4.15 Sterile Diluents

The Center for Veterinary Biologics (CVB) does not consider Sterile Diluent to be a veterinary biological product; however, licensees must provide the proper amount of Sterile Diluent with each licensed veterinary biological product when diluent is required for rehydration or dilution of the product.

Guidance and regulations regarding Sterile Diluent are included in:

- Veterinary Services Memorandum 800.74
- 9CFR 112.3, 112.6, and 113.54

Location of manufacture

Sterile Diluents may be prepared in USDA-licensed establishments or unlicensed facilities, provided the conditions outlined in V.S. Memo 800.74 are met. Diluent used in licensed exported products may be manufactured in foreign, unlicensed facilities. In general, diluents for products distributed in the United States should be manufactured in the U.S., due to issues related to inspection of foreign manufacturing facilities. The location of manufacture is specified in a Special Outline filed by the licensee. In the case of diluent prepared in a foreign manufacturing facility that contains ingredients of animal origin, CVB-Inspection & Compliance will arrange for an inspection of the foreign facility prior to importation of any diluent. If an unlicensed facility prepares the diluent, the Special Outline should not receive final approval until CVB-Inspection & Compliance has inspected the diluent manufacturer.

Packaging of diluents

In most cases, the diluent must be packaged with the final container of licensed product. Exceptions exist for Marek's Disease Vaccine, poultry vaccines administered by automatic vaccinating equipment, and product for *in ovo* administration. In these cases, the licensee must provide the diluent, but not necessarily packaged with the vaccine.

Unregulated additives

Some firms sell dye (which may contain stabilizers) for use with poultry biologics administered in the drinking water. Dyes are not regulated by the CVB. Extenders may also be purchased separately by the poultry industry. These products are used to dilute biologics used to vaccinate poultry. Extenders are not regulated by the CVB. Extenders should not be used in studies submitted for licensure.

Dating

The CVB does not require expiration dating on inert diluents, but the firm may include an expiration date in the Special Outline if they wish to do so. Some countries require expiration dating for diluent. Diluent labels may contain an expiration date even if none is specified in the Special Outline.

Some diluents contain biological components, such as bacterial extracts that serve as adjuvant. The reviewer may require, at his/her discretion, an expiration date in the Special Outline for this type of diluent.