

**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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## General Inspection and Compliance Correspondence Guidance

### 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 guidance is located in **ICSOP0011**, *Outgoing Correspondence*, and **ICWI0011**, *Outgoing Correspondence*.

**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. The VS Correspondence Manual is located at:

[REDACTED]. Templates for IC correspondence, letters, memorandums, and policy documents are located in the Center for Veterinary Biologics (CVB) Quality Management SharePoint site under templates.

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 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 cc: was done.

**2.3** Memorandums are used for internal and intra-departmental correspondence only. Memorandum types include Standard, Decision, Informational, and Briefing. Memorandums which will be sent outside of the CVB are sent through the applicable Section Leader, the IC Director, and the CVB Director. An em (email) copy may be sent to other persons mentioned in the memorandum. Just as in letters, the memorandums may describe who should receive an em copy. Unlike letters, the em distribution is shown on the original of the memorandum. Memorandums to CVB-Policy, Evaluation, and

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Licensing (PEL) are written to the PEL Director (unless responding to a specific request by a Reviewer). For current templates see the Quality Management SharePoint site, CVB Manual, CVB Templates (CVBTEM).

## 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 SharePoint site. The templates are labeled as ICTEM followed by a number. All IC staff members are responsible for keeping the PSA informed of any problems, changes, updates, or new templates needed. See **QMSOP0001, Section 7, Templates**, *Center for Veterinary Biologics Quality Management System Documents*, for further information.

If a new template or template change is identified, it is to be brought to the PSA. The PSA brings the change to the staff member, usually a Section Leader, assigned to that template. The Section Leader decides whether the change is necessary or not.

**3.2** Work Instructions which contain examples of various regulatory actions/activities for reporting the Weekly Activity Report for the President are in the CVB Quality Management SharePoint site as **ICWI0121**, *Inspection and Compliance Weekly Report to the President Examples*.

**3.3** All authors of letters are required to obtain a “clean” 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.
- Est. No. or Est. may be abbreviated everywhere.
- Est., License Number, Product Code, Code, Serial are all capitalized when referring to a specific number.
- Computer entry in a database: remove all dashes, slashes, periods or other marks in serial and license numbers or test and product codes.
- 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).
- In APHIS correspondence and reports persons are usually referred to by first name, middle initial, last name and working title: John A. Doe, Biologics Specialist.

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- The types of inspections are: in-depth (Inspection), follow-up (Inspection), and special (Investigations, etc.). When used in a sentence, they are not capitalized.
- Master Seed (Virus or Bacteria) is usually capitalized.
- Product names and scientific names of organisms are handled differently:

<u>Product</u>	<u>Organism</u>
Clostridium Chauvoei Bacterin	<i>Clostridium chauvoei</i>
Canine Parvovirus Vaccine	canine parvovirus

Use italics for scientific words; underline if italics is not available.

- 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.
- In letters, refer to either “veterinary biological products” or “veterinary biologics”, not “veterinary biologic products”.
- 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.
- 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.....
- Letters or memorandums that are only one paragraph long and less than 10 lines should be double spaced.
- 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 94.2. 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, then 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.

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**5. Summary of Revisions**

**Version .02**

- The document was updated to reflect current correspondence procedures.

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