



November 3, 2008

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 08-18**

**United States  
Department of  
Agriculture**

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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**TO:** VS Management Team  
Directors, Center for Veterinary Biologics  
Biologics Licensees, Permittees, and Applicants

**FROM:** Richard E. Hill, Jr. /s/ Byron E. Rippke for  
Director  
Center for Veterinary Biologics

**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 may 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

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](http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml).

Attachment