

Food and Drug Administration Rockville MD 20857

April 10, 200764 7 APR 12 P3:05

Mr. William Rostov Mr. Joseph Mendelson, III The Center for Food Safety 660 Pennsylvania Avenue, S.E., Suite 302 Washington, DC 20003

Re: Docket No. 2006P-0415

Dear Mr. Rostov and Mr. Mendelson:

This is a tentative response to the Citizen Petition (2006P-0415) filed on behalf of the Center for Food Safety, with the Food and Drug Administration (FDA) on October 12, 2006, pursuant to the Federal Food, Drug, and Cosmetic (FFD&C) Act (21 U.S.C. 321 et seq.). The petition addresses the regulation by FDA of animal cloning and requests that several actions be taken by the agency with regard to this issue.

Pursuant 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 by your citizen petition. However, the agency will require additional time to issue a final response because of the complexity and the number of issues raised in your petition.

FDA will issue a final response to your citizen petition after completing the analyses of all of the legal and policy issues.

Sincerely yours,

Bernadette Bunham DVM, PhD.

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

cc: HFA-305 (Docket No. 2006P-0415)

2006P-0415

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