#187

Guidance for Industry

Regulation of Intentionally Altered Genomic DNA in Animals

Draft Guidance

(This guidance is a revision of Guidance #187, "Regulation of Genetically Engineered Animals," which has been revised to update information concerning the products of different technologies used to produce such animals, and to provide new weblinks.)

Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the Docket No. FDA-2008-D-0394.

For further information regarding this document, contact Laura R. Epstein, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 301-796-8558, email: Laura.Epstein@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either http://www.fda.gov/AnimalVeterinary/default.htm or http://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
January 2017

Table of Contents

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction and Background

FDA is issuing this draft revised Guidance for Industry to clarify its approach to the regulation of intentionally altered genomic DNA in animals. This guidance addresses animals whose genomes have been intentionally altered using modern molecular technologies, which may include random or targeted DNA sequence changes including nucleotide insertions, substitutions, or deletions, or other technologies that introduce specific changes to the genome of the animal.[1,2,3] This guidance applies to the intentionally altered genomic DNA in both the founder animal in which the initial alteration event occurred and the entire subsequent lineage of animals that contains the genomic alteration.

Recombinant DNA (rDNA) technology has been used for the past 40 years to intentionally alter traits in microorganisms, plants, and animals (Cohen and Boyer 1973). Various agencies across the US government (USG) have provided guidance and regulation to affected stakeholders

[1] FDA used the term "genetically engineered" (GE) to describe the animals within the scope of current Guidance for Industry #187. The term "GE" does not suit the discussion in this revised draft guidance because this draft guidance's scope includes animals whose genomes have been intentionally altered with new technologies. The term "transgenic" is also not used for the same reason, except for citation of earlier documents.

[2] In Draft Guidance for Industry #236, "Regulation of Mosquito-Related Products," FDA has proposed to clarify that the phrase "articles (other than food) intended to affect the structure or any function of the body of man or other animals" does not include articles intended to prevent, destroy, repel, or mitigate mosquitoes for population control purposes. Instead, such products are pesticides regulated by the Environmental Protection Agency (EPA) (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM533600.pdf).

[3] The term "modern molecular technologies" does not include selective breeding or other assisted reproductive technologies, including random mutagenesis followed by phenotypic selection.