DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078228

RECEIVED
APR 14 2010
BY:

Akorn, Inc.
Attention: Sam Boddapati, Ph.D.
Vice President, Regulatory Affairs
1925 West Field Court, Suite 300
Lake Forest, IL 60045

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 27, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Hydromorphone Hydrochloride Injection USP, 10 mg/mL, (High Potency Formulation) packaged in 500 mg/50 mL Single-dose Vials for use in the preparation of large volume parenteral solutions.

Reference is also made to your amendments dated November 3, 2006; March 6, 2007; January 28, October 12, and October 23, 2009; and February 11 and February 26, 2010.

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 Hydromorphone Hydrochloride Injection USP, 10 mg/mL, (High Potency Formulation) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Dilaudid-HP® Injection, 10 mg/mL, of Purdue Pharmaceutical Products, LP.

The listed drug product (RLD) referenced in your application, Purdue's Dilaudid-HP Injection, 10 mg/mL, is subject to a period of patent protection. U.S. Patent 6,589,960 (the '960 patent), due to expire on November 9, 2020, is currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book)" for this drug product. The agency has determined that the '960 patent was submitted to FDA after the date of the submission of your ANDA. In addition, the agency has determined that notification

of the '960 patent by the NDA holder was received by the agency more than 30 days after the patent was issued by the U.S. Patent and Trademark Office. Therefore, under 21 CFR 314.94(a)(12)(vi), no person with an appropriate patent certification at the time of the patent submission is required to submit an amended patent certification to address this patent.

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.

We 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 505-1(i).

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 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.

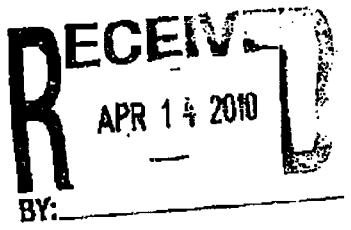
Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved

labeling. 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 078228*".

Sincerely yours,

*[See appended electronic signature page]*

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078261

RECEIVED
APR 14 2010
BY:

Akorn, Inc.
Attention: Sam Boddapati, Ph.D.
Vice President, Regulatory Affairs
1925 West Field Court, Suite 300
Lake Forest, IL 60045

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 12, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Hydromorphone Hydrochloride Injection USP, 10 mg/mL, (High Potency Formulation), packaged in 10 mg/1 mL and 50 mg/5 mL Ampules.

Reference is also made to your amendments dated November 3, 2006; March 6, 2007; October 12, and October 23, 2009; and February 11, and February 26, 2010.

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 Hydromorphone Hydrochloride Injection USP, 10 mg/mL, (High Potency Formulation), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Dilaudid-HP® Injection, 10 mg/mL, of Purdue Pharmaceutical Products, LP.

The listed drug product (RLD) referenced in your application, Purdue's Dilaudid-HP Injection, 10 mg/mL, is subject to a period of patent protection. U.S. Patent 6,589,960 (the '960 patent), due to expire on November 9, 2020, is currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product. The agency has determined that the '960 patent was submitted to FDA after the date of the submission of your

ANDA. In addition, the agency has determined that notification of the '960 patent by the NDA holder was received by the agency more than 30 days after the patent was issued by the U.S. Patent and Trademark Office. Therefore, under 21 CFR 314.94(a)(12)(vi), no person with an appropriate patent certification at the time of the patent submission is required to submit an amended patent certification to address this patent.

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.

We 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 505-1(i).

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:

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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 078261***".

Sincerely yours,

*(See appended electronic signature page)*

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| ANDA-78261 | ORIG-1 | AKORN INC | HYDROMORPHONE HYDROCHLORIDE |

**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
04/14/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| ANDA-78228 | ORIG-1 | AKORN INC | HYDROMORPHONE HYDROCHLORIDE |

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ROBERT L WEST
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Deputy Director, Office of Generic Drugs
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