SOPP 8001.2: Accessing the FDA Lists of Disqualified and Restricted Clinical Investigators, Debarred Individuals, and Firms Under the FDA Application Integrity Policy

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I. Purpose

A. This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff to instruct where to access the lists of Disqualified and Restricted Clinical Investigators, FDA Debarred Individuals, and firms under the Application Integrity Policy maintained on FDA's Internet Web pages.

B. It also instructs CBER staff to review the Public Health Service (PHS) list of individuals who have been Debarred or Suspended by the Department of Health and Human Services (DHHS) Office of Research Integrity.

II. Scope

A. This SOPP applies to:

- the review of applications and supplements (including investigational new drug applications (INDs), investigational device exemptions (IDEs), biologics license applications (BLAs), premarket approval applications (PMAs), and new drug applications (NDAs);
- Inspection and compliance actions;
- Procurement activities;

- Personnel selections (including selection of advisors, consultants, and advisory committee members); and,
- Grant and contract awards and administration.

III. Background

A. The Agency maintains listings of individuals and firms determined to have engaged in various types of misconduct. The lists are divided into the following categories:

- Permanent Debarment From FDA
- Temporary Debarment/Administrative Sanctions
- Investigators Ineligible to Receive Investigational Products ("Disqualified")
- Investigators Agreeing to Some Restriction of their Use of Investigational Products
- Assurances Accepted for the Future Performance of Studies with Investigational Products
- Firms under the Application Integrity Policy

B. The list of debarred individuals is located on the FDA Debarment List (Drug Product Applications) web page.

C. The listing of clinical investigators whom the Agency has determined to be in significant violation of Good Clinical Practice in the performance of clinical trials according to our regulations is located on FDA's Clinical Investigators – Disqualifications Proceedings web page. The list includes the following:

- Clinical Investigators ineligible to receive investigational products (disqualified clinical investigators)
- Clinical investigators agreeing to some restriction of the use of investigational products
- Clinical investigators whose assurances were accepted for future performance of studies with investigational products. (These are investigators whose work was found to be in violation of regulations but on whom no sanctions were imposed because of the assurances given for future compliance. They are not disqualified. Studies performed by the investigators prior to the dates of FDA action should not be considered in support of any sponsor's claims unless the data can be validated. The statement in the regulations that permitted the giving of assurances was removed in 1987.)

D. The list of firms under FDA's Application Integrity Policy is located on the Application Integrity Policy List web page. This list includes firms which were notified that FDA has deferred substantive scientific review of their applications and/or is proceeding to withdraw approved applications.

E. The Agency updates the electronic listing as necessary. The lists are releasable under the Freedom of Information Act.

F. An introductory page at the beginning of each category describes the general nature of the misconduct for firms and individuals listed in that category, as well as the type of sanctions and actions appropriate to the category.

G. Furthermore, PHS maintains a listing of individuals who have been debarred or suspended from activities by any Executive Branch department. A person who is debarred or suspended by PHS shall have a government-wide effect. The list of persons debarred or suspended by the Public Health Service is found on the PHS Administrative Action Report web page.

IV. Definitions

Not Applicable

V. Policy

In order to protect the public interest, it is the policy of the Federal Government to conduct business only with responsible persons. Under Executive Order 12549, DHHS developed regulations (46 CFR Part 76) describing debarment and suspension. Furthermore, FDA maintains lists of clinical investigators who have been or are disqualified or restricted, and firms under the Application Integrity Policy. CBER staff should access the FDA and PHS lists to ensure that identified persons are not involved in prohibited activities, and therefore do not adversely impact agency regulated products.

VI. Responsibilities

A. CBER Staff - check the appropriate FDA lists to ensure that involved individuals or firms are not disqualified, debarred, or restricted.

B. Bioresearch Monitoring Branch (BMB) – during the review of an application, reviews and acts on reports.

VII. Procedures

A. Check the following FDA lists to ensure that involved individuals or firms are not disqualified, debarred, or restricted: **[CBER Staff]**

1. FDA's Clinical Investigators – Disqualifications Proceedings

2. FDA Debarment List (Drug Product Applications)

3. Application Integrity Policy List

4. PHS Administrative Action Report

B. If it is discovered that a party or parties indicated on any of these lists may be involved in matters under consideration by CBER, notify the Office of Compliance and Biologics Quality, Division of Inspections and Surveillance, Bioresearch Monitoring Branch at CBER BIMO Notification. **[CBER Staff]**

C. Review the documentation demonstrating the involvement and coordinate the appropriate follow-up actions. **[BMB] Note:** Follow up actions may involve several FDA and/or PHS organizational units.

VIII. Appendix

Not Applicable

IX. References

A. References below can be found on the Internet:

1. FDA's Clinical Investigators – Disqualifications Proceedings
2. FDA Debarment List (Drug Product Applications)
3. Application Integrity Policy List
4. PHS Administrative Action Report

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Mampilly/Raza/ Monser	Martha Monser, Regulatory Review Document Lead RABOB/DROP/ ORO	October 15, 2025	4	Re-formatted throughout for better clarity.
Monser	N/A	February 25, 2020	3	Technical update to correct hyperlinks, typos, update contact information and to current font/format
OCBQ	Robert Yetter, PhD	April 8, 2005	2	Technical changes to include individuals debarred and suspended by the PHS.
		April 1, 1998	1	Original Version