DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Lachman Consultant Services, Inc.
Attention: Robert W. Pollock
1600 Stewart Ave.
Suite 604
Westbury, NY 11590

DEC 20 2001

Docket No. 01P-0442/CP1

Dear Mr. Pollock:

This is in response to your petition filed on September 28, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Hydrocodone Bitartrate and Ibuprofen Tablets, 10 mg/200 mg. The listed drug product to which you refer in your petition is Vicoprofen® (Hydrocodone Bitartrate and Ibuprofen) Tablets, 7.5 mg/200 mg, approved under NDA 20-716, held by Abbott Laboratories Pharmaceutical Products.

Your request involves a change in the strength of the hydrocodone bitartrate component from that of the listed drug product (i.e., from 7.5 mg to 10 mg). 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 component 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. 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 for your proposed drug product. The total daily dose for hydrocodone bitartrate may not exceed 60 mg.

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.

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The approval of this 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.

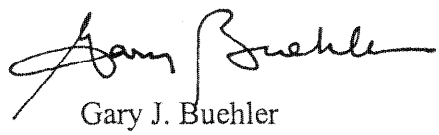
For your information, the listed drug product to which you refer is covered by a period of patent protection which appears in the Approved Drug Products With Therapeutic Equivalence Evaluations, 21st Edition, published by the Agency. The existence of such a patent will require a certification upon submission of an ANDA for your proposed drug product and may also affect the approval date of any ANDA.

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