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

Docket No. 2004P-0252/CP1

Dear Mr. Pollock:

This is in response to your petition filed on May 27, 2004, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Hydrocodone Bitartrate and Acetaminophen Tablets, 5 mg/700 mg, 7.5 mg/700 mg and 10 mg/700 mg. The listed drug product to which you refer in your petition is Hydrocodone Bitartrate and Acetaminophen Tablets, 10 mg/650 mg, approved under NDA 81-223, held by Mikart.

Your request involves a change in the strength of the hydrocodone bitartrate component (i.e., from 10 mg to 5 mg and 7.5 mg) and a change in strength of the acetaminophen component (i.e., 650 mg to 700 mg) from that of the listed drug product. The change you request is the type of change that is 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. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the Agency 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 Agency finds that the change in strength of the hydrocodone bitartrate and acetaminophen components for the specific proposed drug product does not pose questions of safety or effectiveness because the use and route of administration of the proposed drug product are the same as that of the listed drug product. The Agency has previously approved other single higher doses of acetaminophen (750 mg) in combination with 10 mg of hydrocodone bitartrate as safe and effective.

The Agency 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.

In addition, when an ANDA is submitted for your proposed drug product, the proposed labeling should reflect the maximum number of doses per day that can be administered. The total daily dose of the acetaminophen component should not exceed the maximum total daily dose for adults of 4000 mg established by the Agency for its safe and effective range, and a single dose of

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Hydrocodone Bitartrate and Acetaminophen Tablets, 5 mg/700 mg, 7.5 mg/700 mg and 10 mg/700 mg

acetaminophen may not exceed 1000 mg. Please refer to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (53 FR 46204, November 16, 1988) for information regarding acetaminophen. In addition, the total daily dose for Hydrocodone Bitartrate may not exceed 60 mg.

The approval of your suitability petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the Agency 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 Agency.

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 Agency 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.

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