



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 25 2008

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Richard S. Wyde, Esq.
Roberta Kraus Wyde, MPH, Ph.D.
4048 East Mercer Way
Mercer Island, WA 98040

Re: Docket No. 06P-0126

Dear Mr. and Dr. Wyde:

This is a tentative response to the Citizen Petition (06P-0126) filed with the Food and Drug Administration (FDA) on March 20, 2006, pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3211 et seq.). The petition requests that FDA take a variety of actions against an animal product that is manufactured by S&M NuTec LLC and that is known as a "Greenie." The petition maintains that this product ultimately led to the death of your pet dog.

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,

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

cc: HFA-305 (Docket No. 06P-0126)

2006P-0126

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