United States Department of Agriculture
Center for Veterinary Biologics

Standard Operating Policy/Procedures

Processing Administrative Inspection Reviews

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1. Purpose and Scope

The purpose of this document is to give guidance to employees on the procedures for processing Administrative Inspection Reviews (AIRs).

The AIR is an annual review of records on file with the Center for Veterinary Biologics (CVB) for active licensees and permittees to ensure the information is accurate and complete. This annual review provides open communication between the regulatory authority and the regulated entity and facilitates the review of all other submissions. This authority is granted under title 9, *Code of Federal Regulations* (9 CFR), part 116.5(a).

Administrative Inspection Review documents will be electronically sent from the CVB, Inspection and Compliance (IC). Validated information regarding the AIR documents will be electronically submitted by the licensee/permittee for review.

2. Definitions

2.1 Administrative Inspection Review (AIR): A review of information on file with the CVB by the active licensee/permittee to validate accuracy and completeness of the data regarding all aspects of the regulatory process. The components of this review are specific to each licensee and permittee; this may include reports from CVB's databases, certified documents, and a generated list of requested information about the licensee and permittee. These documents are reviewed for sufficiency and authenticated by the licensee's official liaison.

2.2 Licensing, Special Requests, Testing and Information System (LSRTIS) Database: A secure internet system that maintains an integrated, real-time, automated information management system for CVB. Refer to the Program Documentation file located on the CVB Intranet under [redacted] for complete instruction of use.

2.3 LSRTIS – Mail Log: A module within the LSRTIS database in which documents are routed and tracked.

3. Responsibilities

3.1 Biologics Clerk, IC, or those acting in their capacity, shall receive incoming mail.

3.2 Biologics Compliance Assistants (BCAs), or those acting in their capacity, shall finalize any outgoing correspondence. The BCAs are also responsible for LSRTIS updates for personnel information.

3.3 Biologics Specialists (Specialists), or those acting in their capacity, shall provide assistance, when necessary for review of incoming submissions.

3.4 Product Specialist, or those acting in this capacity, shall provide assistance when necessary, and follow up on any information that may be necessary. They are also responsible for updates to serial release information.

3.5 Legal Instrument Examiner (LIE), Program Assistant (PA), File Clerk, or those acting in their capacity, shall perform updates to the appropriate database entries, when necessary. They may contact the Product Specialist, or designates, for any questions or issues with the documents.

3.6 Lead Biologics Compliance Assistants (Lead BCA), or those acting in their capacity, shall verify documents prior to submission to the licensee/permittee and validate the review process has been completed prior to closing the request.

4. Procedures

4.1 Overview

The CVB-IC sends AIR requests to the firms on an annual basis. This request usually consists of verification of reports containing the firms' data pertaining to licensed or unlicensed products. The majority of these reports are produced from the LSRTIS databases.

4.2 Assignment of Administration Inspection Reviews

The Biologics Clerk, BCA, or those acting, will draft AIR documents based upon a set schedule of firms for each month. They will also initiate Mail Log items by following procedures in **ICWI0241**, *Processing Incoming Administrative Inspection Review (AIRs) Documents by CVB*. The Mail Log number is the identifier used to track progress with the AIR.

4.3 Preparation and Distribution of AIR Documents

The process will be completely electronic and up to 11 reports may be generated to be submitted to biologics manufacturers.

Follow **ICWI0242**, *Preparation of Administrative Inspection Review.* Some documents are not submitted to the firms for specified years. The current work instruction will determine the listing of reports to be sent.

4.4 Firm Responsibilities when responding to AIR

4.4.1 All reports and directions will be uploaded and submitted via email to the firm's primary liaison from the cvb.ic.distribution@aphis.usda.gov email address, or other acceptable means. A submittal sheet (**ICFRM1004**) will be attached to indicate the reports that should be included in the submission.

4.4.2 Each report should be reviewed for accuracy by the licensee/permittee in accordance with the instructions provided. The manufacturers should utilize the drawing mark-ups and/or annotations through Adobe comments, or any other suitable means, to indicate the changes needed.

4.4.3 Digital signature will be an acceptable means to authenticate the changes made on the reports.

4.4.4 The submittal sheet and reports, with comments, can be emailed back to the CVB via the cvb.ic.distribution@aphis.usda.gov email address. Hard copies may also be mailed to the CVB, if desired by the manufacturer.

4.4.5 See **CVB Notice 15-08**, *Changes to the Administrative Inspection Review Program*, for more information.

4.5 Review of Incoming Documents for AIR.

See **ICWI0241** for specific processes.

4.5.1 Receipt of Documents

Documents will be submitted electronically to a dedicated CVB email address, cvb.ic.distribution@aphis.usda.gov.

4.5.2 Review of Documents and Updating Information in LSRTIS

Many of the attachments will have corrections that need to be validated and entered into LSRTIS in a timely fashion. Different positions within the Center are responsible for this review and data entry.

4.5.3 If at any time there are questions or issues that need to be brought back to the firm, the Product Specialist, IC, will be the point of contact for CVB personnel.

4.6 Requests for Additional or Clarifying Information

4.6.1 If there are questions regarding the information submitted, the CVB responsible person has two options.

4.6.1.1 Return the item in question to the licensee/permittee requesting more information or a clarification of information. This can be done in an email, which is added to the Mail Log item.

4.6.1.2 Contact the liaison via phone or email to clarify information. If a phone call, attach the phone log to the Mail Log.

4.6.2 This information should be informationally linked to the original Mail Log item for tracking purposes, if a new Mail Log item is created.

NOTE:
1. There will not be an acknowledgement of receipt to the firm if there are no issues in regard to the submission. There may be correspondence with the liaison if there is any follow-up needed, usually within 90 days of receipt.

2. The AIR documents are kept in the CVB Mail Log; therefore, documents will not be routinely printed and/or filed by Records Management. In cases of additional correspondence, files will be kept within the Records Management, Administrative Inspection Review files.