AIR - 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 [URL]
   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 2022 – Only Items – 4, 6, 7, 10, 11, 12, and 13 should be supplied to the manufacturers.

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) Master Seeds
   Licensing>Master Seeds
   Enter: Establishment #
   Inventory Status = Active Inventory

_ 5) Master Cells
   Licensing>Master Cells
   Enter: Establishment #
   Inventory Status = Active Inventory

*_ 6) Active Labels
   Licensing>Labels Search
   Enter: Establishment #
Label Status = Active

*_7) 2008s Without Samples_
Serial Release>Serial Search
Enter: Establishment #
Serial Status = Active
Has No Samples = Checked

_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)_
Open Establishment # folder
Within the Library Tab, Select the “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

- Open Macros icon in the Developer Tab > Run “OP4AIRs”
- Add the date list was ran in Top Left header.
- Save as “【REPLACE WITH NAME】” as macro-free workbook (if an option is provided)
* _12) Special Outlines of Production

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
- Open Macros icon in the Developer Tab > Run “SO4AIRs”
- You may need to make column D smaller to fit on 1 page
- Add the date the list was ran in top left header.
- Save as [Redacted] as macro-free workbook (if an option is provided)

* _13) Combination Packages

Reports & Searching > Reports > Combination Package Relationships
Enter: Establishment #, License Status (Active)
Choose: Combination Packages report

B. Create 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 Manager. Contact the Product Manager for potential dates.
4. Save as “Est. XXX Submittal Sheet_AIR_FY2022” in .docx format under [Redacted]

5. PDF the document
6. Add to ML as Outgoing General Correspondence
D. Determine if Firm is Portal-Enabled

1. If Not Enabled – Refer to Step E.2. (*AIR is sent via mail carrier*). Communication needs to be initiated with BCA that is in the office for that week.
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]
   - 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 the date sending for signature.
   c. Set the “Follow-up User” to whomever will follow up
   d. Click “Update”

G. Send to Product Manager, or designated alternate, as Sign Correspondence (IC)
   The Outgoing Correspondence will be signed (Digitally or hard copy) and uploaded.

H. Quality Review Check: *Inspection and Compliance Specialist (ICS) (Lead BCA serves as back-up)*:
   The QA should be separate from the employee running the reports.

1. Review information in the Outgoing Correspondence:
   a. Liaison’s full name is correct
   b. In the body, ensure establishment number and establishment name are correct
   c. Ensure the number of documents included matches the number attached (not including the directions)
   d. Ensure the attached reports are for the correct manufacturer.
2. **Close out the Record**
   Send to Workflow Completed - No Records Management.