drug application.[2]

- For convictions or conduct related to drugs or foods, FDA has five years from the date of the triggering conviction or conduct (if person was not the subject of a

[2] Other than the responsibilities assigned to DIRO, the imposition of civil penalties under section 307(a)(6) and (7) for conduct related to debarment are outside the scope of this SMG.

triggering conviction) to initiate debarment proceedings, as set forth in section 306(l)(2).

- Hearings on debarment, debarment period and considerations, and termination of debarment (under section 306(d)(3)) are conducted pursuant to 21 CFR part 12 (21 CFR 10.50(c)(20)). Applications for special termination (under section 306(d)(4)) are resolved via informal hearing pursuant to 21 CFR part 16 (see section 306(d)(4)(B)-(C)).

5. Responsibilities and Agency-Wide Procedures[3]

A. All FDA Employees

Any FDA employee who observes conduct or receives an oral or written notice indicating that a person may be subject to mandatory or permissive debarment (including any petition for debarment) will notify DIRO and forward copies of all relevant materials in that employee's possession (i.e., any written notice or petition and any information supporting debarment).

If the person who may be subject to debarment (1) has an approved or pending drug application, (2) is an employee of such a person, (3) is a clinical investigator, (4) is currently engaged in importing food or offering it for import, (5) is currently engaged in importing a drug or offering it for import, or (6) has been convicted of a felony under section 301(gg) of the Act, the FDA employee will notify DIRO as soon as is practicable. Otherwise, the FDA employee will notify DIRO within ninety (90) days of observing conduct or receiving an oral or written notice indicating that a person may be subject to debarment.

OCI will provide quarterly reports to DIRO that set forth all convictions occurring within the preceding three (3) months that may trigger debarment.

An FDA employee who observes conduct or receives an oral or written notice indicating that a person is violating an active debarment order must notify the Debarment Specialist in DIRO by sending an email to debarments@fda.hhs.gov within the time frames indicated above for notifying DIRO of a person that may be subject to debarment. The Debarment Specialist will be responsible for forwarding that notification to the appropriate office whether in DIRO or OCI for further investigation.

[3] There may exist a backlog of debarment candidates at the time this SMG is issued. As noted below, the timelines set forth in this SMG will not become effective until the agency clears any such backlog. DIRO, the Centers, the Commissioner, OSI, and OCC intend to immediately commit resources to eliminate any backlog of debarment candidates as soon as practicable.

B. The Division of Inspectorate Recall Operations

The Division of **Inspectorate Recall Operations'** (DIRO) responsibilities include, but are not limited to, the following:

- notifying the Office of the of the Associate Commissioner for Inspections and Investigations (ACII) of the issuance of a proposal to debar or a final debarment order.

- processing and addressing petitions for debarment;

- adopting procedures in cooperation with other relevant FDA components and the United States Department of Justice to facilitate the communication of information about convictions or conduct triggering debarment, including periodic queries of those components and the Department of Justice, as necessary;

- determining whether to initiate debarment proceedings against a person, in response to a petition or at its own initiative, for convictions or conduct triggering debarment, which will include the following:

    - seeking consultation with the appropriate Center;

    - seeking consultation with OIO regarding importers and import procedures; and

    - seeking consultation with the Office of Chief Counsel (OCC);

- initiating debarment proceedings, when deemed appropriate, by sending the debaree a proposal to debar that provides the debaree with notice of opportunity for hearing on the proposal:

    - except when there is a particularized reason for postponing the start of a non-permanent debarment period or an unanticipated delay in the collection of information pertinent to debarment, DIRO will prepare the proposal to debar (when deemed appropriate) and forward its draft to OCC for clearance within ninety (90) days of receiving notice that a person is subject to debarment;

    - DIRO will address any concerns raised by OCC and send the proposal to debar to the debaree within twenty (20) days of receiving clearance from OCC;

- drafting and processing the final debarment order through clearance to the "appropriate official" who has the delegated authority to approve final debarment orders[4] under the following circumstances:

    - when a person fails to respond to the proposal to debar:

        - DIRO will prepare the final debarment order and forward its draft to OCC within thirty (30) days of the expiration of the time provided either to request a hearing or to provide evidence or other information to justify a hearing,

        - DIRO will address any concerns raised by OCC and finalize the final debarment order with the appropriate official within thirty (30) days of receiving clearance from OCC;

    - when a person declines an opportunity for a hearing in response to a proposal to debar or acquiesces to debarment:

        - DIRO will prepare the final debarment order and forward its draft to OCC within thirty (30) days of receipt of the written communication declining a hearing or acquiescing to debarment,

        - DIRO will address any concerns raised by OCC and finalize the final debarment order with the appropriate official within thirty (30) days of receiving clearance from OCC;

- pursuing debarment on behalf of the Center with authority over the implicated products when the debaree submits a request for a hearing;

- maintaining a list of debarred persons in accordance with the requirements of section 306(e) of the Act;

- initiating administrative proceedings for civil penalties, as appropriate, when available evidence establishes that a person is liable for civil money penalties under section 307(a)(6) or (7); and

- processing applications for termination or special termination of debarment in the following manner:

    - when DIRO determines that granting the application without a hearing is appropriate:

[4] See Staff manual Guide (SMG) 1410.35 and any supplements to SMG 1410.35.

- DIRO will prepare an order granting the application without a hearing and forward its draft to OCC within sixty (60) days of receiving the application;

- DIRO will address any concerns raised by OCC and finalize the order with the appropriate official within thirty (30) days of receiving clearance from OCC;

  - when DIRO determines that denying the application (absent additional evidence) is appropriate:

    - DIRO will prepare a notice of opportunity for hearing on a proposal to deny the application and forward its draft to OCC within sixty (60) days of receiving the application; and

    - DIRO will address any concerns raised by OCC and send the notice to the applicant, after coordinating with the appropriate official, within thirty (30) days of receiving clearance from OCC;

  - when an applicant waives a hearing on a proposal to deny the application:

    - DIRO will prepare an order denying the application and forward its draft to OCC within sixty (60) days of the waiver;

    - DIRO will address any concerns raised by OCC and finalize the order with the appropriate official within thirty (30) days of receiving clearance from OCC;

- pursuing denial of applications for termination and special termination of debarment on behalf of the Center with authority over the implicated products when the applicant submits a request for a hearing in response to a proposal to deny the application.

C. The Centers and OIO

CDER, CBER, CVM, HFP, or CDRH, as appropriate in light of the products implicated, will provide DIRO expert assistance in addressing petitions, pursuing debarment and civil penalty proceedings, applying the relevant considerations for permissive debarments and periods of debarment (see section 306(c)(3)), and evaluating applications for termination or special termination of debarment. When DIRO requests such information or advice, the relevant Center will provide, at a minimum, a preliminary response within thirty (30) days and will exercise due diligence in providing all requested information as soon as is practicable. OIO will

provide support for import-related debarment cases and will provide field staff with guidance for implementation and operational follow up.

D. OSI

The Director, Office of Scientific Integrity (OSI), Office of the Chief Scientist responsibilities include, but are not limited to, the following:

- issuing the final debarment order upon a determination that a person responding to a proposal to debar with a request for a hearing has failed to present a genuine and substantial issue of fact to justify a hearing under 21 CFR 12.24(b):
    - OSI will issue a denial of hearing (*see* 21 CFR 12.28) and the final debarment order within ninety (90) days of the agency's receipt of the request;
    - within ninety (90) days of receiving the request for a hearing, granting a hearing under Part 12 if the debaree's request for a hearing provides grounds on which to grant a hearing under 21 CFR 12.24(b) and issuing a notice of hearing in accordance with 21 CFR 12.35;
    - determining whether there are any genuine and substantial issues of fact, or any other reason, to justify a hearing under 21 CFR 12.24(b) for termination of debarment or under 21 CFR 16.26(a) for special termination of debarment;
        - within sixty (60) days of the date of the applicant's request for hearing (in response to a proposal by DIRO to deny the application), OSI will grant or deny a hearing under 21 CFR part 12 or 16 and, if granting a hearing under Part 12, issue a notice of hearing under 21 CFR 12.35.

E. The Commissioner

The Commissioner's responsibilities include, but are not limited to, the following:

- deciding appeals from initial decisions by presiding officers with respect to debarment, debarment period and consideration, and termination of debarment (*see* 21 CFR 12.125, 12.130):
    - the Commissioner will issue a final decision on such appeals within ninety (90) days of the date of receipt of the appeal unless the Commissioner determines that additional briefings or oral arguments are advisable or a statutory deadline requires greater expediency;[5]

[5] All timelines in this SMG for hearings under 21 CFR part 12 are designed not only to encourage

- ensuring that the final debarment order or notice of final action of the agency, as appropriate, is published in the Federal Register whenever there is a hearing for debarment, debarment period and consideration, or termination of debarment (*see* 12 CFR 12.120(f), 12.130(e)):

    - the Commissioner will issue the final debarment order or notice of final agency action within sixty (60) days of the final decision or the date on which the presiding officer's initial decision becomes final (see 21 CFR 12.120(e)), unless a statutory deadline requires greater expediency;

- reviewing interlocutory appeals of decisions rendered by the presiding officer under limited circumstances (*see* 21 CFR 12.97):

    - the Commissioner will decide such appeals within sixty (60) days of the date of the receipt of the appeal, unless a statutory deadline requires greater expediency; and

- rendering the final decision of the agency for special termination of debarment based on the administrative record (*see* 21 CFR 16.95(b)):

    - the Commissioner will render such decisions within ninety (90) days of the date of the presiding officer's report under 21 CFR 16.60(e).

F. The Presiding Officer

The presiding officer's responsibilities include, but are not limited to, the following actions. The presiding officer will conduct formal evidentiary hearings on debarment, debarment period and consideration, and termination of debarment under 21 CFR part 12. The presiding officer will also conduct informal hearings on special terminations of debarment under 21 CFR part 16. The following timeframes apply unless a statutory deadline requires greater expediency:

- For hearings on special terminations of debarment, the presiding officer will conduct the hearing within sixty (60) days of when the matter is referred for a hearing, unless one of the parties files a motion for summary decision (*see* 21 CFR 16.26(b)) and will issue written reports of hearings or summary decisions (16.60(e)) within ninety (90) days of when any motion for summary decision becomes ripe for review or conclusion of the hearing, as appropriate;

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expedience but also to take into account the statutory deadline of 180 days for granting or denying an application for termination of debarment in section 306(d)(2). Because there are so many variables in the Part 12 process, however, it is impossible to ensure that the process will conclude within 180 days without providing very short deadlines for every step of the process. If the deadline of 180 days becomes an issue, FDA personnel will time the execution of their responsibilities accordingly.

- The presiding officer will rule on any non-substantive motion within sixty (60) days; and

- For hearings with respect to debarment, debarment period and consideration, and termination of debarment, the presiding officer will issue any initial decisions (*see* 21 CFR 12.120) within ninety (90) days after the filing of briefs and oral argument and will issue any summary decisions (*see* 12.93) within ninety (90) days of when any motion for summary decision becomes ripe for review or conclusion of the hearing, as appropriate.

G. The Office of the Chief Counsel

The Office of the Chief Counsel is responsible for providing legal advice to DIRO, OCI, the Centers, the Commissioner, the OSI and presiding officers. For Part 12 and, as a matter of policy, for Part 16 debarment matters, OCC observes separation of functions once there is a request for a hearing. As a result, OCC attorneys providing advice to DIRO and the Centers will not provide advice to the Commissioner, the OSI, or presiding officers (other attorneys will advise the Commissioner, OSI, and presiding officers).

OCC will review any document or written decision discussed elsewhere in this SMG, or otherwise provided for by CFR Parts 12 and 16, and must provide clearance before it is finalized (unless prepared by an administrative law judge). OCC will complete its review within the timeframes below, unless a statutory deadline requires greater expediency.

- OCC attorneys advising DIRO and the Centers will complete their review of all notices and orders within thirty (30) days.

- The following timeframes will apply to OCC attorneys advising the Commissioner, the OSI, and presiding officers:

    - For summary decisions (21 CFR 16.26(b)), initial decisions (21 CFR 12.120), and written reports of hearings (21 CFR 16.60(e) issued by a presiding officer under 21 CFR parts 12 or 16 (unless prepared by an administrative law judge), OCC will complete its review within sixty (60) days;

    - For decisions on appeals from initial decisions (21 CFR 12.125 and 12.130) and final decisions (21 CFR 16.95(b)), OCC will complete its review within sixty (60) days;

    - For all other orders and decisions, OCC will complete its review within thirty (30) days.

6. Effective Date

The guide is effective immediately.

7. Document History - SMG 7712, "Debarment Proceedings"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	03/13/2009	N/A	OC/OPPL/O, AI, HF-22	Frank M. Torti, MD, MPH, Acting Commissioner of Food and Drugs
Revision	02/28/2020	N/A	ORA/OEIO/DE	James M. Sigg, FDA Chief Operating Officer
Change	01/09/2023	Amend OEIO to OIO; DE to DCE	ORA/OPOP/ OPCE/DCE	Steve Tave, Director ORA/OPCE
Change	11/07/2024	Amend ORA to OII; ACRA to ACII; DCE to DFE; CFSAN to HFP	OII/OFOR/OFRO/DFE	CAPT Catherine Beer, Division Director
Change	10/05/2026	Amend DFE to DIRO.	OII/OIPO/DIRO	CAPT Catherine Beer, Division Director

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