

# Manual of Standard Operating Procedures and Policies

## Regulatory - General Information - Review

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

SOPP 8001.2

Version #2

Date: April 8, 2005

#### 1. Purpose

Instruct CBER personnel 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 page. Instruct CBER personnel to review the Public Health Service list of individuals who have been Debarred or Suspended by the DHHS Office of Research Integrity.

#### 2. Background

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

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

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.

Furthermore, the Public Health Service 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 the Public Health Service shall have a government-wide effect.

#### 3. 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.

**4. Procedures**

- The FDA lists are posted on the FDA Web page. Center staff should consult these lists during activities that include, but are not limited to the following:
  - 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.
  
- The listing of clinical investigators whom the Agency has found to be guilty of misconduct in the performance of clinical trials according to our regulations is located at the Internet address [http://www.fda.gov/ora/compliance\\_ref/bimo/dis\\_res\\_assur.htm](http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm). 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.)
  
- The list of debarred individuals is located at the Internet address [http://www.fda.gov/ora/compliance\\_ref/debar/default.htm](http://www.fda.gov/ora/compliance_ref/debar/default.htm).
  
- The list of firms under FDA's Application Integrity Policy is located at the Internet address [http://www.fda.gov/ora/compliance\\_ref/aipolist.html](http://www.fda.gov/ora/compliance_ref/aipolist.html). 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.
  
- The list of persons debarred or suspended by the Public Health Service is found at <http://silk.nih.gov/public/cbz1bje.@www.orilist.html>.
  
- If you discover that a party or parties indicated on these lists may be involved in matters under consideration by CBER, information concerning the involvement should be reported to the Office of Compliance, Bioresearch Monitoring Branch, HFM-664. HFM-664 will review the documentation demonstrating the involvement, and coordinate the appropriate follow-up actions that may involve several FDA and PHS organizational units.

**5. Effective Date**

April 8, 2005

**6. History**

Written/Revised	Approved	Approval Date	Version Number	Comment
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

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