confidential
Bill Riker
Impax
May 16, 2016 19:09

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 40-156

" " 15 1996

RECEIVED
JUL 22 1996
By_____

Chelsea Laboratories, Inc
Attention: Ernest Lengle, Ph.D.
P.O. Box 15686
8606 Reading Road
Cincinnati, OH 45215-0686

Dear Sir:

This is in reference to your abbreviated new drug application dated July 25, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Hydroxyzine Pamoate Capsules USP, (equivalent to Hydroxyzine Hydrochloride 25 mg and 50 mg).

Reference is also made to your amendments dated January 26, April 9, April 26, and June 6, 1996.

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 that your Hydroxyzine Pamoate Capsules USP, (equivalent to Hydroxyzine Hydrochloride 25 mg and 50 mg) are bioequivalent and, therefore, therapeutically equivalent to the listed drug (Vistaril® Capsules, equivalent to 25 mg and 50 mg Hydroxyzine Hydrochloride, respectively, of Pfizer Laboratories).

Your dissolution testing should be incorporated into the stability and quality control program using the same method as proposed in your application.

Under 21 CFR 314.70, 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. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253

confidential
Bill Riker
Impax
May 16, 2016 19:09

confidential
Bill Riker
Impax
May 16, 2016 19:09

(Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign, be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

D. L. Sporn

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

confidential
Bill Riker
Impax
May 16, 2016 19:09

confidential
Bill Riker
Impax
May 16, 2016 19:09