



SEP 28 2004

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

Docket No. 2003P-0413/CP1

Dear Mr. Pollock:

This is in response to your petition filed on September 4, 2003, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Hydrocodone Bitartrate and Acetaminophen Tablets, 7.5 mg/300 mg. The listed drug to which you refer in your petition is Norco® (Hydrocodone Bitartrate and Acetaminophen) Tablets, 7.5 mg/325 mg, approved under ANDA 40-148 held by Watson Laboratories.

Your request involves a change in strength from that of the listed drug product (i.e., from 325 mg of the acetaminophen component to 300 mg of the acetaminophen component). 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 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 Agency 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. 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.

When an ANDA is submitted for your proposed drug product, the proposed labeling should reflect the maximum number of tablets per day that can be administered for your proposed drug product. 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.

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Lachman Consultant Services  
Hydrocodone Bitartrate and Acetaminophen Tablets 7.5 mg/300 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). In addition, a single dose of Acetaminophen may not exceed 1000 mg. The total daily dose for Hydrocodone Bitartrate may not exceed 60 mg.

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 the 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 drug product that is the same as the subject of this petition, that drug product will be a listed drug. Thereafter, the 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