



International Pharmaceutical Excipients Council of the Americas

Debarment and Excipient Manufacturing

Introduction

This document is designed to provide information regarding the debarment provisions of the Federal Food Drug and Cosmetic Act ("FFDCA" or "the Act") so that both drug manufacturers and excipient suppliers have a complete understanding of the law at this time.¹

Summary of Law

Drug manufacturers are forbidden from obtaining services in any capacity from a debarred individual, and drug manufacturers must certify to the Food and Drug Administration ("FDA" or "the Agency") that they did not and will not use in any capacity the services of any person debarred in connection with an application for a drug product.

FDA has not yet developed a clear policy on whether debarred individuals can work at any position within those companies that provide goods and services to pharmaceutical companies (*e.g.*, excipient manufacturers). There is some caselaw that supports the theory that a third party supplier may be able to hire a debarred employee for certain low-level jobs far removed from the ownership, management, production, and quality-control aspects of supplying goods to pharmaceutical companies (*e.g.*, janitor, cook, etc.), but FDA has neither accepted nor rejected this viewpoint.²

Debarred Individuals and Organizations

Under the FFDCA, the Secretary of Health and Human Services is required to debar individuals or organizations who have been convicted of certain felonies from being involved in practices related to the development, approval, importation, or regulation of a drug or food product.³ The FFDCA also gives the Secretary the authority to permissively debar individuals and organizations if they have committed certain felonies,

¹ This White Paper describes the law regarding debarment as of the date of publication. There has been proposed federal legislation that, if passed, would amend the law to provide FDA more ability to regulate the production and distribution of excipients. A change in the regulation status of excipients could impact the application of the law related to debarment and create a situation where anyone debarred would be prohibited from working in any capacity at a company that manufacturers or distributes excipients. Companies should always consult the current state of the law before hiring a debarred individual for any position.

² See *DiCola v. Food and Drug Administration*, 77 F. 3d 504 (D.C. Cir. 1996).

³ FFDCA § 306.

misdemeanors, or engaged in certain actions with individuals who were convicted of crimes that undermine the regulation of drugs.⁴

If FDA discovers that a debarred individual is working for a drug company, it can refuse to accept a drug application, prohibit the individual from providing future services to the company, and/or assess a civil penalty against the debarred individual or company who received these services.⁵

Scope of Debarment

A debarred individual is forbidden from providing services in any capacity to any person that has an approved or pending drug application.⁶ If a debarred individual violates this provision, both the individual and the drug company can be punished.⁷ In order to ensure that companies can check to see whether an employee has been debarred, FDA publishes the name of any person or organization that has been debarred and maintains a list on its website stating all of the individuals that are currently debarred.⁸

As stated above, a company with an approved or pending drug application cannot obtain services from a debarred individual. The Agency interprets "services in any capacity" "to mean any service provided to the drug applicant, regardless of whether related to drug regulation" and this includes providing any "non-drug-related services to a drug product applicant (*e.g.*, as a landscaper, a computer software supplier, an accountant, a telephone repair person, a janitor, an interior decorator, a landlord)."⁹ Thus, FDA's stated interpretation of the Act is that a debarred individual is prohibited in all manners from providing **any** direct services to a drug product applicant. Courts have agreed with this interpretation and stated that "all direct employment by a drug company, whether in the board room or the cafeteria or somewhere in between, comes within the remedial scope of [a] debarment order."¹⁰ Thus, any debarred individuals cannot be a direct employee of a drug company.

Employment of Debarred Individuals by Third Parties

Courts have recognized that it is difficult to determine whether a debarred individual is providing a prohibited service when the debarred individual is employed by a third party that provides goods or services to a drug manufacturer.¹¹ Under current caselaw, one of

⁴ FFDCA § 306(b).

⁵ FFDCA § 306(c).

⁶ FFDCA § 306(a).

⁷ FFDCA § 307.

⁸ FDA/ORO Debarment List available at http://www.fda.gov/ora/compliance_ref/debar (listing all debarred individuals); FFDCA § 306(e).

⁹ FDA, Draft Guidance, Submitting Debarment Certification Statements (September 1998) ("Draft Guidance") at 4 available at <http://www.fda.gov/cber/gdlns/debar.pdf>.

¹⁰ DiCola v. Food and Drug Administration, 77 F. 3d 504, 509 (D.C. Cir. 1996).

¹¹ Id.

the major factors to determine whether the service provided by an employee of a third party supplier is prohibited by the debarment of that employee is whether the "position in question would . . . put [the debarred individual] into regular contact with the management of the drug company."¹² Under this theory, a third party excipient supplier may be able to hire a debarred employee for certain low-level jobs far removed from the ownership, management, and quality control aspects related to the supplying of materials to a drug company (*e.g.*, janitor, cook, etc.).

Caselaw also states that if there is a question regarding the employment of an individual, the individual could file a citizen petition with the FDA to get a prospective ruling from the Agency regarding whether his debarment would forbid his activities.¹³

Debarment Certification

In addition to the restrictions that debarment itself creates, the FFDCA requires that every drug application submitted to the Agency include a certification that the applicant did not and will not use in "any capacity the services of any person debarred . . . in connection with [their] application."¹⁴ FDA stated in its September 1998 Draft Guidance that this certification requirement is required for all New Drug Applications ("NDAs"), Abbreviated New Drug Applications ("ANDAs"), New Animal Drug Applications ("NADAs"), Abbreviated New Animal Drug Applications ("ANADAs"), export applications for certain unapproved products, Biological License Applications ("BLAs"), and supplements to certain drug product applications.¹⁵

FDA has stated that the debarment certification requirement is both retrospective and prospective so an applicant has an ongoing duty to ensure that it will not use any debarred person in connection with its drug application.¹⁶

The scope of the debarment certification is limited to require that an applicant certify that it will not use the services of any debarred person **in connection with their application**.¹⁷ FDA has stated that it considers services that are provided "in connection to an application" to include "services related to the collection, monitoring, evaluation, analysis, or reporting of data or information that appears or is specifically incorporated by reference in the application."¹⁸ Generally, this requirement will restrict debarred individuals from being employees, employees of a contract research organization, consultants to the drug applicant, clinical investigators, or individuals that would contribute data and information to an applicant's Drug Master File ("DMF").¹⁹ In some

¹² Id.

¹³ Id.

¹⁴ FFDCA § 306(k).

¹⁵ Draft Guidance at 1-2.

¹⁶ Draft Guidance at 3.

¹⁷ Draft Guidance at 4-5.

¹⁸ Id.

¹⁹ Id.

ways this certification is broader than the general debarment provisions because FDA interprets the certification to cover all persons that have contributed data or information that appears or is incorporated by reference into the application "regardless of whether such persons submit certifications directly to the FDA or to the applicant."²⁰

Compliance

As FDA has not yet provided guidance on compliance for third parties providers of goods and services, each company that provides excipients and/or active pharmaceutical ingredients to a pharmaceutical company should carefully evaluate the law and determine a course of action that is appropriate for their organization.

Some companies that provide excipients or active pharmaceutical ingredients to pharmaceutical companies have adopted a policy, based on their understanding and interpretation of the law, whereby all new hired individuals are checked against FDA's list of debarred individuals.²¹ FDA has not provided an opinion on whether such actions constitute compliance.

²⁰ Draft Guidance at 3.

²¹ FDA/ORR Debarment List [available at](http://www.fda.gov/ora/compliance_ref/debar) http://www.fda.gov/ora/compliance_ref/debar (listing all debarred individuals).