ANDA 74-567 April 17, 2001

Ohm Laboratories, Inc.
Attention: Shirley Ternyik, U.S. Agent
Ranbaxy Pharmaceuticals, Inc.
600 College Road East
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application dated October 31, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ibuprohm Cold and Sinus Tablets (Ibuprofen and Pseudoephedrine Hydrochloride Tablets USP), 200 mg and 30 mg, respectively.

Reference is also made to your amendments dated January 30, March 1, and March 28, 2001.

The listed drug product referenced in your application, Advil Cold and Sinus Tablets of Whitehall Laboratories, Inc., is subject to a period of patent protection which expires on October 9, 2004, (Patent No. 4,552,899). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Ibuprohm Cold and Sinus Tablets will not infringe on the patent or that the patent is otherwise invalid. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action is brought prior to the expiration of forty-five (45) days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified the agency that Ohm Laboratories, Inc. (Ohm) complied with the requirements of Section 505(j)(2)(B) of the Act and that as a result Richardson-Vicks, Inc., a subsidiary of the Proctor and Gamble Company, initiated a patent infringement suit against you in the United States District Court for the District of New Jersey (Richardson-Vicks Inc., v. Ohm Laboratories, Inc., Civil Action No. 96-3788 (WHW)). You have also notified the agency that on December 22, 1997, the litigation referenced above was dismissed without prejudice. The Agency also 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 has expired.

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 Ibuprohm Cold and sinus Tablets, 200 mg/30 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug Advil Cold and Sinus Tablets of Whitehall Laboratories, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Furthermore, we note that Ohm was the first ANDA applicant to submit a substantially complete ANDA containing a Paragraph IV Certification to the '899 patent. Therefore, with this approval Ohm Laboratories, Inc. is eligible for 180-days of generic drug market exclusivity. Such exclusivity will commence on the date Ohm begins commercial marketing of the drug product.

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 commenced commercial marketing of this product.

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 proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-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-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

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