



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-104

Food and Drug Administration
Rockville MD 20857

MAY 28 2004

Eon Labs, Inc.
Attention: Enna Krivitsky
227-15 North Conduit Avenue
Laurelton, NY 11413

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 19, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Itraconazole Capsules, 100 mg.

Reference is also made to our Tentative Approval letter dated May 8, 2002, and to your amendments dated March 30, 2001; November 4, 2003; and March 12, and April 5, 2004.

The listed drug product referenced in your application, Sporanox Capsules of Janssen Pharmaceutica Products LP, is subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 5,633,015 (the '015 patent) is scheduled to expire on May 27, 2014. Your application contains a paragraph IV patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Itraconazole Capsules, 100 mg, under this ANDA will not infringe on the patent or that the patent is otherwise invalid or unenforceable. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Eon Labs Inc. (Eon) for infringement of the '015 patent by either the NDA or patent holder. You have notified the agency that Janssen Pharmaceutica N.V. initiated a patent infringement suit against you in the United States District Court for the Eastern District of New York (Janssen Pharmaceutica N.V. v. Eon Labs Manufacturing, Inc., Civil Action No. 01-2322 NG).

The agency recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application, was extended on multiple occasions by the court. The agency also recognizes that the 30-month period, as extended, expired on March 7, 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 Itraconazole Capsules, 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug Sporanox[®], Capsules, 100 mg, of Janssen Pharmaceutica Products LP. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

With respect to 180-day generic drug exclusivity, we note that Eon Labs, Inc. was the first ANDA applicant to submit a substantially complete ANDA containing a paragraph IV certification to the '015 patent. Therefore, with this approval Eon Labs, Inc. is eligible for 180-days of market exclusivity for Itraconazole Capsules, 100 mg. Such exclusivity will begin to run either from the date Eon Labs, Inc. begins commercial marketing of the drug product, or in the absence of marketing, from the date of a decision of a court finding the patent invalid or not infringed whichever event occurs earlier [Section 505(j)(5)(B)(iv)].

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this product, or the date of a decision of the court holding the relevant patent invalid, unenforceable or not infringed.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

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.

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 final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-42). Please do not use Form FDA 2253 (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-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6)

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