Animal and Plant Health Inspection Service

Veterinary Services

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AIR - Processing Incoming Administrative Inspection Review Documents by CVB

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Section/Area: CVB-WI-IC

Effective Date: 28 Oct 2022

Notes:

Processing Incoming Administrative Inspection Review (AIR) Documents by CVB

Source Document: Title 9, Code of Federal Regulations, part 116.5; CVB-SOP-0028, Processing Administrative Inspection Reviews

The process below outlines steps and responsible individuals related to receiving the AIR from the manufacturers and the steps to route the information within the CVB.

Export Document Examiner

A. Receipt of Incoming AIR documents:

1. Upon receipt of the hard-copy AIR Submittal form (CVB-TEM-0047) that is signed by the firm representative, enter this into the mail log (ML), and scan all documents and upload to the ML item. Route this to the Inspection and Compliance Specialist (ICS) or backup under Review (BCA).
2. Upon receipt of the electronic AIR submission through the NCAH Portal from the firms, the ML is directly routed to Inspection and Compliance Specialist (ICS) or backup under Review (BCA)

ICS

B. Open attachments to determine if updates are needed based on the firm's submission. This step may consist of doing a cursory review to determine if updates have already been completed or if there are inconsistencies noted. This information may be relayed to the individuals assigned in the AIR update child workflows.

C. Send child loop activity "AIR Updates" to responsible individuals for updates, if needed. Include the report assigned and a time frame (i.e., 30 days) for the closure of the activity in the comments area; for example, "Master Seed list. Please respond by October 30, 2020".

To send a child loop, choose "Initiate Child Workflow" with the activity "AIR Updates." Select the first person assigned to a document. In the routing comments, enter the report name(s) assigned to the individual, Initiate, then Yes for "*Are you sure?*".
For subsequent child loops, go to the Pending Other Input tab to find the ML item and open it. Repeat the process to initiate child workflow. A message of "*You are initiating a child loop for an activity that is already open. Do you wish to continue?*" – choose OK

1. **Biologics Compliance Assistant assigned to the firm**
   - Personnel
     a) New APHIS Form 2007: New Employees, New Titles, New Site, Role (Liaison/Alternate, or Sampler)
     b) Updates based on P&I from firm: Phone #, Fax #, Roles (Except Liaisons/Samplers)

2. **Records Management –** or designated back up
   - Active Labels
     a) Inactivations for expired labels, no notifications needed to PEL Reviewer.
     b) Inactivations for other reasons, Prior Notification needed by PEL Reviewer
     c) Must check if inactivating last label for product license. If so, contact Product Manager

   - Special Outlines
     a) If changes needed (typos, etc.), update SharePoint
     b) If Firm has requested inactivations, contact Reviewer prior to inactivating. Special attention should be paid to if an Outlines of Production reference the special outline.

   - Outlines of Production Review
     a) If changes needed (typos, etc.), update SharePoint
     b) If Firm has requested inactivations, contact Product Manager
     c) If Firm has requested Terminations, contact Reviewer. The firm must return product licenses per CVB-WI-0236.

3. **ICS –** or designated back up
   - Master Seeds
     a) For errors noted, confirm with filed Outline of Production.
     If the change matches the Outline, make update to the Record. *Important – each outline associated with this seed should be reviewed for the same correction. If discrepancies – a letter of advice should be drafted.
     If the change does not match the Outline, a letter of advice should be drafted informing the firm that the change cannot be made. Each Outline should be reviewed for the change for the associated seed.

   - Master Cell
     a) For errors noted, confirm with filed Outline of Production
     If the change matches the Outline, make update to the Record. *Important – each outline associated with this cell should be reviewed for the same correction. If discrepancies – a letter of advice should be drafted.
     If the change does not match the Outline, a letter of advice should be drafted informing the firm that the change cannot be made. Each Outline should be reviewed for the change for the associated cell.

4. **Product Manager/Biologics Specialist**
   - APHIS Form 2008s (Form 2008s) without Samples
     a) Double check if samples are rejected from Sample Processing Unit; no action may be needed
     b) The firm may need to be contacted if samples are pending due to prelicensing activities or other reasons.

- Outline of Production Review
  a) If the firm has inactivated licenses, may need to issue Hold releases.
  b) If the firm has not performed its annual review (and not on Hold), may need to issue regulatory letter.

- Special Outline of Production Review
  If the firm has not performed its annual review (and not on Hold), may need to issue regulatory letter.
- Samples without Form 2008s
  The firm may need to be contacted if a 2008 has not been sent in (mainly due to destruction).

5. Legal Instruments Examiner/Program Assistant or designated back up
Follow procedures in CVB-SOP-0090 for the following areas:

- Licensed/Permitted Products
  a) If Firm has requested inactivations, contact Product Manager to ensure products are on Hold. (This is separate from termination requests)
  b) If Firm has requested Terminations, contact Reviewer (For termination procedures, refer to CVB-WI-0236) Check Mail Log for open records for terminations.

- Pre-licensing Activity
  a) Check Mail Log for open records for inactivations
  b) If Firm has requested inactivations, contact Reviewer
  c) Follow procedures in CVB-WI-0343, Checklist for inactivating a Prelicense Product.

- Establishment Site Information
  a) For updates to Phone #/Fax #, update LSRTIS
  b) For updates to addresses/status, review establishment license/APHIS Form 2001/2005 application. If errors appear, contact PEL Reviewer.
  c) If no errors in data entry, contact Product Manager to request firm to resubmit application for new licenses

- Potency References
  a) For errors, confirm with filed Outline of Production and the Reviewer as needed to make a determination.
  b) For reference to be inactivated, confirm with PEL Reviewer prior

Responsible Individuals (AIR Updates)– respond to ML

D. Review information for needed program/LSRTIS updates or comments made by the firms.

E. Enter, Update, and/or Archive appropriate documents

Refer to appropriate guidance for entry or archiving of files

1. Inspection and Compliance Quality Manual
2. CVB Program Information
3. Policy, Evaluation, Licensing (PEL) Reviewer-Support Staff Info
4. PEL Support Staff Manual

F. Once data has been updated, the responsible individual will close their child loop by choosing "Complete My Child Workflow." A return comment may be entered, if needed.

ICS

G. Once all child loops are closed, the ML will return back to the Active queue under current activity – BCA Review.

1. Confirm all updates were made.
2. Ensure the ML of the original outgoing is informationally linked. Complete the follow up dates of original AIR submission.
3. Tag the open ML as "No Outgoing Correspondence".
4. Route the ML to the Product Manager, using the activity "Section Leader, Final Authorization." Hard copy submittal sheet returned to the Product Manager.

Product Manager

H. If questions or if there are actions based on the information submitted by the firm, the Product Manager (or backup) will respond, and the activity will be marked as "Specialist Review."

1. Product Manager, Biologics Specialist, or ICS will contact firms for questions/issues that come up.
2. Send letters to firm, if necessary, with a new mail log item or request more info from submitter (for portal submissions).
3. Informationally link the two mail logs together.

I. Product Manager would send the ML to "Workflow completed, No Records Management" if no further action needed by firm or CVB personnel.

Signature Manifest

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Review for Doc Format

Name/Signature	Title	Date	Meaning/Reason
TIANA BLANCO (TABLANCO)	Quality Management Assistant	25 Oct 2022, 11:27:30 AM	Approved

Section Leader Final Approval

Name/Signature	Title	Date	Meaning/Reason
KENDALL GRABER (KGRABER)	Inspection Section Leader	25 Oct 2022, 04:10:12 PM	Approved

Final Quality Check

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QA Specialist/CVB MC SME	28 Oct 2022, 01:47:57 PM	Approved