Preparation of 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 ███████████████████████
The document name should match the listings below. For example, the list of prelicensed products should be named "███████████████████████████."

For FY 2019 – Items 1-3, and 5-9 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) 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

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_ 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 ▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮
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Under the Library Tools, Open Library
Click on "Export to Excel" icon
Run the OPcleanup Macro to clean the Excel spreadsheet
In the ▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮
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▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮)
Open Macros> Run OP_Formatting2016

_ 12) Special Outlines of Production

SharePoint for ▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮
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Under the Library Tools, Open Library
Click on "Export to Excel" icon

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Run the SOcleanup Macro to clean the Excel spreadsheet
In the ███████████████
████████████████████████ (██████████
███████████████████████████)
Open Macros> Run SO_Formatting2016

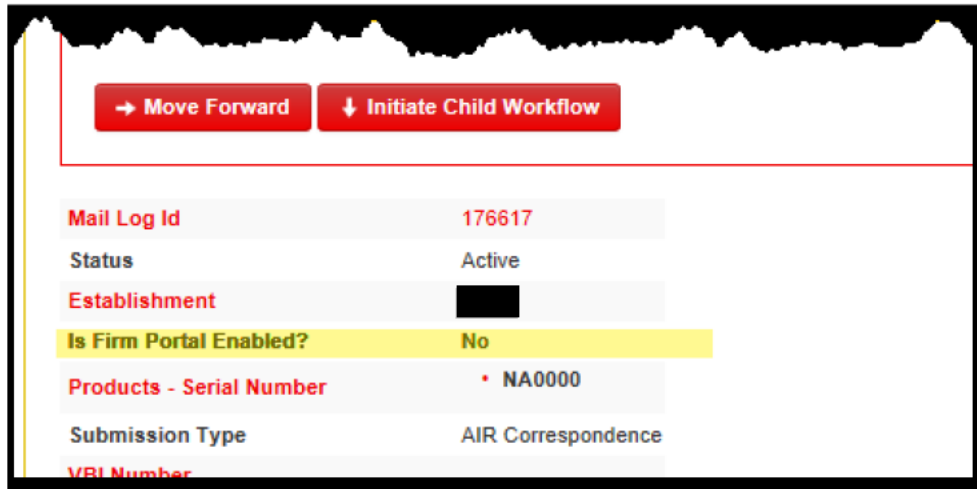**B. Creates Mail Log for each Firm**

   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 and Return Action Required by the Firm
      f. Brief Description – FYxx
   2. Click "Create"

C. Creates Outgoing Correspondence, ICTEM1004

   1. Add the establishment number and mail log (ML) number
   2. Utilize the "Report Title" drop downs to add all the documents to be included in the AIR
   3. Save as "Est. XXX Submittal Sheet_AIR" in .docx format under ██
███████████████
   4. PDF the document
   5. Add to ML as <u>Outgoing General Correspondence</u>

D. Determine if Firm is Portal-Enabled

   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*)

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E. Attach the Reports to ML
  1. Attach the following documents as Outgoing Enclosures:
     - Directions (pdf format) for each report - located on ████████████
       ████████
     - Individual Reports
  2. Non Portal Submissions are also printed out and provided in hard copy
     - Tag the document as Suppress Response from Portal

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 days from today
        c. Set the "Follow-up User" to whoever 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. Move ML to Section Leader – Final Authorization
  1. If Hard Copy – non portal – Send to Section Leaders
  2. If Portal submission – Send to Workflow Completed - No Records Management.