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# Manual of Standard Operating Procedures and Policies

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## Communication

### Headquarters Contacts With Regulated Manufacturers During Agency Inspections

SOPP 8103

Version #2

April 9, 1999

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#### 1. Purpose

Describes the steps that the staff within the Center for Biologics Evaluation and Research (CBER) should follow when contacts are received from regulated manufacturers during inspections being conducted by CBER and/or Office of Regulatory Affairs (ORA) staff.

#### 2. Background

Section 351 of the Public Health Service Act (42 U.S.C. 262) provides the regulatory authority for licensure of biological products for introduction or delivery for introduction into interstate commerce. 21 CFR 601.12 requires that licensed manufacturers report important changes in their approved applications to CBER. Changes that have a substantial potential to have an adverse effect on the product must be approved by CBER prior to implementation. As a result of these requirements, there is continuous dialogue between CBER regulatory staff and licensed biological product manufacturers.

CBER also regulates, and reviews submissions for, drugs and devices under separate authorities contained in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq.*) and implementing regulations.

Licensed, biological product manufacturers may also produce within the same facility pharmaceutical or device products that are not subject to U.S. licensure. These establishments will, therefore, be subject to inspection by CBER and/or ORA personnel either jointly or independently. Inspections are conducted routinely as an FDA statutory obligation (i.e., annual or biennial), as a pre-licensing or pre-approval requirement, or due to an assignment requesting a directed inspection.

#### 3. Policy

It is CBER's policy that, when contacted by regulated industry, every effort should be made by staff members to determine if such inquiries are related to an ongoing inspection/investigation or regulatory action. The intent is not to interfere with any ongoing inspection or investigation.

#### 4. Procedure

## **General**

When contacted by representatives of a manufacturer of a product regulated by CBER (either licensed or unlicensed), determine if the call is due to an active and ongoing inspection or investigation being conducted by either CBER or ORA Staff.

### **NOTE:**

Requests for information on a pending license application or supplement are ordinarily not related to an inspection unless the pre-license inspection is ongoing.

## **Calls Related to an Ongoing Inspection/Investigation**

If the call is related to an ongoing inspection or investigation, determine the reason for the inspection and the product(s) involved. Also determine if the inquiry is related to an inspectional issue or an established CBER policy or guideline pertaining to licensing, product review, or scientific/research matter.

If the call relates to an ongoing inspection or investigation by ORA investigators and the inquiry relates to ORA inspectional policy, process, or procedures, advise the caller to contact the District office and speak with the investigator's supervisor or the Director, Investigations Branch. The caller may also be directed to the Division of Inspections and Surveillance, OCBQ at 301-827-6220.

If the inquiry relates to an ongoing inspection or investigation by Team Biologics investigators, the caller should be advised to contact the Director, Office of Regional Operations, at 301-443-6230. The caller may also be directed to the Team Biologics Liaison Staff, 301-827-6191.

## **Calls Related to a CBER Licensing or Product Approval Policy**

If the call relates to a CBER licensing or product approval policy, process, or procedure, direct the caller to the appropriate applications review division in the Office with product review responsibility. If the inquiry relates to a CBER inspectional policy, process, or procedure, direct the caller to the Division of Inspections and Surveillance, OCBQ at 301-827-6220.

## **Calls Related to Completed Inspections or General Inspection Questions**

CBER applications review divisions should provide factual advice concerning CBER policies and procedures, but should not advise the manufacturer concerning how to respond to ORA or CBER investigator(s). Contacts should be promptly documented, and contacts relating to inspectional issues should be reported to the following:

- Blood and Tissue: Division of Inspections and Surveillance, OCBQ who will forward the information to the appropriate District Office, Investigations Branch, as appropriate.
- Other product areas: Team Biologics Liaison Staff

## **Documentation of Contact**

CBER application review and compliance staffs are to prepare written records of telephone conversations during which substantive advice or information is exchanged and discussed and for all meetings with representatives of licensed biological product manufacturers as well as firms that also produce unlicensed pharmaceutical or device products.

In instances when the communication is related to an ongoing inspection or investigation, TBLS or Division of Inspections and Surveillance will forward these records to the CBER, Document Control Center and to the District Office or Team Biologics that has inspectional obligations relating to the firm's manufacturing operations, as appropriate.

**5. Effective Date**

April 9, 1999

**6. History**

<b>Written/Revised</b>	<b>Approved</b>	<b>Approval Date</b>	<b>Version Number</b>	<b>Comment</b>
RMCC	R. Devine	April 9, 1999	2	Incorporates changes resulting from the creation of the Office of Compliance and Biologics Quality. Replaces version 1 issued August 27, 1997
B. Fogle	M. Beatrice	January 31, 1994	1	Reissued as SOPP 8103 in August 1997. No change to Guide content.

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