

Mail Receipt, Process, and Distribution for CVB – IC Hard Copy Submission

This document provides guidance for receiving hard copy incoming mail and processing/distributing it to appropriate Inspection and Compliance (IC) Section personnel. It is to be used as a reference tool while performing these duties.

In order to process mail, materials needed are: highlighter, paper clips, letter opener, BCA's Firm Distribution List, each Biologics Compliance Assistant's (BCA's) "Incoming 2008" folder, and a "CVB-IC RECEIVED" date stamp.

Sorting Mail

1. The mail is delivered daily (usually at 10 a.m.) to the CVB mail in-box located at the CVB mail drop site (Cubicle 2N011).
 - a. Mail addressed to the IC Section is sorted from the rest of the mail (refer to the BCA's Firm Distribution list for a listing of IC personnel). (Policy Evaluation and Licensing (PEL) mail should be left to be handled by PEL staff.) IC mail is taken from the CVB mail drop site to the BCA desk with the following exceptions:
 - i. Interoffice envelopes addressed to IC personnel should be hand delivered to the addressee's desk.
 - ii. General mail addressed to IC personnel (credit card statements, fliers, magazines, junk mail, etc.) is placed in the corresponding person's mailbox. General mail is not date stamped.
 - iii. Returned U.S. Postal Service Certified Mail Receipts addressed to IC are date stamped and given to the BCA.
 - b. Mail delivered to the CVB mail drop site that is not IC or PEL mail is placed in the CVB out-box for delivery to the correct mail drop site.
2. Open each piece of mail, sorting into separate piles.
 - a. APHIS Form 2008 (plus any additional documentation provided by the firm regarding the specific Form 2008 it is attached to)
 - b. Export Certificates (APHIS Forms 2017, CLIs)
 - c. Firm Correspondence
 - d. Facility Documents

Processing Mail

1. Form 2008

- a. EDE or BCA reviews incoming Forms 2008. Processing Forms 2008 is a program priority and should be FIRST document processed each day.
 - i. Establishments should submit both an original and a copy of the Form 2008. Attach each original Form 2008 to the copy with a paperclip.

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1. If the original Form 2008 has multiple pages, staple all pages together. Staple all pages of the copy together. Finally, paperclip the original Form 2008 and its copy together, with the original on top.
 2. If the Form 2008 has accompanying correspondence, it should be scanned and entered into LSRTIS Mail Log (see **ICWI0071**, *BCA Entry and Review of Incoming Correspondence*). The Mail Log number should be written in the “Remarks” section (Block 11) of the Form 2008.
 - ii. Stamp each page of each Form 2008 in the “Remarks” section (Block 11) with a “CVB-IC RECEIVED” date stamp.
- b. Review each page of the Form 2008 for the following:
- i. Verify that there are two Forms 2008, an original and a copy. If only one Form 2008 was sent by the firm, make a photocopy of the original and attach it under the original and make note of the error.
 - ii. Skim the results of the tests on the right side of the Form 2008 (Column 9E).
 1. Highlight any results other than “S”.
 - iii. Skim the “Firm Disposition” section (Block 12) of the Form 2008.
 1. Highlight any boxes NOT marked “Eligible for Release.”
 - iv. Skim the “True Name of Product” section (Block 8) at the top of the Form 2008.
 1. If found, highlight the word “Autogenous”
 - a. If the product is autogenous, then skim the box marked “Total No. of Containers” (Column 10A).
 - b. Highlight if number is ≤ 50 .
 2. If found, highlight “For Further Manufacture.”
 - v. Finally, skim the “Remarks” section (Block 11).
 1. Highlight any reference to a VBI number.
 2. If found, highlight “For Further Manufacture.”
 3. Highlight references to inventory transfer information, short dating, etc.
- c. Sort the Forms 2008 according to establishment number (Block 2) by referring to the “BCA’s Firm Distribution List” and place in the corresponding “Incoming 2008” folder for each BCA.

Open each “Incoming 2008” folder and arrange the Forms 2008 in numerical order by firm.

- d. EDE log the Forms 2008 into LSRTIS (see **ICWI1210**, *Log APHIS Form 2008*). If BCAs are logging the Forms 2008, gather all of the “Incoming 2008” folders and distribute for LSRTIS entry so that no BCA enters their own Forms 2008.
- e. After logging, give folder of Forms 2008 to correct BCA

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2. Firm Correspondence

All pages of firm correspondence are scanned and digitally attached to a new Mail Log entry in LSRTIS (see **ICWI0071**).

IF a firm submits a preliminary drawing for a new facility or proposed remodeling of an existing facility; this is entered as General Correspondence with the Subtype of Preliminary facility drawing. The entire submission should be scanned unless the size of the drawing prohibits scanning.

3. Administrative Inspection Reviews

All pages of Administrative Inspection Reviews are scanned and digitally attached to a new Mail Log entry in LSRTIS (see **ICWI0071**). *These are sent directly to the Lead BCA*

4. Certificates of Licensing and Inspection (CLIs), APHIS Forms 2046, 2046-S, 2047, 2047-S)

- a. For those CLIs with a cover letter attached, stamp **only** the cover letter with the CVB-IC date stamp. If no cover letter is enclosed with the CLIs, stamp a sheet of paper indicating “No Cover Letter” with the CVB-IC date stamp.
- b. Give stamped CLI’s to the EDE for entry into LSRTIS (see **ICWI0068**, *Entry and Primary Review of Export Documents (APHIS Form 2017 and Certificates of Licensing and Inspection)*).

5. Export Certificates (APHIS Form 2017)

- a. For those Export Certificates with a cover letter attached, stamp **only** the cover letter with the CVB-IC date stamp. If no cover letter is enclosed with the Export Certificates, stamp a sheet of paper indicating “No Cover Letter” with the CVB-IC date stamp.
- b. Date stamp each Export Certificate on the back in the bottom right corner.
- c. Give stamped Export Certificates to the BOA for entry into LSRTIS (see **ICWI0068**).

6. Facility Documents

- a. The cover letter and all pages of facility documents submitted by firms (legends, blueprints, plot plans, blueprint addendums) are date stamped in the **lower left hand corner**, including all large blueprints.
- b. The cover letter is scanned to be digitally attached to the Mail Log entry.
- c. Log the facility documents into the Mail Log (see **ICWI0071**). After logging the facility documents into the Mail Log, write the Mail Log number in the upper right hand corner of the cover page.

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d. Binder clip or rubber band the entire packet and place in the “pending firm requests” drawer located in the files by the BCA area. File according to the stamp date. For example, if the facility documents are stamped March 5th, then file in the “5” folder. (*Facility documents for prelicense firms are given directly to the Lead BCA.*)