



**Animal and Plant
Health Inspection
Service**

Veterinary Services

**Center for Veterinary
Biologics**

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Preparation of Administrative Inspection Reviews

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Notes:

Preparation of Administrative Inspection Reviews

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

Lead Biologics Compliance Assistant (BCA) (or back-up)

A. Runs Administrative Inspection Review (AIR) Reports from LSRTIS 2014

Save Items 1-10 as Adobe PDF. Save Items 11 and 12 as Excel spreadsheet.
Save all documents under the [REDACTED]

The document name should match the listings below. For example, the list of prelicensed products should be named "Est. XXX Pre-Licensing Activity."

For FY 2020 – Items 1-12 should be supplied to the manufacturers; with the exception that item 9 may not need to be included. (Item 9 Licensed/permitted product would overlap in the same information requested in 11 (Outline of Production)).

Search Parameters:

_ 1) Pre-Licensing Activity

Licensing>Product License

Enter: Establishment #

Licenses Status = Prelicense

_ 2) Establishment Employees

Licensing>Establishment Employees

Enter: Establishment #

Only Active Employees = checked

Only Active Employees for Establishment = checked

_ 3) Potency Reference

Testing>References

Enter: Establishment #

Status = Active

_ 4) 2008s Without Samples

Serial Release>Serial Search

Enter: Establishment #

Serial Status = Active

Has No Samples = Checked

_ 5) Master Seeds

Licensing>Master Seeds

Enter: Establishment #

Inventory Status = Active Inventory

_ 6) Master Cells*Licensing>Master Cells**Enter: Establishment #**Inventory Status = Active Inventory***_ 7) Active Labels***Licensing>Labels Search**Enter: Establishment #**Label Status = Active***_ 8) Establishment Information***Licensing>Establishment Sites**Enter: Establishment #**Status = Active***_ 9) Licensed / Permitted Products***Licensing>Product Licenses**Enter: Establishment #**Status = Active***_ 10) Samples without 2008s***Reports & Searching> Sample Search**Enter: Establishment # (be aware, this is the 3rd field)**Sample Type = Final**Sample Purpose = Routine**Has No APHIS 2008 = click to check the toggle box***_ 11) Outlines of Production (Licensed/Permitted Product option)***SharePoint for CVB e-Collaboration Site, File Room, Outlines of
Production – Licensed and Prelicense Products**Open Establishment # folder******The rest needs to be done under the “Classic SharePoint” view****Under the Library Tools, Open Library**Click on “Export to Excel” icon**Run the OP4AIRs macro to format the Excel spreadsheet******Note: Make sure the **DEVELOPER** tab is present at the top of the Excel spreadsheet. To display the Developer tab, click on the File Menu and then select Options from the drop down menu. When the Excel Options window appears, click on the Customize Ribbon option on the left. Click on the **Developer** checkbox under the list of Main **Tabs** on the right. Then click on the OK button.****In the Developer Tab, Choose Visual Basics**File>Import File>OP4AIRs**Documents (then close visual basics)**Open Macros icon in the Developer Tab > Run “OP4AIRs”**Save – as macro-free workbook (if an option is provided)*

_ 12) Special Outlines of Production

SharePoint for CVB e-Collaboration Site, File Room, Special Outlines

Open Establishment # folder

*****The rest needs to be done under the "Classic SharePoint" view***

Under the Library Tab, Click on "Export to Excel" icon

Run the SOcleanup Macro to clean the Excel spreadsheet

In the Developer Tab, Choose Visual Basics

File>Import File>SO4AIRs

Documents (then close visual basics)

Open Macros icon in the Developer Tab > Run "SO4AIRs"

Save – as macro-free workbook (if an option is provided)

B. Creates Mail Log for each Firm

1. Enter:
 - a. Establishment number
 - b. Product Code – NA0000
 - c. Date submitted – today's date (date the report was ran)
 - d. Submission Type – AIR Correspondence
 - e. Tag = No Incoming Submission and Return Action Required by the Firm
 - f. For Non-Portal submissions: Tag = Suppress Response from Portal
 - g. Brief Description – FYxx
2. Click "Create"

C. Creates Outgoing Correspondence, CVB-TEM-0047

1. Add the Date, Establishment information, number of documents and mail log (ML) number
2. Utilize the "Report Title" drop downs to add all the documents to be included in the AIR
3. Postdate the letter and submittal sheet to date to be finalized by Product Specialist.
4. Save as "Est. XXX Submittal Sheet_AIR" in .docx format under F: drive/AIR_In Process_Est#
5. PDF the document
6. Add to ML as Outgoing General Correspondence

D. Determine if Firm is Portal-Enabled

Mail Log Id	176617
Status	Active
Establishment	[REDACTED]
Is Firm Portal Enabled?	No
Products - Serial Number	NA0000
Submission Type	AIR Correspondence
VBI Number	[REDACTED]

1. If Not Enabled – Refer to Step E.2. (*AIR is sent via mail carrier*)
2. If Portal Enabled – Skip Step E.2. (*AIR is sent via Portal*)

E. Attach the Reports to ML

1. Attach the following documents as Outgoing Enclosures: (select more than one at a time if needed)
 - Directions (pdf format) for each report - located on [REDACTED] Reports\Direction Documents
 - Individual applicable reports
2. Non Portal Submissions are also printed out and provided in hard copy

F. Updates to ML

1. Click “Edit”
2. In the “Follow-Up” section:
 - a. Change “Follow-up Action Required” change it to “yes”
 - b. Set the “Follow-up Date” to 60 calendar days from today
 - c. Set the “Follow-up User” to whomever will follow up
 - d. Click “Update”

G. Send to Product Specialist, or designated alternate, as Sign Correspondence (IC)**Quality Review Check: Product Specialist (Lead BCA serves as back-up):**

The QA should be separate from the employee running the reports.

H. Review information in the Outgoing Correspondence:

1. Liaison’s full name is correct
2. In the body, ensure establishment number and establishment name are correct
3. Ensure the number of documents included matches the number attached (not including the directions)
4. Digitally sign the Correspondence

J. Close out the Record

Send to Workflow Completed - No Records Management.