SOPP 8103: Headquarters Contacts with Regulated Manufacturers during Agency Inspections

Version: 5
Effective Date: July 31, 2022

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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 361 of 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 biological products under section 351 of 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-license or pre-approval requirement, or 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.

a. If related to an ongoing inspection/investigation, forward the inquiry to the Division of Inspections and Surveillance (DIS)/Office of Compliance and Biologics Quality (OCBQ) at CBERInspections@fda.hhs.gov (for FDA internal use only) for review and further sharing.

b. If not related to an ongoing inspection/investigation, forward the inquiry to the appropriate product office in CBER for response.

VII. Procedures

A. General

1. Determine if the inquiry relates to an active and ongoing inspection by either CBER or ORA Staff regarding a CBER- regulated product. **[CBER Staff]**

    a. Determination should be made by asking the manufacturer's representative. This contact may be via telephone or email.

    b. **NOTE:** Requests for information on a pending marketing application or supplements are ordinarily not related to an inspection unless the pre-license/pre-approval inspection is ongoing.

B. Incoming Communications Related to an Ongoing Inspection/Investigation

1. To address inspectional inquires for inspections conducted by CBER inspectors, determine the reason for the inspection (i.e., pre-license or pre-approval inspection) and the product(s) involved; direct communications to OCBQ/Division of Manufacturing and Product Quality (DMPQ) for biological products and OBRR for blood or blood components. **[CBER Staff]**

2. To address inspectional inquires for inspections conducted by ORA investigators, advise the inquirer to contact ORA BIO Inspectional Correspondence at orabioinspectionalcorrespondence@fda.hhs.gov and forward communications or summary of phone conversation to OCBQ/DIS at CBERInspections@fda.hhs.gov (for FDA internal use only) for review and further sharing. **[CBER Staff]**

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

1. Forward inquiry to DIS/OCBQ to ensure responses do not conflict with guidance provided during inspection at CBERInspections@fda.hhs.gov (for FDA internal use only). **[CBER Staff]**

E. Documentation of Contact

1. 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]**

2. Forward the communication records related to an ongoing inspection or investigation to the appropriate ORA Division Office that has inspectional obligations relating to the firm's manufacturing operations. **[DIS/OCBQ]**

3. 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 system and uploading into CBER's Electronic Repository. **[DIS/OCBQ]**

VIII. Appendix

N/A

IX. References

A. The following reference may be found on the Internet:

1. SOPP 8104: Documentation of Telephone Contacts with Industry

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Mampilly	Darlene Martin, MS, PMP ORO/DROP Director	July 31, 2022	5	Updated to current procedures.
Monser	N/A (Review by Template Coordinator)	December 11, 2020	4	No Content Change: Technical Update for EDR retirement and to correct typos and update to current font/format
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

Written/ Revised	Approved By	Approval Date	Version Number	Comment
B. Fogle	M. Beatrice	Jan 31, 1994	1	Reissued as SOPP 8103 in August 1997. No change to Guide content.