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Animal Biotech Products to Include Novel Medicines and Better Foods
FDA Finalizes Regulatory Guidance Governing Genetically Engineered Animals

Washington, D.C. (January 15, 2009) – Breakthroughs in human health care and food production from the genetic engineering of animals are closer to being realized now that the U.S. Food and Drug Administration (FDA) is finalizing a regulatory system.

The FDA announced today it will make final the guidance describing a regulatory framework for governing genetically engineered (GE) animals. The draft guidance was initially issued on September 18, 2008, and the agency took public comments until November 18, 2008.

Dr. Barbara Glenn, Managing Director for Animal Biotechnology at the Biotechnology Industry Organization (BIO) released the following statement expressing the industry's support for the FDA's actions today:

“BIO is pleased that the FDA has made final the first U.S. government regulatory guidance governing genetically engineered animals. This system will ensure the products made available through this science will go through a rigorous and transparent review process before being approved for the marketplace.

“Through years of scientific research with goats, pigs, sheep, chicken, fish and cattle, new products have been developed that hold the promise of advancing human health. GE animals can produce pharmaceutical proteins and replacement tissues in their milk, eggs, and blood, which can be used in the treatment of human disease. In addition, research is being conducted to produce transplant organs in pigs that may be a source of organs for humans.

“Animals that are genetically engineered can have improved food production capabilities, enabling them to help meet the global demand for more efficient, more nutritious, higher quality and lower-cost sources of food.

“GE animals can also contribute to improving the environment by consuming fewer resources and producing less waste. In addition, genetic engineering offers tremendous benefits to the animals themselves by imparting disease resistance traits and enhancing their overall health and well-being.

“These benefits will not be realized without a transparent and rigorous science-based regulatory process that assures safety for consumers, animals and the environment.

“BIO supports the FDA process for regulating GE animals and their products, which is based on the Food, Drug and Cosmetic Act’s New Animal Drug (NAD) framework. The process is consistent with international guidelines established last year by the Codex Alimentarius Commission. Codex standards are recognized as international benchmarks and act as models for governments in the establishment of their own food safety policies.

“BIO and its members engaged in animal biotechnology support a strong federal regulatory system to oversee development and approval of all genetically engineered (GE) animals and the products derived from them. The industry’s goal is to ultimately provide to the marketplace products that have been approved as safe and beneficial for society.”

* The potential of GE animals has been detailed in the report, *Genetically Engineered Animals and Public Health – Compelling Benefits for Health Care, Nutrition, the Environment and Animal Welfare*, released last year. For more information, visit BIO’s GE Animals Web Resource Page at www.bio.org and visit FDA’s GE Animals Web Resource Page at www.fda.gov/cvm/GEAnimals.htm.

About BIO

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world’s largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

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February 9-11, 2009
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Milan, Italy

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April 13-15, 2009
New York, New York

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July 19-22, 2009
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