



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

FEB 13 2001

3 10 9  
02 FEB 16 10:20

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

Docket No. OOP-1462/CP1

Dear Mr. Pollock:

This is in response to your petition filed on August 17, 2000, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Extended Phenytoin Sodium Capsules, 200 mg, and 300 mg. The listed drug product to which you refer in your petition is Dilantin® (Extended Phenytoin Sodium) Capsules, 100 mg, manufactured by Parke-Davis.

Your request involves a change in strength from that of the listed drug product (i.e., from 100 mg to 200 mg, and 300 mg). The change you request is the type of change that is authorized under the Act.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (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 products.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a strength which 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. In addition, doses of 200 mg or 300 mg Extended Phenytoin Sodium Capsules may be administered under certain circumstances outlined in the approved labeling 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.

The approval of this petition 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.

OOP-1462

PAV

00P-1462/CP1

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 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  
Acting Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research