

Food and Drug Administration
Rockville MD 20857

3728 '01 MAY 10 09:38

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

MAY - 8 2001

Docket No. 01P-0081/CP1

Dear Mr. Pollock:

This is in response to your petition filed on February 23, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Midodrine Tablets, 10 mg. The reference listed drug product to which you refer in your petition is ProAmatine® (Midodrine) Tablets, 5 mg, manufactured by Roberts Laboratories, Inc. You also note that ProAmatine® (Midodrine) Tablets are marketed in 2.5 mg and 5 mg strengths.

Your request involves a change in strength from that of the reference listed drug product (i.e., from 5mg to 10 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 product.

The Agency finds that the change in strength for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, dose, 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.

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.

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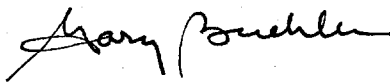
For your information, the listed drug product to which you refer is covered by periods of new chemical entity and orphan drug exclusivity which appear in the Approved Drug Products With Therapeutic Equivalence Evaluations, 21st Edition, published by the Agency. The existence of new chemical entity exclusivity will prevent the submission of an ANDA until such exclusivity expires. The orphan drug exclusivity will require a statement 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
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research