

ANDA 75-461

August 26, 1999

Zenith Goldline Pharmaceuticals, Inc.
Attention: Jason A. Gross, Pharm.D.
140 Legrand Ave.
Northvale, N.J. 07647-2485

Dear Sir:

This is in reference to your abbreviated new drug application dated September 15, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Nizatidine Capsules USP, 150 mg and 300 mg.

Reference is also made to your amendments dated October 6 and October 29, 1998; and January 6, January 20, May 3, May 21, June 3, and July 9, 1999.

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), and is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product referenced in your application, Axid Capsules 150 mg and 300 mg of Eli Lilly and Co., is subject to periods of patent protection which expire on April 12, 2002, (U.S. Patent No. 4,375,547, the '547 patent), and May 3, 2000 (U.S. Patent No. 4,832,090 and U.S. No. Patent 4,760,075, the '090 and '075 patents, respectively). Your application contains a Paragraph IV Certification to the '547 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on this

patent and that the patent is invalid. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received. You have notified the Agency that Zenith Goldline Pharmaceuticals, Inc. (Zenith) has complied with the requirements of Section 505(j)(2)(B) of the Act and that the patent holder, Eli Lilly and Co. (Lilly) initiated a patent infringement suit against you in the United States District Court for the Southern District of Indiana (Eli Lilly and Company v. Zenith Goldline Pharmaceuticals, Inc., Civil Action No. IP 99-0038 C (H/G)). In addition, your application contains a Paragraph III Certification to both the '090 and '075 patents under Section 505(j)(2)(A)(vii)(III) of the Act. Thus, final approval of this application cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii) since the date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,
 - b. the date of court decision [505(j)(5)(B)(iii) (I), (II), or (III)], which has been interpreted by the Agency to mean the date of the final order or judgement of that court from which no appeal can be or has been taken, or,
 - c. the patent has expired, and
2. The Agency is assured there is no new information that would affect whether final approval should be granted.

Because the Agency is granting a tentative approval for this application, please submit an amendment 60 to 90 days prior to the date you believe that your application may be considered for final approval. This amendment should inform the Agency of the circumstances that may affect the effective date of final approval. Your amendment should also provide (as applicable):

1. A copy of a final order or judgement from which no appeal may be taken (which might not be the one from the district court), or a settlement agreement between the parties, whichever is applicable, or a licensing

agreement between you and the patent holder, or any other relevant information, and

2. a. updated information related to final-printed labeling, chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or
- b. a statement that no such changes have been made to the application since the date of tentative approval.

This amendment should be clearly identified as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may at any time prior to the final date of approval, request that you submit an additional amendment containing the information described above. Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter or a delay in issuance of the final approval letter.

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

The drug product that is the subject of this abbreviated application 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 before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"). Should you believe that there are grounds for issuing the final approval letter prior to the expiration of the '547 patent on April 12, 2002, you should amend your application as previously noted.

Prior to submitting an amendment, please contact Ms. Kassandra Sherrod, Project Manager, at (301) 827-5849, for further instructions.

Sincerely yours,

Roger L. Williams, M.D.
Deputy Center Director for
Pharmaceutical Science
Center for Drug Evaluation and Research

