Revising CVM Documents for External Stakeholders

FDA is dedicated to ensuring that the information it publishes accurately reflects the Agency's policies and procedures, is of high quality, and is timely. In addition, the Agency is committed to disseminating its public information broadly and promptly.

Documents for external stakeholders published by FDA's Center for Veterinary Medicine (CVM) should reflect the Agency's and the Center's current thinking, policies, and procedures that often change and evolve over time. These changes, especially when they are significant, may require revising documents developed throughout CVM. These SOPs **do not** apply to Guidance for Industry (GFI) or Policy and Procedures (P&P Guidance).

The CVM Communications Staff (CS) works with the rest of the Center to develop, edit, and distribute many CVM documents to the Center's external stakeholders. Often the CS is aware of changes in Center policies, procedures, and thinking, and recognizes the need to revise public documents. The Communications Staff relies on the subject matter expertise throughout the Center for technical assistance on most of these publications. Some documents are initiated in the program offices, and those groups may become aware that changes are necessary. The following procedures are intended to define a process for identifying when documents need to be revised and assigning them an appropriate priority for revision. These procedures apply to updating CVM documents distributed to external stakeholders other than GFI and P&P Guidance.

(1) Director, Communications Staff→Associate Director for Executive Programs→Office Director

The Director of the Communications Staff will identify publications that need to be revised in order to be useful for the public. The Director will provide reasons the revision is needed, will highlight the out-of-date text for quick review, may propose a subject matter expert to assist in the review, and will propose a work plan with timelines for completing the change. This information will be provided to the Associate Director for Executive Programs, who will present this information to the pertinent Office Director.

Within 30 days, the Office Director (or designee) will (1) suggest a plan of action to update the document, or (2) request that it be removed[1] from circulation. The Communications Staff will follow-up until corrective action is agreed upon.

Corrections to CVM documents submitted by CVM stakeholders are subject to the HHS and FDA guidelines.

[1] Removal from circulation would include, but not be limited to: halting distribution of the document; halting citation of the document by other documents, halting reference to the document's contents in response to queries, announcement within the Center of withdrawal of the document; removal from the Home Page with new contact information.

(2) Office Director➔Associate Director for Executive Programs➔Director, Communications Staff

When program offices identify documents that need revision, they will contact the Director of the Communications Staff to develop a work plan for revising the document. The Office will convey the reasons the revision is needed, may highlight the out-of-date text for quick review, will propose a subject matter expert in their Office to assist in the review, and will propose a work plan with timelines for completing the change. The Director of the Communications Staff and the program Office need not involve the Office Director or Associate Director for Executive Programs unless there are resource issues that need resolution.

Criteria for Revising, Modifying, or Updating CVM Documents

Criteria for updating CVM documents distributed to external stakeholders should include, but not be limited to:

- changes in the regulations;
- changes in Agency or CVM policies or procedures;
- publication of new documents;
- changes in personnel or points of contact;
- changes in availability of publications or forms;
- corrections submitted by CVM constituents; and,
- editorial corrections.