



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUN 03 2004

Mr. Robert Cohen  
560 Oradell Avenue  
Oradell, NJ 07649

Re: Citizen Petition #04P-0067

Dear Mr. Cohen:

This is a tentative response to the citizen petition (#04P-0067) which you submitted to the Food and Drug Administration (FDA) on February 6, 2004. The citizen petition requests that the Center for Veterinary Medicine (CVM) of the FDA revoke the regulation that approved POSILAC, Monsanto's bovine growth hormone.

According to the administrative regulations at 21 CFR 10.30, FDA is required to respond to a citizen petition within 180 days. FDA is currently considering the issues raised in your citizen petition. Because of the complex nature of the action requested, which requires careful and thorough scientific, legal and policy consultation, analysis and coordination within the agency, FDA will require additional time to issue a final response to your citizen petition. Upon our resolution of these outstanding issues, FDA will issue the final response.

Sincerely yours,

Stephen F. Sundlof, D.V.M., Ph.D.  
Director, Center for Veterinary Medicine

cc: HFA-305 (Docket 04P-0067)

2004P-0067

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