



December 6, 2010

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 10-11

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
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TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Management Team

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

SUBJECT: Obtaining the Testing Plan for Authorized Master Seed/Master Cell
Sample Submissions

I. PURPOSE

This notice informs veterinary biologics licensees, permittees, and applicants of the procedure to obtain the Center for Veterinary Biologic (CVB) Master Seed/Cell testing plan after samples have been submitted.

II. BACKGROUND

Biological Licensees, Permittees, and Applicants test candidate Master Seed and Cell Lots extensively for identity and purity. Upon completion of this testing, the firm submits to the CVB a complete report of the testing as described in Veterinary Services Memorandum 800.109. In response to an acceptable testing report, the CVB authorizes the submission of samples and provides an authorization number. Upon receipt of the samples, a preliminary testing plan is developed. Testing by the CVB may utilize alternative methods of testing from the firm's protocols and may include testing not conducted by the firm.

III. POLICY

Following the authorized submission of candidate Master Seed/Cell, a firm may request in writing the testing plan for the samples. The preliminary testing plan, provided in response to the request, will specify the tests to be conducted on the submitted samples. The firm will be notified when additional tests may be deemed necessary. If a Master Seed/Cell cannot be propagated or is found to be contaminated, testing will be terminated and reported as unsatisfactory.



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