



Comments Due October 6, 2008

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. DRAFT-361

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services
Center for Veterinary
Biologics

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TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

FROM: Steven A. Karli
Director, Inspection and Compliance

SUBJECT: Changes to the Administrative Inspection Review Program

I. PURPOSE

The purpose of this notice is to inform interested parties of the changes to the Center for Veterinary Biologics (CVB) Administrative Inspection Review (AIR) program.

II. BACKGROUND

The CVB requests information from licensed firms for the AIR program in accordance with Title 9 CFR Part 116.5(a). Since the inception of the AIR program in 2005, the CVB has received a large volume of submissions from firms. Most of the information the CVB has requested has been repetitive from year to year. In an attempt to simplify the process and alleviate the amount of information required from the firms, the CVB has made modifications to the AIR process.

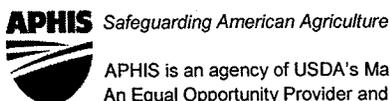
III. GUIDANCE

The AIR will continue to be sent to all licensees each fiscal year (FY); however, effective October 1, 2008 (FY 09), the CVB will initiate a 3-year rotation for the AIR process, as follows:

- First year, FY 09 – condensed version of the AIR Form
- Second year, FY 10 – condensed version of the AIR Form
- Third year, FY 11 – full version of the AIR form

EXCEPTIONS:

- 1) The permittees will continue to receive the full-length version in FY 09, with the condensed version provided the following 2 years (FY 10 and 11)
- 2) All newly licensed and permitted firms will begin with the full version of the AIR form.



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The AIR form will consist of two sections for both versions described above; however, the condensed AIR form will request only a few key items. Attached is a copy of the new AIR form for FY 09, subject to change.

Please note, the CVB will also be including a new focus question to the AIR form each fiscal year. For FY 09, information concerning expiration date determination (Title 9 CFR Part 114.13) will be required. The CVB will be reviewing each firm's expiration date confirmation for all products. This request will include the following:

- list of all licensed products
- date the stability study was completed
- date the final report was submitted to the CVB
- date the CVB responded to the report
- verification that the approval date is in the respective outline of production

A screen fillable AIR form, for licensed firms, will be posted on the CVB website located at: http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml.

Attachment

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