



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 4, 2013

Elisabeth Holmes
Staff Attorney
Center for Food Safety
660 Pennsylvania Avenue, SE
Suite 302
Washington, D.C. 20003

Re: Docket No. FDA-2013-P-0351

Dear Ms. Holmes:

This is a tentative response to the Citizen Petition (FDA-2013-P-0351) filed with the Food and Drug Administration (FDA) on March 15, 2013, on behalf of the Center for Food Safety and the Institute for Agriculture and Trade Policy.

The petitioners request that the Commissioner of Food and Drugs promulgate regulations prohibiting antibiotic use in the production of distillers grains sold as animal feed for food-producing animals. Alternatively, the petitioners request that antibiotics used in distillers grains production be regulated as new animal drugs.

Pursuant to the administrative regulations at 21 CFR 10.30, FDA is required to respond to your petition within 180 days. We are currently considering the issues raised by your citizen petition. However, we 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 raised in the petition.

Sincerely yours,

Bernadette M. Dunham, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

cc: David Wallinga, M.D.
Food and Health Program
Institute for Agriculture and
Trade Policy