



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

FEB 1 2000

Food and Drug Administration  
Rockville MD 20857

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Ms. Heather Johnston  
1517 Mulberry Dr.  
Libertyville, IL 60048

Dear Ms. Johnston:

This is in response to your letter dated January 10, 2000, concerning the use of recombinant Bovine Growth Hormone (rBGH) in dairy cows.

Thank you for sharing your concerns on this issue. The use of drugs in livestock and poultry is strictly regulated. Before any drug intended for use in animals is approved, it must undergo extensive chemical and toxicological testing which must demonstrate that the food from these animals is safe for human consumption.

Bovine somatotropin (bST) was approved by the Food and Drug Administration (FDA) in 1993. The recombinant, or genetically engineered form of bST (rbST) is virtually identical to a cow's natural somatotropin, a hormone produced in its own pituitary gland that stimulates milk production. Since bST is a protein-based hormone, rbST is broken down during digestion, which makes it biologically inactive and incapable of having any effect in humans or animals. Over 120 studies were reviewed by FDA scientists that examined the safety of milk and meat from dairy cows treated with rbST. They concluded that there was no increased health risk to consumers.

I am enclosing materials that provide further information concerning this matter. In addition, I am forwarding your letter to Dockets Management Branch for inclusion in Docket Number 98P-1194 -- Withdrawal of NADA Approval for Posilac -- rBGH. Please visit our Internet Home Page at <http://www.fda.gov/cvm>.

Sincerely yours,

*Karen A. Kandra*  
Karen A. Kandra  
Consumer Safety Officer  
Center for Veterinary Medicine

Enclosures

98P-1194

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