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United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-23

Subject: Chimera as an Additional Naming Convention for
Live Recombinant Products

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

I. PURPOSE

This notice serves to inform licensees, permittees, and applicants of an additional descriptive term in the True Name of products containing recombinant master seeds. The use of “Chimera” in addition to the term “Vector” will be utilized. A definition of the term “Chimera” versus “Vector” follows.

II. BACKGROUND

Previously licensed live recombinant products have utilized the word “Vector” in the True Name to define a backbone that carries non-essential foreign genes that express immunogenic proteins. Therefore, the organism that receives the foreign genes is replication competent without the gene inserts.

Constructs that (1) are not replication competent when the recombination event is reversed and (2) are comprised of segments from two or more genomes in which each segment consists of multiple essential genes are sometimes referred to as chimeras. The working definition of the term “chimera” is a new hybrid microorganism created by joining nucleic acid fragments from two or more different microorganisms in which each of at least two of the fragments contain essential genes necessary for replication. For these types of microorganisms, the term “Chimera” will be used in the True Name in the place of “Vector”.

Since this substitution generally requires that the two microorganisms be closely related, the resulting construct will be named by the family name (rather than the two individual microorganisms) followed by the word “Chimera”.

The initial part of the True Name will reflect the target disease for which a claim for protection has been approved. This will be set apart by a comma and followed by the family name of the parental strain and the word “Chimera”.



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III. ACTION

When submitting the license application (APHIS Form 2003) for products based on a chimeric construct, please indicate the disease and the family name followed by the word “Chimera” for the True Name (Box 4).

When submitting labeling for this type of product, the circular should clearly designate the species of the two parental microorganisms combined to construct the chimera.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics