## Animal & Veterinary

# FDA RESPONDS TO CITIZEN PETITION ON BST

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On April 20, 2000, FDA responded to a Citizen Petition (Docket No. 99P-4613) from Mr. Robert Cohen concerning Posilac®, the only FDA-approved recombinant bovine growth hormone (rbGH) product for increasing milk production in dairy cattle. FDA's Center for Veterinary Medicine (CVM) approved Monsanto Company's rbGH product, Posilac in November 1993 after a comprehensive review of the product's safety and efficacy, including human food safety.

The petition requested that FDA rescind the approval of Posilac, and immediately remove it from the market based on "new evidence" that the product poses "serious health consequences for human consumers." Later, Mr. Cohen amended this petition, most recently on December 2, 1999. As amended, the petition raised three primary issues in support of the request for withdrawal of Posilac. These issues are as follows: (1) that a recently reported increase in serum levels of insulin-like growth factor-1 (IGF-I) in humans following milk consumption represents absorption of dietary IGF-I, invalidating a basic premise of FDA's safety assessment and proving that IGF-I in milk represents a hazard to human health; (2) that Monsanto changed the manufacturing process for rbGH after the studies supporting the New Animal Drug Application (NADA) were completed, thereby invalidating the research used to support the approval; and (3) that the 90-day toxicology study and/or the information derived from the additional 90 days of the study demonstrate both that rbGH is absorbed and that it is not safe.

In response to Mr. Cohen's petition, the Agency stated that these arguments do not demonstrate any human food safety issue related to the use of Posilac. Therefore, the petition requesting withdrawal of the approval of Posilac was denied.

An electronic copy of FDA's response to Mr. Cohen's petition is available on the Internet Home Page of FDA's Center for Veterinary Medicine. Readers who do not have access to the Internet, may file a Freedom of Information (FOI) request for this response to: Food and Drug Administration, Freedom of Information Staff (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. FOI requests also may be sent via fax to: (301) 443-1726.

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