DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Arnall Golden & Gregory, LLP
Attention: Alan G. Minsk
2800 One Atlantic Center
120 1 West Peachtree St.
Atlanta, GA 30309-3450

JAN 16 2001

Docket No. OOP- 1551/CP1
Docket No. OOP-1551/CP2

Dear Mr. Minsk:

This is in response to your petitions filed on October 2, 2000, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Propoxyphene Napsylate and Acetaminophen Tablets 50 mg/500 mg and 100 mg/500 mg. The listed drug product to which you refer in your petitions is Darvocet-N®100 (Propoxyphene Napsylate and Acetaminophen) Tablets 100 mg/650 mg, manufactured by Eli Lilly, Inc.

Your requests involve a change in strength from that of the listed drug product (i.e., from 100mg/650 mg to 50 mg/500 mg and 100 mg/500 mg). The changes you request are the type of changes that are authorized under the Act.

We have reviewed your petitions under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that they are approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug products.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve petitions 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 for the specific proposed drug products does not pose questions of safety or effectiveness because the uses and route of administration of the proposed drug products 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 products can be expected to have the same therapeutic effect as the listed reference drug product.

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When an ANDA is submitted for your proposed drug products, the proposed labeling should reflect the maximum number of tablets per day that can be administered for your proposed drug products. 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. 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, the total daily dose of propoxyphene napsylate component should not exceed 600 mg per day.

The approval of these petitions to allow an ANDA to be submitted for the above-referenced drug products does not mean that the Agency has determined that an ANDA will be approved for the drug products. 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 products 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 to the Office of Generic Drugs, Division of Bioequivalence for these drug products 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 these petitions. In addition, you should refer in your ANDA to the appropriate petition docket numbers cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petitions 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
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research