



Animal and Plant
Health Inspection
Service

Veterinary Services
Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 23-03

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

FROM: David White
Acting Director

SUBJECT: Change of True Name for antivenin products

I. PURPOSE

The intended purpose of this Notice is to inform licensees, permittees, and applicants of a change in the True Name of antivenin products to transition to the use of the term “antivenom” on labeling, product summaries, and other documents.

II. BACKGROUND

Historically, products containing immune sera against animal venom have been referred to by different synonymous names. The terms “antivenin” and “antivenom”, among others, have been used interchangeably. This inconsistency is a potential source of confusion for the end-user and more consistent, harmonized terminology would be beneficial. The Center for Veterinary Biologics (CVB) assigns a True Name to each biological product per title 9, *Code of Federal Regulations*, part 101.4(d). The True Name serves to define a product and differentiate individual products from others in a clear and consistent manner. In the True Name for such products in the past, CVB has utilized the term “antivenin” to be consistent with both other regulatory bodies and the naming of historical products. While multiple terms continue to be used in modern scientific and medical literature, “antivenom” is the term most used currently by the healthcare and veterinary communities and by regulatory agencies internationally. Through communication with internal and external stakeholders CVB has determined that adoption of the term “antivenom” is most appropriate going forward.

III. ACTION (or POLICY)

CVB will use the new nomenclature for the assigned True Name for all products in the prelicense stage and new licenses going forward. For licensed and permitted products, Outlines of Production, labeling, and other related documents should be revised within 2 years of the posting of this notice. Firms may continue to use “antivenin” in the True Name on international labels only. CVB will reissue a new license or permit for currently licensed and permitted products within 90 days of the date of the notice and will re-issue product summaries upon approval of new

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labeling. It is not necessary for the firm to make a submission to request reissuance of a new license with an updated True Name.

IV. IMPLEMENTATION/ APPLICABILITY

This action is effective immediately.