DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-510

OCT 24 2006

IMPAX Laboratories, Inc.
Attention: Mark C. Shaw
Vice President, Regulatory Affairs and Compliance
30831 Huntwood Avenue
Hayward, CA 94544

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 30, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Colestipol Hydrochloride Tablets, 1 gram.

Reference is also made to your amendments dated November 7, 2005; and January 13, February 6, February 7, March 8, June 7, and August 22, 2006.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Colestipol Hydrochloride Tablets, 1 gram, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Colestid Tablets, 1 gram, of Pharmacia and Upjohn Co.

The reference listed drug (RLD) upon which you have based your ANDA, Colestid Tablets, 1 gram, of Pharmacia and Upjohn Co., is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,490,987 (the '987 patent), is scheduled to expire on February 13, 2013.

Your ANDA contains a paragraph IV certification to the '987 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be

infringed by your manufacture, use, or sale of Colestipol Hydrochloride Tablets, 1 gram, under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against IMPAX Laboratories, Inc. (IMPAX) for infringement of the listed '987 patent. This action must have been brought against IMPAX prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that IMPAX complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '987 patent was brought against IMPAX within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).[1]

With respect to 180-day generic drug exclusivity for this drug product, the agency has determined that IMPAX was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '987 patent. Therefore, with this approval, IMPAX is eligible for 180-days of generic drug exclusivity for Colestipol Hydrochloride Tablets, 1 gram. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

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1 Because information on the '987 patent was submitted to FDA before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) was enacted. See MMA § 1101(c)(3).

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Robert Buehler for

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