DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Lachman Consultant Services, Inc.
Attention: Robert W. Pollock
1600 Stewart Avenue
Westbury, NY 11590

Docket No. 2006P-0007/CP1

Dear Mr. Pollock:

This is in response to your petition filed on January 6, 2006, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Oxycodone Hydrochloride and Acetaminophen Oral Solution, 10 mg/300mg. The listed drug product to which you refer in your petition is Roxicet (Oxycodone Hydrochloride and Acetaminophen) Oral Solution, 5 mg/325 mg, approved under ANDA 89-351 held by Roxane Laboratories, Inc.

Your request involves changes in strengths from that of the listed drug product for both components of the combination drug product Oxycodone Hydrochloride and Acetaminophen Oral Solution (i.e., from Oxycodone Hydrochloride 5 mg to Oxycodone Hydrochloride 10 mg and from Acetaminophen 325 mg to Acetaminophen 300 mg). The changes you request are the types of changes that are authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. [1] This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength

The FDA finds that the changes in strength for the specific proposed drug product do not pose questions of safety or effectiveness because the uses and route of administration of the proposed drug product are the same as that of the listed drug product. A previous product in a solid oral dosage form has been approved that contains the dose of Oxycodone Hydrochloride 10 mg and Acetaminophen 300 mg. Therefore, there are no safety or efficacy concerns with this dose. The labeling of the reference listed drug indicates that "It may occasionally be necessary to exceed the usual dosage recommended below in cases of more severe pain or in those patients who have become tolerant to the analgesic effect of narcotics." In addition, the dosing instructions will

[1] We also acknowledge the comments submitted by Mr. David Lowe on 2/2/06 and 2/22/06 and the comments of Dr. Richard Harris submitted on 4/28/2006.

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remain the same, 5 mL (one teaspoon) every six hours as needed for pain. The FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for this drug product to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

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