



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

December 8, 2006

Mr. Daniel E. Troy  
Sidley Austin LLP  
1501 K Street, N.W.  
Washington, DC 20005

Re: Docket No. 2006P-0249

Dear Mr. Troy:

This is a tentative response to the Citizen Petition (2006P-0249) filed on behalf of Bayer HealthCare, Animal Health Division, with the Food and Drug Administration (FDA) on June 13, 2006, pursuant to the Federal Food, Drug, and Cosmetic (FFD&C) Act (21 U.S.C. 321 et seq.). The petition addresses potential future abbreviated new animal drug applications under sections 512(d) and 512(n) of the FFD&C Act (21 U.S.C. 360b(d) and (n)) for copies of Bayer's Baytril 100 Injectable Solution, which is the subject of an approved New Animal Drug Application.

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. 2006P-0249)

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