

Program Coordinator Duties

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Source Document and Date of Issue or Edition: CVB-SOP-0038, *Receiving Adverse Event Reports at the Center for Veterinary Biologics*; CVB-SOP-0032, *Processing Serial Records*

The Program Coordinator, also known as PC, receives telephone calls from the public specifically to adverse event reports (AERs), firm questions, or general questions in regard to the CVB. The PC also is responsible for signing APHIS Form 2008s (Form 2008s) for market release and reviewing other Form 2008s. The PC also moderates the daily Specialist Meetings.

The PC is assigned on a weekly basis by the Product Manager but can be reassigned on a daily basis if needed. Changes to the assigned PC duty should be documented in the IC Calendar, but to enhance communication, the Specialist may inform the BCAs and the CVB Administration Unit. PC duty is covered Monday through Friday, 8 a.m. through 4 p.m.

I. Signing and Reviewing 2008s for Market Determination

1. See CVB-SOP-0032, *Processing Serial Records*, for information on Serial Release processes.
2. Signing and Reviewing Form 2008s
 - a. See CVB-SOP-0032, *Ready for Signature Action in LSRTIS (Specialist and BCA duties)*, for LSRTIS workflow.
 - b. Priority for the PC is signing Form 2008s for market determination. This is usually done prior to 10:30 a.m. for Electronic Notification for Serial Release (ENSR) emails to be sent to the manufacturers. The second ENSR goes out at 3 p.m. daily as well.
3. Reviewing Form 2008s at Specialist Review
 - a. See CVB-WI-0082, *Specialist Review Action within LSRTIS*.
 - b. Next priority is reviewing Form 2008s needing attention (i.e., those with “I” or “NT” conclusions in testing, or those with specific Firm Dispositions or comments). This occurs after the Form 2008s are entered and QA’d for entry requirements (usually after lunch).

II. Phone Calls from Outside the CVB

Phone calls should be documented and recorded in the PhoneLog module within LSRTIS. See the current version of CVB-WI-0141, *Tracking Customer Service using LSRTIS Phone Log*, for instructions on documenting these.

1. Adverse Event Reports – should first determine if Epidemiologist are available, if so, they should field these calls.
 - a. See CVB-SOP-0038, *Receiving Adverse Event Reports at the Center for Veterinary Biologics*, for further information.
 - b. The employee can take the report directly from the caller and enter the information directly into the AER Website.

Program Coordinator Duties

CONTROLLED//PROPIN//BASIC

- c. The employee can direct the caller to the CVB Website. There is currently a shortened website URL for the AER landing page. See the Program Information Management and Security (PIMS) Program Analyst for this URL.

2. FOIA

Callers wanting specifics on previous AERs or other Confidential Business Information (CBI) may have to request this information through the Freedom of Information Act (FOIA) staff. Questions can be directed to the CVB PIMS Section Leader or the caller can be directed to the APHIS FOIA Website. Remind the caller that the licensing information and studies performed are property of the manufacturers (if applicable), and the manufacturers will have the opportunity to review this information for redaction of Confidential Business Information (CBI) prior to release.

Remember that information already shared on the CVB Website or label information is public knowledge and does not have to be directed to FOIA staff.

Current contact:

APHIS FOIA Contact Information

Tonya Woods, FOIA Director
Legislative and Public Affairs
Freedom of Information Act
4700 River Road, Unit 50
Riverdale, MD 20737

Phone: 301-851-4102

Fax: 301-734 -5941

Email: foia.officer@aphis.usda.gov

3. Requests for Licensing of a New Biologic Product

- a. The employee can direct the caller to the CVB Website under Veterinary Biologics/Licensing a Biologic. The caller may want to familiarize themselves with this information prior to speaking with PEL staff.
- b. Take down the caller's information and send this on to PEL by emailing the information to the CVB Inbox: cvb@usda.gov.

4. 116.5 Notifications from Licensed Manufacturers

- a. Be sure to get the following information from the manufacturer:
 - i. Product(s), serial(s), or fraction(s) involved
 - ii. Time frame of event
 - iii. Preliminary suspect event
 - iv. Location of event (especially important if manufacturer has multiple sites)

Program Coordinator Duties

CONTROLLED//PROPIN//BASIC

- v. Manufacturer's actions (internal hold, voluntary stop sale, destruction of the serial(s), or any other action)
 - b. The employee provides the information to the Specialist assigned to the firm, if applicable, and to the Section Leader, Compliance, for concurrence on manufacturer's action.
 - c. If samples have been received and still within the 7 or 3 days at risk window for testing, provide the information to the Laboratory Vet/Micros, [REDACTED]
 - d. Also, determine if testing has been initiated by the Laboratory (do a serial stat). Discuss with the Laboratory if they should stop testing or not.
- 5. Questions from Licensed Manufacturing
 - a. Verbal releases: CVB does not routinely give out verbal releases due to the ENSR. Further information can be found in CVB-SOP-0032, *Processing Serial Records*.
 - b. Other information regarding specific submission questions may be provided to firm personnel who have APHIS Form 2007s on file for such information. The employee should do their due diligence to assure the information can be provided. See a Section Leader or Manager for questions.
 - c. Reagent Requests – send requests to the applicable laboratory.
Inform the caller they may email the APHIS Form 2018 requests to the CVB@usda.gov mailbox; which will then be forwarded to the applicable laboratory.
- 6. Information not under CVB Jurisdiction – examples:
 - a. Owners wanting to know what to do with animals possibly exposed to Rabies
 - i. Inform the owner to contact their local or State Veterinarian
 - ii. Consult with IC Management regarding specific responses
 - b. Information regarding importation of non-biological products
 - i. Inform the caller to contact National Import Export Services (NIES) – Previously NCIE
 - ii. May direct the call to the ePermits Website via the CVB Import/Export Website
 - c. Information regarding NVSL testing
Inform the caller to contact the applicable NVSL laboratory (DVL, DBL, PL). Current contact phone numbers can be found at the NVSL SharePoint site/Contact Info for NVSL Testing (NVSL Disease List)/external list.

Program Coordinator Duties

CONTROLLED//PROPIN//BASIC

7. Media Inquiries

a. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

III. Moderator of Specialist Meetings

1. The PC will moderate the Specialist Meetings, take notes if needed, and consult with Section Leaders if employee absences warrant cancelling the meeting.