DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-856

Food and Drug Administration
Rockville MD 20857

MAR 1 2005

IMPAX Laboratories, Inc.
Attention: Mark C. Shaw
30831 Huntwood Avenue
Hayward, CA 94544

received
03/01/2005

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 30, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dantrolene Sodium Capsules, 25 mg, 50 mg and 100 mg.

Reference is also made to your amendments dated April 14, June 9, June 30, August 30, September 29, November 5, December 3, and December 8, 2004.

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 Dantrolene Sodium Capsules, 25 mg, 50 mg and 100 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Dantrium® Capsules, 25 mg, 50 mg, and 100 mg, respectively, of Procter and Gamble Company). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these

submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research