DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 28 2006

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Michael Bannester
1720 W. Wabansia Avenue
Chicago, IL 60622

Re: Docket No. 2006P-0089

Dear Mr. Bannester:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on February 27, 2006. Your petition requests that the Agency stay approval of all supplements to biologics licenses issued to Genentech (BLA #103705) and Biogen (BLA #103737) for Rituxan (Rituximab).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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