United States Department of Agriculture Center for Veterinary Biologics

Standard Operating Policy/Procedure

General Inspection and Compliance Correspondence Guidance

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General Inspection and Compliance Correspondence Guidance

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1. Purpose

1.1 The purpose of this document is to set forth the various procedures established for correspondence not covered elsewhere in the Inspection and Compliance Manual. General Office Guidelines are listed in Chapter 15 of the Inspection and Compliance Manual. Additional policy guidance is located in **CVB-WI-0033**, *Outgoing Correspondence*, **CVB-WI-0101**, *Biologics Compliance Assistant (BCA) Finalization of Correspondence.*; and **CVB-SOP-0049**, *IC Correspondence Procedure*.

1.2 For purposes of this document, the term Specialist refers to individuals performing "Biologic Specialist" activities.

2. Correspondence

2.1 Style, form, and standard nomenclature are determined for this office by the Inspection and Compliance (IC) Program Support Assistant (PSA) based on guidance from the VS Correspondence Manual. Templates for IC correspondence, letters, memorandums, and policy documents are located in the Center for Veterinary Biologics (CVB) Decision Tracker, Quality Management module.

Additional helpful links are:

U.S. Government Style Manual (2008): https://www.gpo.gov/fdsys/search/pagedetails.action?granuleId=&packageId=GPO-STYLEMANUAL-2008

Plain Writing Act: http://www.plainlanguage.gov/index.cfm

2.2 Correspondence is received in many different forms (i.e., verbal, e-mail, etc.). **However, all official CVB-IC correspondence is by letter.** Letters are used for correspondence going outside the department. Letters (carbon copy (cc) or original) sent to an establishment are addressed to the official liaison. In certain instances, the author may choose to include a visible cc: so the recipient of the letter knows that the carbon copy was done.

2.2.1 Notifications to the following: See CVB-WI-5309 for details on who gets notified on specific correspondence types.



3. Templates for Inspection and Compliance Correspondence

3.1 IC Templates for correspondence are located in the Inspection and Compliance Manual or on the CVB Quality Management within Decision Tracker. The templates are labeled as CVB-TEM followed by a number. All IC staff members are responsible for keeping the IC PSA, or others in that capacity, informed of any problems, changes, updates, or new templates needed

If a new template or template change is identified, it is to be brought to the Section Leader. The Section Leader decides whether the change is necessary or not.



3.3 All authors of letters are required to obtain a "Current" template for their outgoing correspondence. Do not work from previous letters.

4. Common Conventions used in the Veterinary Biologics Program

- Only one space after a period or colon.
- There should be two spaces between the state and zip code in the address line in an official correspondence (i.e. Ames, IA 50010).
- Letters or memorandums that are only one paragraph long and less than 10 lines should be double spaced.
- If a correspondence is longer than one page, ensure that the full official name of the addressee is in the header on subsequent pages (i.e. Dr. Jane Doe, Mr. John Smith).

- Use of the possessive tense. Instead of writing: This is in response to Mr. Zamboni's letter dated November 18, 2011, concerning...... Rearrange to: This is in response to the letter dated November 18, 2011, from Mr. Zamboni concerning......
- Est. No. or Est. may be abbreviated everywhere.
- Est., License Number, Product Code, Code, Serial are all capitalized when referring to a specific number.
- To cite the Code of Federal Regulations: For the first use of the Code of Federal Regulations, refer to and format as follows:

title 9, Code of Federal Regulations (9 CFR), section 114.8(d).

Note that *Code of Federal Regulations* is italicized and that "title" and "section" are lowercase. If you are referring to a part (e.g., part 94), "part" would also be lowercase. If you only refer to the CFR once, than you do not need the acronym. For subsequent use, omit the words "section" or "part" if 9 CFR is used: 9 CFR 94.2 or 9 CFR 94; if 9 CFR is not used then cite section 94.2 or part 94.

- When listing the product code in a sentence, place it after the product name. Unless needed for clarification, just use the term "Code" with the product number: Autogenous Bacterin, Code 2051.00.
- The dashes, slashes, dots or other marks should be left in the numbers in all correspondence and reports (exactly as shown on the APHIS Form 2008).
 - Computer entry in a database: remove all dashes, slashes, periods or other marks in serial and license numbers or test and product codes.
- In APHIS correspondence and reports persons are usually referred to by first name, last name and working title: John Doe, Biologics Specialist.
- For letters that are addressed to an audience that is familiar with the CVB, the letter does not have to spell out the Center for Veterinary Biologics prior to use of the acronym.
- The types of inspections are: in-depth (Inspection), follow-up (Inspection), and special (Investigations, etc.). When used in a sentence, they are not capitalized.
- Numbers less than 10 are spelled out (one, two, etc.) while numbers greater than 10 can be written as figures with the exception of time (time/years/hours). For time, use figures (2 years, 2 hours, etc.)

- When referring to time, the correct way to state in a correspondence is a.m or p.m. (lower case).
- When referring to a state within a correspondence, spell out the state with a comma immediately following (i.e. Ames, Iowa, ...)
- A comma should follow after a date within a correspondence (i.e. August 22, 2022, ...)
- When referencing Mail Log numbers withing a correspondence, (ML) may be used as an abbreviation throughout the rest of the document (i.e. Mail Log (ML) 123456...ML 123456)
- Master Seed (Virus or Bacteria) is usually capitalized.
- Product names and scientific names of organisms are handled differently:

Product
Clostridium Chauvoei Bacterin
Canine Parvovirus Vaccine

<u>Organism</u> *Clostridium chauvoei* canine parvovirus

Use italics for scientific words; underline if italics is not available. Abbreviations may be used after the first instance: i.e. *C. chauvoei*

• In letters, refer to either "veterinary biological products" or "veterinary biologics", not "veterinary biologic products".

5. Summary of Revisions

Version .03

- Updated to reflect current correspondence procedures to add additional CVB document rules.
- Updated to current SOP and WI numbers.

Version .02

• Updated to reflect current correspondence procedures.