



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 20-13

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

FROM: Byron Rippke
Director

SUBJECT: Use of Nonproprietary Names from the United States Adopted Names (USAN) Council as True Names for Veterinary Biologic Immunotherapeutics

I. PURPOSE

The intended purpose of this Notice is to inform licensees, permittees, and applicants of a change which will allow the use of nonproprietary names as True Names on labeling, product summaries, and other documents for immunotherapeutic veterinary biologics.

II. BACKGROUND

The Center for Veterinary Biologics (CVB) assigns a formal True Name for each veterinary biologic as the primary method to describe a product per title 9, *Code of Federal Regulations*, part 101.4(d). Additional nomenclature assigning organizations such as the United States Adopted Names (USAN) Program¹ provide an alternative nomenclature system which is applicable to immunotherapeutics regulated by CVB. Manufacturers can request and be assigned a nonproprietary name from the USAN Council; however, nonproprietary names are not currently allowed on CVB approved labeling and product summaries because they are not the CVB assigned True Name. In contrast to the highly descriptive CVB assigned True Name, the USAN nomenclature system assigns a nonproprietary name using a less descriptive nomenclature system, which would be useful for naming an immunotherapeutic approved for treating two or more different diseases. Allowing the use of nonproprietary names assigned by the USAN Council will provide advantages for industry in marketing immunotherapeutics, be helpful to the end user in identifying and prescribing immunotherapeutics, and be consistent with the nomenclature used in scientific publications.

III. ACTION (or POLICY)

CVB will allow the use of a nonproprietary name assigned by the USAN Council for a veterinary biologic immunotherapeutic to become the CVB True Name. This will allow the manufacturer to use the nonproprietary name on labels and product summaries. The use of nonproprietary names will be limited to immunotherapeutics

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such as monoclonal antibodies and does not apply to other classes of products such as vaccines, bacterins, toxoids, serum-derived products, and diagnostic test kits. The use of USAN nonproprietary names is voluntary, as CVB will continue to create and assign product True Names following the existing nomenclature system.

CVB will assign a True Name during the prelicense process. Firms may request that the assigned True Name be replaced with the USAN nonproprietary name anytime during the prelicense process once they have obtained USAN approval. The request for the name change must include the formal USAN response assigning the USAN nonproprietary name. If the request is accepted by CVB, the process of changing the True Name to the USAN nonproprietary name would occur at or prior to licensure. The Outline of Production and Labels must be changed to be consistent in representing the USAN nonproprietary name as the True Name. Preferably, firms should begin the process of obtaining a USAN nonproprietary name early in the licensure process, so that the transition from the assigned True Name to the USAN nonproprietary name as the new True Name can be concluded by the time of licensure.

For products that are initially licensed or permitted with the CVB assigned True Name, firms may request that the CVB assigned True Name be replaced with the USAN nonproprietary name at any time after licensure/permitting. If the proposal is accepted by CVB, the USAN nonproprietary name will become the new True Name for the product. CVB will reissue the license or permit with the USAN nonproprietary name as the new True Name for the product. Firms must update labels, the Outline of Production, and other related documents within one year of reissuance of the license. CVB will re-issue product summaries upon approval of new labeling. Since these products will have already been marketed with the True Name assigned at licensure or permit issuance, firms may use both the assigned True Name and the USAN nonproprietary name on labels during the one-year transition period. After a maximum of one year, the True Name assigned at licensure or permit issuance must be removed from labels, Outline of Production and other related documents.

IV. IMPLEMENTATION/ APPLICABILITY

This policy is effective immediately.

References

1. <https://www.ama-assn.org/about/united-states-adopted-names>