

Reviewing Incoming Form 2008s and Related Serial Release Documents

BCA Checklist for Reviewing Incoming Form 2008s

- Have all copies been stamped in the remarks section with the current date as received by CVB-IC?
- Do the serial numbers match up that are paper clipped together by the OAA for entry?
- Have all “Is”, “NTs”, and comments contained in the “Remarks” section been provided along with supporting documentation to the specialist for initialing off on prior to entry?
- **Have you checked the Form 2008 against the mock?**
 1. Does the Form 2008 have all required section V testing listed?
 2. Is the expiration date within allowed parameters according to the filed OP?
 3. Have all remarks that can not be validated been forwarded on the specialist for review?
 4. If you mock checked the Form 2008 are your initials in the remarks section of the 2008?
 5. Have you validated release of any FFM products contained in the final use product?
 6. All program diseases are to be 100% mock checked, 50% of incoming received that day as well as other Codes put on surveillance by a specialist. See list of 100% mock check item in the Product Inspection Folder on the “I” drive.
- Have you checked the status of other subserials referenced in the remarks section?
- Has the BCA that entered and verified the information on the Form 2008 initialed in the upper right hand corner after all appropriate reviews have been completed?
- After entry of Form 2008s, the BCA is to verify data entry. The BCA shall print a list of incoming Form 2008s and compare it to the hard copy Form 2008s. After verification, the BCA is to initial the List of Incoming Serials and the Form 2008s (upper right hand corner).

BCA Checklist for Reviewing Action Sheets and Form 2008s

- Make sure that the Action Reports reflect the current date.
- Pull Form 2008s for processing according to the Product Code and Serial Number listed on the Action Report.

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- Process the Form 2008s according to the Action Report (disposition, title, date, check test reports from the PEL-Laboratory).
- BCA prepares the Form 2008s and then clips all releases according to the Est. number in the order listed on the Action Sheet.
- BCA submits to the Program Coordinator (PC) for signature.
- PC returns to the BCA assigned that day for serial release.
- BCA who released gives the Form 2008s and the List of Serial Releases to the Lead BCA for verification prior to distribution to the other BCAs.
- The Lead BCA returns all releases to the BCA assigned to release for the day for distribution to the other BCAs according to firm assignments.
- BCAs prepare the Form 2008s for mailing back to the firms.
- BCAs check each others outgoing mail for verification and record this double check on the List of Serial Releases for that day.

Lead BCA's Checklist for Reviewing the List of Serial Releases

- Has the BCA checked and initialed the List of Serial Releases as correct?
- Are all Form 2008s listed on the Action Sheet accounted for in the List of Serial Releases?
- Are all hard copy Form 2008s that are listed on the List of Serial Releases accounted for physically?
- Was the correct product code and serial number released?
- Does the disposition on the Form 2008 correspond with the action sheet?
- Are special notes entered on serials that are needed? (Example: R&R requests, Destroyed Serials, special circumstances, etc.)
- Were the correct test results entered off the Form 2008s when asked for?
- **Prelicensing Serials**
 1. Is the Licensing Action Report included with the release paperwork?

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2. Does the Licensing Action Report match the Action Sheet?
3. Are the Form 2008s marked prelicensing and were the Form 2008s mock checked prior to release?
4. Are the PEL test reports included? Do they correspond with the dispositions?