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APPLICATION NUMBER:

ANDA 200644

APPROVAL LETTER



ANDA 200644

InnoPharma, Inc.
Attention: Christy Meng
Manager, Regulatory Affairs
10 Knightsbridge Road
Piscataway, NJ 08854

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) received on November 24, 2009, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Acetylcysteine Injection, 200 mg/mL, packaged in 6 g/30 mL Single-use Vials).

Reference is also made to your amendments dated August 11, 2010; February 2, February 22, April 5, May 11, May 25, November 30, December 14, and December 22, 2011; and March 27, April 4, April 5, April 6, April 9, April 10, and May 25, 2012.

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 Acetylcysteine Injection, 200 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Acetadote Injection, 200 mg/mL, of Cumberland Pharmaceuticals Inc. (Cumberland).

The RLD upon which you have based your ANDA, Cumberland's Acetadote Injection, 200 mg/mL, 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. 8,148,356 (the '356 patent), is scheduled to expire on May 21, 2026.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '356 patent is

invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Acetylcysteine Injection, 200 mg/mL, under this ANDA. You have notified the agency that InnoPharma, Inc. (InnoPharma) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against InnoPharma for infringement of the '356 patent in the United States District Court for the District of Delaware [Cumberland Pharmaceuticals, Inc., v. InnoPharma, Inc., Civil Action No. 12-CV-618]. The agency notes that the '356 patent was listed after submission of your ANDA and therefore cannot serve as the basis for a 30-month stay of approval.

With respect to 180-day generic drug exclusivity, we note that InnoPharma was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Acetylcysteine Injection, 6 g/30 mL (200 mg/mL). Therefore, with this approval, InnoPharma is eligible for 180-day generic drug exclusivity for Acetylcysteine Injection, 200 mg/ml, (6 g/30 mL).¹ This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the commercial marketing date 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.

As of October 1, 2012, you must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). Because your ANDA was pending on October 1, 2012, your ANDA is now subject to a backlog fee. However, you will not be penalized until the backlog fee payment is overdue. As indicated in the Federal Register (FR) notice (77 FR 65199) published on October 25, 2012, the fee is due no later than 30 days after publication of the notice. If you do not pay the fee by the due date, statutory penalties take effect. At that time, FDA cannot receive any further ANDAs or supplements from InnoPharma or its affiliates, and InnoPharma will be placed on a publicly available arrears list until the fee is paid.

¹ As noted above, ANDA 200644 was received on November 24, 2009. It was never tentatively approved. 30 months from November 24, 2009, is May 24, 2012. Therefore, this ANDA was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV). Nevertheless, the agency has determined that the failure to obtain tentative approval within the 30-month period was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed, specifically, the approval of a formulation change for the RLD which, along with two citizen petitions (Docket Nos. FDA-2011-P-0339 and FDA-2012-P-0507) prompted the agency's review of the formulation for the ANDA. We therefore conclude that the exclusivity period described in section 505(j)(5)(B)(iv) of the Act was not forfeited by InnoPharma.

In addition, your ANDA is now subject to facility fees. As noted above, you must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). You will not be penalized for nonpayment of the facility fee until the fee payment is overdue. The fee must be paid by the date listed in the Federal Register (FR) notice announcing the facility fee amount. If the facility fee is not paid by the due date, statutory penalties take effect. At that time, FDA will deem misbranded this ANDA product and all products from facilities that have not paid the appropriate fee. In addition, facilities that have not paid the fee will be placed on a publicly available arrears list, until the fee is paid or the facilities are removed from the ANDA.

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.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA 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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Amundson 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 Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required).

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

<http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

11/07/2012

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.