

July 30, 1998

Mylan Pharmaceuticals, Inc.
Attention: John P. O'Donnell, Ph.D.
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 13, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ranitidine Tablets USP, 150 mg (base) and 300 mg (base).

Reference is also made to your amendment dated May 1, 1995; April 12, and November 19, 1996; January 30, April 7, and June 26, 1997; and April 9, and June 19, 1998.

The listed drug product referenced in your application is subject to a periods of patent protection which expire on June 4, 2002, (patent 4,521,431) and May 13, 2008 (patent 4,880,636). Your application contains patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Ranitidine Tablets, USP will not infringe on the patents or that the patents are otherwise invalid. You further informed the Agency that Glaxo, Inc. initiated a patent infringement suit ('431 patent) against you in the United States District Court for the District of Maryland (Glaxo Wellcome Inc. and Glaxo Group Limited v. Mylan Pharmaceuticals, Inc., Civil Action No. AMD96-3477). The suit was subsequently moved to the United States District Court for the Eastern District of North Carolina [Civil Action No. 97-CV-252-BO(2)]. You have also notified the Agency that on March 19, 1998, the North Carolina court issued a Stipulation and Order of Dismissal officially terminating the litigation with Glaxo Wellcome Inc. and Glaxo Group Limited. In accord with 21 CFR 314.94(a)(12)(vi), Mylan is not required to submit a patent certification for the '636 patent.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Ranitidine Tablets USP, 150 mg (base) and 300

