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March 17, 2006

By First-Class Mail

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Re: Docket # 2006P-0089

Dear Ms. Butler:

On February 27, 2005, Michael Bannester submitted a citizen petition requesting that the agency stay approval of all supplements to biologics licenses issued with respect to RITUXAN (rituximab). On behalf of Genentech, Inc. (Genentech), which is the co-developer and -marketer of RITUXAN, I am writing to oppose the grant of this petition.

The petition has been rendered moot by FDA's approval on February 28 of an sBLA supplement for the use of RITUXAN in rheumatoid arthritis. For this and other substantial reasons, we respectfully request that the petition be denied.

In accordance with 21 C.F.R. § 10.30(d), Genentech intends to submit more comprehensive written comments opposing the petition by April 28, 2006, which is 60 days from the petition's filing date.

Sincerely yours,

Coleen Klasmeier

CK:dlf
cc: Scott Gottlieb, M.D.
Steve Galson, M.D.
Robert Temple, M.D.
John Jenkins, M.D.
Robert Meyer, M.D.
Bob A. Rappaport, M.D.
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