

February 25, 2002

Roxane Laboratories, Inc.
Attention: Elizabeth Ernst
P.O. Box 16532
Columbus, OH 43216

Dear Madam:

This is in reference to your abbreviated new drug application dated May 15, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Midazolam Hydrochloride Syrup, 2 mg (base)/mL.

Reference is also made to your amendments dated August 23, and August 30, 2001.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). The determination is subject to change on the basis of new information that may come to our attention.

As noted in the agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), the reference listed drug product (RLD) upon which you have based your application, Versed Syrup of Hoffmann La Roche, Inc., is currently subject to a period of new dosage form (NDF) market exclusivity. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(D) of the Act until this exclusivity period has expired, i.e., April 15, 2002.

In order to reactivate this application prior to final approval, please submit a MINOR AMENDMENT - FINAL APPROVAL REQUESTED at least 60 days prior to the date you believe it will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

Please note that this drug product may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Orange Book". Should you believe that there are grounds for issuing the final approval letter prior to April 15, 2002, you should amend your application accordingly.

Upon submission of your MINOR AMENDMENT - FINAL APPROVAL REQUESTED, please contact Jeen Min, R.Ph., Project Manager, at 301-827-5849, for further instructions.

Sincerely yours,

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