



May 9, 2011

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-12

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
Veterinary Services Management Team

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

SUBJECT: Product Licensing Plans

I. PURPOSE

The purpose of this notice is to announce the availability of Product Licensing Plans for biological products in the pre-approval stage of regulatory review.

II. BACKGROUND

Based on industry best practices, biological manufacturers and importers often create product development plans, with set procedures and goals for achieving regulatory approval. In the past, the Center for Veterinary Biologics (CVB) provided comment on these plans if they were submitted for review. To provide additional assistance to industry, the CVB will begin making available standardized, comprehensive regulatory plans for each product proposed for a Biological Product License or a Permit for Distribution and Sale.

III. POLICY

As early in the licensing/permitting process as possible, the assigned CVB Reviewer works with the applicant to identify requirements to approve a specific product. Minimum information necessary to initiate the Product Licensing Plan includes:

- Draft Outline of Production or equivalent manufacturing and testing information
- Proposed product claims and recommendations for use
- Relationships to existing approved products, if any

The applicant has the opportunity to discuss specific approaches to fulfill each of the requirements and may enter into Critical Path Agreements with the CVB, as desired. A Critical Path Agreement provides formal documentation of an agreement *in principle* regarding the study design or approach needed to fulfill a regulatory requirement. It



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represents a commitment that the CVB will not later alter perspectives on this issue *for this particular product* unless a product quality or animal health concern appears that the CVB did not recognize at the time the issue was assessed. It is not a guarantee of acceptance of all possible study outcomes.

The Product Licensing Plan, maintained in a standardized spreadsheet format, itemizes all required protocols, studies, data, and documentation. The spreadsheet is updated as those items are submitted and reviewed by the CVB, so that it reflects real-time status toward product approval. Although the Plan is intended to be as complete as possible from the beginning, the spreadsheet is a living document and may be amended if repeat studies or addenda become necessary.

Applicants may request a copy of their Product Licensing Plan at any time by contacting their CVB Reviewer.

IV. IMPLEMENTATION/ APPLICABILITY

This policy is effective for all products, domestically manufactured or imported, for which applications are received from this time forward. Applicants also may request a Product Licensing Plan for any product currently in the pre-approval stage of review.

Product Licensing Plans are intended to be interactive between the CVB and the applicant, but the applicant may decide upon the degree of involvement to take in plan development. Applicants are not required to submit their own development plans or any other related documentation that they have not historically provided, but the CVB welcomes the submission of information that will facilitate the compilation of a complete and meaningful Product Licensing Plan.