

**ABSTRACTS**  
**\* Author Presenting Paper**

**80 An FDA perspective on the regulation of genetic engineering in animals.** J.C. Matheson\*, *US FDA Center for Veterinary Medicine, Rockville, MD.*

FDA regulates the products of biotechnology, not biotechnology processes. Products of animal biotechnology are regulated according to existing product categories.

Animals are used as manufacturing sites for drugs, biologicals and diagnostics. The success of the biomedical industry has led to an increased use of large animal species that are also commonly used to produce food. These animals, which are sometimes transgenic, are used for producing immunochemical agents, like antibodies; biological agents, like vaccines; and to produce drug products in milk or blood (biopharming). Depending upon how the product is used, it may be regulated as a medical device, a biologic, or drug for humans or animals.

The use of food-producing species in the production of diagnostic kits and other biomedical products includes a special responsibility to plan for the ultimate disposition of culled animals, their offspring and meat, milk, and eggs from these animals. As a general matter, use of animals from biomedical research or production facilities as sources of human food or as feed ingredients for other animals is considered by FDA not to be a safe means of disposition. However, FDA may consider specific requests for special circumstances.

Animals are also recipients of biotechnology products. Some biotechnology products for animals are designed to provide animal health or increased productivity benefits for animals and, therefore may require approved new animal drug applications. Some are designed to increase the nutrition value of food for humans or to change the functional characteristics of a food product derived from animals and may require approval as food additives.

These products work through genetic modifications, either by somatic cell therapy or by heritable germ-line modifications. Both types of genetic modifications are being investigated to change the structure or function of animals to improve animal health or increase productivity. In those cases, gene therapy and germ-line transgenics are simply additional methods to deliver animal drug products, like growth hormones.

**Key Words:** Biotechnology, Regulation, Animal drugs