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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090485

Amneal Pharmaceuticals
Attention: Alpesh Patel
Sr. Director, Global Regulatory Affairs
131 Chambers Brook Road
Branchburg, NJ 08876

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 10, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Tramadol Hydrochloride and Acetaminophen Tablets, 37.5 mg/325 mg.

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 Tramadol Hydrochloride and Acetaminophen Tablets, 37.5 mg/325 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Ultracet Tablets, of Ortho-McNeil Janssen Pharmaceuticals, Inc. (Ortho-McNeil). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Ortho-McNeil's Ultracet Tablets, 37.5 mg/325 mg, 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. RE39221 (the '221 patent), is scheduled to expire on August 9, 2011.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '221 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Tramadol Hydrochloride and Acetaminophen Tablets, 37.5 mg/325 mg, 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 is brought against Amneal Pharmaceuticals (Amneal) for infringement of the listed '221 patent. You have notified the agency that Amneal complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '221 patent was brought against Amneal within the statutory 45-day period in the United States District Court for the District of New Jersey [Ortho-McNeil Janssen Pharmaceuticals, Inc. vs. Amneal Pharmaceuticals, Civil Action No. 2:08-cv-04494-JLL-CCC]. You have also notified the agency that the court decided that the '221 patent is invalid; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

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(s) directly to:

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] 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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence – SPL for Approved ANDA 090485".***

Sincerely yours,

(See appended electronic signature page)

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-90485	ORIG-1	AMNEAL PHARMACEUTICALS	ACETAMINOPHEN AND TRAMADOL HYDROCHLORIDE

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

/s/

GARY J BUEHLER
12/09/2009