

SMG 1410.35

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY

**ISSUANCE OF NOTICES RELATING TO PROPOSALS AND ORDERS FOR
DEBARMENT AND DENIAL OF AN APPLICATION TO TERMINATE
DEBARMENT**

Effective Date: May 6, 2013

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

- A. The Director, Deputy Director, Office of Enforcement and Import Operations (OEIO) Director, Deputy Director, Division of Enforcement, OEIO, Office of Operations, Office of Regulatory Affairs, Office of Global Operations and Policy (OGROP) are authorized to issue the following notices and make all findings required in relation to these notices under Section 306 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 335a):
1. Notices of opportunity for hearing on proposals for mandatory or permissive debarment.
 2. Final debarment orders when opportunity for a hearing has been waived.
 3. Final debarment orders where the person notifies the agency that the person acquiesces to debarment under Section 306(c)(2)(B) of the Act (21 U.S.C. 335a(c)(2)(B)).
 4. Orders granting an application for termination or special termination of debarment under Section 306(d)(3) or (d)(4) of the Act (21 U.S.C. 335a(d)(3) or (d)(4)).
 5. Notices of opportunity for hearing on proposals denying an application for termination or special termination of debarment under Section 306(d)(3) or (d)(4) of the Act (21 U.S.C. 335a(d)(3) or (d)(4)).
 6. Orders denying an application for termination or special termination of debarment under Section 306(d)(3) or (d)(4) of the Act (21 U.S.C. 335a(d)(3) or (d)(4)) when opportunity for a hearing has been waived.
- B. The Director, Office of Scientific Integrity, Office of the Chief Scientist, Office of the Commissioner, are authorized to issue the following orders

and make all findings required in relation to those orders under Section 306 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 335a).

1. Orders denying a hearing and final debarment orders when a person responding to a proposal for debarment fails to present a genuine and substantial issue of fact, or other reason, to justify a hearing, under 21 CFR part 12.
2. Orders granting a request for a hearing and notices of hearing under 21 CFR part 12 on proposals for debarment.
3. Orders granting or denying requests for a hearing, and all orders associated with such grant or denial, under 21 CFR part 12 or 16 in response to a proposal to deny an application for termination or special termination of debarment under Sections 306(d)(3) or (d)(4) of the Act (21 U.S.C. 335a(d)(3) or (d)(4)).

2. REDELEGATION

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

This delegation was approved by the Commissioner on May 6, 2013.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	04/04/2011	N/a	ORA/ORM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	05/06/2013	N/a	OGROP/ ORA/ORM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs