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Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs (1/15/2009)

"...FDA defines 'genetically engineered (GE) animals' as those animals modified by rDMA techniques, including the entire lineage of animals that contain the modification. The term 'GE animal' can refer to animals with heritable rDMA constructs..."

<u>The rDNA construct</u> (an article) in a GE animal that is intended to affect the structure or function of the body of the GE animal, regardless of the intended use of products that may be produced by the GE animal, meets the FFDCA (Federal Food, Drug, and Cosmetic Act) drug definition.

Recombinetics' gene-edited animals DO NOT contain rDNA



Generally Recognized as Safe: GRAS

Assertion: Gene-edited animals contain DNA that is IDENTICAL to what is widely consumed and generally recognized as safe (GRAS)

GRAS exemptions are granted for substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or through experience based on common use in food) to be safe under the conditions of their intended use.

Self-affirmed. The manufacturer of this chemical or substance had performed all necessary research, including the formation of an expert panel to review safety concerns, and is prepared to use these findings to defend its product's GRAS status.

