

APPENDIX D.

DOCKET NOS. 01P-0515/CP1 AND 01P-0109/CP1



DEPARTMENT OF HEALTH & HUMAN SERVICES

HTA-805
201115

Food and Drug Administration
Rockville MD 20857

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

APR 12 2002

Docket No. 01P-0515/CP1

Dear Mr. Pollock:

This is in response to your petition filed on November 9, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Doxycycline (Monohydrate) Tablets, 75 mg. The reference listed drug product to which you refer in your petition is Monodox® [Doxycycline (Monohydrate)] Capsules USP, 100 mg approved under NDA 50-641 held by Oclassen Pharmaceuticals, Inc. You also note that Monodox® [Doxycycline (Monohydrate)] Capsules USP are marketed in both 50 mg and 100 mg strengths.

Your request involves a change in strength and dosage form from that of the listed drug product (i.e., you are requesting an intermediate strength of 75 mg and are requesting a change in dosage form from capsules to tablets). The changes you request are the type of changes that are 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 and dosage form that differ from the strength and dosage form of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength and dosage form.

The FDA finds that the change in strength and dosage form 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 FDA 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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01P-0515/CP1

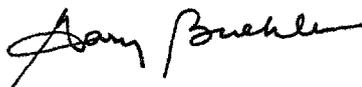
The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed 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 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 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.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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The Weinberg Group Inc.
Attention: Nicholas M. Fleischer, R.Ph., Ph.D.
1200 Nineteenth St. N.W., Suite 300
Washington, DC 20036-2400

Docket No. 01P-0109/CP1

Dear Dr. Fleischer:

This is in response to your petition filed on March 2, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Doxycycline (Monohydrate) Capsules USP, 75 mg. The reference listed drug product to which you refer in your petition is Monodox® [Doxycycline (Monohydrate)] Capsules USP, 100 mg, approved under NDA 50-641 held by Oclassen Pharmaceuticals, Inc. You also note that Monodox® [Doxycycline (Monohydrate)] Capsules are marketed in both 50 mg and 100 mg strengths.

Your request involves a change in strength from that of the reference listed drug product (i.e., from 100 mg to 75 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.

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 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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01P-0109/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 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 to the Office of Generic Drugs, Division of Bioequivalence for this drug product 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