SOPP 8103: Headquarters Contacts with Regulated Manufacturers during Agency Inspections

Version #3

Effective Date: January 27, 2016

I. Purpose

This Standard Operating Policy Procedure (SOPP) describes the steps that Center for Biologics Evaluation and Research (CBER) staff should follow when contacted by regulated manufacturers during inspections being conducted by CBER and/or Office of Regulatory Affairs (ORA) staff.

II. Scope

This SOPP applies to CBER-regulated products.

III. Background

A. 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.

B. 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.

C. CBER regulates human cells, tissues, and cellular and tissue-based products (HCT/Ps) under section 361of the Public Health Service Act (PHS Act) and 21 CFR part 1271. In addition, HCT/Ps that do not meet all the criteria in section 1271.10(a) are regulated as drugs, devices and/or biologics under section 351of the PHS Act, and/or the Federal Food, Drug, and Cosmetic Act.

D. 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 on a risk based schedule, as a pre-licensing or pre-approval requirement, or due to an assignment requesting a directed inspection.

IV. Definitions

N/A

V. Policy

It is CBER's policy that, when contacted by regulated industry about licensed or unlicensed products 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.

VI. Responsibilities

A. **CBER staff**
   1. Determine if such inquiries are related to an ongoing inspection/investigation or regulatory action
   2. Advise the inquirer to contact the appropriate person

B. Division of Inspections and Surveillance (DIS/OCBQ)
   1. Forward information to the appropriate District Office, Investigations Branch or Team Biologics Branch
   2. Forward the communication records to the appropriate office

VII. Procedures

A. General

1. Determine if the inquiry relates to an active and ongoing inspection of a product regulated by CBER by either CBER or ORA Staff. **[CBER Staff]**
   a. The contact may be a telephone or email contact
   b. Determination should be made by asking the manufacturer's representative
   c. **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.

B. Incoming Communications Related to an Ongoing Inspection/Investigation

1. Determine the reason for the inspection and the product(s) involved. **[CBER Staff]**
   a. Inquiry is related to an inspectional issue or an established CBER policy or guideline pertaining to licensing, product review, or scientific/research matter.
   b. Inquiry relates to an ongoing inspection or investigation by ORA investigators (non-Team Biologics) and the inquiry relates to ORA inspectional policy, process, or procedures

2. Advise the inquirer to contact the appropriate person: **[CBER Staff]**

a. ORA inspectional inquiries (non-Team Biologics): the inquirer should contact the District office and speak with the investigator's supervisor or the Director, Investigations Branch. The inquirer may also be directed to the Division of Inspections and Surveillance, OCBQ at 240-402-9159.
b. Team Biologics inspectional inquiries: inquirer should be advised to contact the Director, Division of Medical Products and Tobacco Program Operations, at 301-796-5521, or the Chief, Team Biologics Branch, at 301-796-2720.

C. Incoming Communications Related to a CBER Licensing or Product Approval Policy

1. Determine the reason for the inquiry and advise the inquirer to contact the appropriate person **[CBER Staff]**
    a. If the inquiry relates to a CBER licensing or product approval policy, process, or procedure, direct the inquirer to the appropriate applications review division in the Office with product review responsibility.
    b. If the inquiry relates to a CBER inspectional policy, process, or procedure, direct the inquirer to the Division of Inspections and Surveillance, OCBQ at 240-402-9159.

D. Incoming Communications Related to Completed Inspections or General Inspection Questions

1. Provide factual advice concerning CBER policies and procedures, but do not advise the manufacturer concerning how to respond to ORA or CBER investigator(s). **[CBER Staff]**
2. Promptly document all contacts **[CBER Staff]**
3. Report all contacts relating to inspectional issues to the Division of Inspections and Surveillance (DIS), OCBQ **[CBER Staff]**
4. Forward the information to the appropriate District Office, Investigations Branch or Team Biologics Branch, as appropriate. **[DIS/OCBQ]**

E. Documentation of Contact

a. Document telephone conversations during which substantive advice or information is exchanged and discussed, including all meetings, with representatives of licensed biological product manufacturers as well as firms that also produce unlicensed pharmaceutical or device products. Refer to *SOPP 8104: Documentation of Telephone Contacts with Regulated Industry* for additional information **[CBER Staff]**
b. Forward the communication records related to an ongoing inspection or investigation to the CBER, Document Control Center and to the District Office or Team Biologics Branch that has inspectional obligations relating to the firm's manufacturing operations, as appropriate. **[DIS/OCBQ]**
c. Forward the communication records related to an ongoing inspection for a pending application or supplement to the Regulatory Project Manager (RPM) in

the appropriate CBER product office for entering in the regulatory database and uploading into CBER's EDR. **[DIS/OCBQ]**

VIII. Appendix

N/A

IX. References

N/A

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
OCBQ	C. Joneckis, PhD	Jan 18, 2016	3	Incorporates changes resulting from FDASIA, new HCT/P regulations, ORA reorganization, new SOPP format, and CBER move to White Oak. Replaces version 2 issued April 9, 1999.
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	Jan 31, 1994	1	Reissued as SOPP 8103 in August 1997. No change to Guide content.