March 19, 2009

United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

510 S. 17th Street
Suite 104
Ames, IA 50010

(515) 232-5785
FAX (515) 232-7120

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-05

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

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

SUBJECT: Consistency of Avian Safety Testing Parameters in Outlines of Production for Multi-fraction Avian Products

I. PURPOSE

The purpose of this notice is to clarify how firms should complete Part V of the Outline of Production in regards to avian safety tests for multi-fraction products. Conflicting interpretations of Title 9, Code of Federal Regulations (9 CFR) requirements have resulted in a great deal of variability in the designation of safety birds and safety tests in Outlines of Production. This variability exists for both live and killed products.

II. BACKGROUND

The basis for the safety testing of poultry products is laid out in 9 CFR 113.64, 113.100, 113.200, or 113.300 depending on the type of product (live vs. killed or viral vs. bacterial) and in the specific standard requirements.

For multi-fraction products, the requirement for a safety test can be interpreted to be per fraction with each fraction having its own safety test or by product requiring the choice of one of the fraction's safety tests. These two interpretations have resulted in considerable variation in the Outlines for the structure of the safety test.

III. POLICY

For multi-fraction poultry products which have a vaccination-challenge or vaccination-serology potency format for several fractions, all the vaccinated birds should be considered as safety test birds and the safety test parameters should include all vaccinated birds. Since the birds are already in use for the potency test, this does not require additional animal usage. Therefore, each fraction's safety test should be indicated in Section V of the Outline of Production, and the results of safety testing of all vaccinated

birds should be reported on the APHIS Form 2008 for the purpose of serial release. For example, the Outline for Killed Products might read as follows in Section V. B:

1. Observation of all vaccinated potency test chickens will constitute the product safety test.
2. If any untoward reactions attributable to the vaccine occur in the vaccinated chickens, the serial is unsatisfactory.
3. If unfavorable reactions that are not attributable to the product occur in one chicken of a given fraction's test, test results shall be determined by observing the remaining chickens. The test is inconclusive and may be repeated if unfavorable reactions that are not attributable to the product occur in two or more chickens, but the serial is unsatisfactory if the test is not repeated.

For multi-fraction poultry products, which have *in vitro* potency tests, the CVB recommends selecting the most sensitive test for inclusion in Section V.B of the Outline of Production. This will allow the reduction in animal usage without compromising the safety determination for the serial of product. For live products, the Outline would just cite the chosen safety test. The summary of changes page would then indicate the logic for determining which was the most sensitive test. If the Outline is currently prepared in this fashion, the information could be provided at the annual review of the Outline of Production.

IV. ACTION

At the next annual review of the Outlines of Production, firms are requested to update their Outlines for killed poultry products to designate all vaccinates as safety birds for the purpose of serial safety determination. For live multi-fraction poultry products with *in vitro* potency tests, firms are asked to review the applicable 9 CFR Sections to determine which test is most sensitive and alter their Outlines of Production accordingly. Since 9 CFR 114.8(d) requires that Outlines of Production be reviewed not less frequently than once per year, it is expected that firms will have all their Outlines of Production in compliance with these guidelines in 18 months from the date of this notice.