



THE WEINBERG GROUP INC.

VIA COURIER

November 26, 2002

Dockets Management Branch
Food and Drug Administration
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WASHINGTON
NEW YORK
SAN FRANCISCO
BRISSELL
TABLET

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR §10.20 and §10.30, as provided for in 21 CFR §314.93 and Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act, to request the Commissioner of the Food and Drug Administration to declare that the drug product Metformin Hydrochloride Tablets for Oral Solution 500 mg, 850 mg and 1000 mg are suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Metformin Hydrochloride Tablets for Oral Solution 500 mg, 850 mg and 1000 mg are suitable for submission as an ANDA. The reference listed drug product upon which this petition is based is Glucophage® (metformin hydrochloride tablets) 500 mg, 850 mg and 1000 mg, manufactured by Bristol-Myers Squibb Company. Metformin hydrochloride will be marketed as tablets for oral solution in dosage strengths of 500 mg, 850 mg and 1000 mg. The drug, the route of administration and the recommendations for use are the same as the listed drug product. The proposed product would differ only in dosage form from the Bristol-Myers Squibb Company marketed product.

The proposed drug product is expected to demonstrate bioequivalence to the 1000 mg tablet dosage form of the listed product; data will be submitted at a later date.

B. Statement of Grounds

Metformin Hydrochloride Tablets for Oral Solution are presented for administration by dissolving a single tablet in a specified amount of water.

The tablets for oral solution would be a viable alternative to the currently marketed tablet dosage form for patients who have problems swallowing the solid oral dosage form.

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The proposed drug product will differ only in dosage form. The indications, strengths, route of administration, intended patient population and recommendations for use will remain the same as the Bristol-Myers Squibb Company marketed product. Therefore, there will be no difference in the safety and efficacy of the proposed tablets for oral solution.

The package insert for Bristol-Myers Squibb Company's Glucophage® (metformin hydrochloride tablets) as well as the draft package insert for the proposed Metformin Hydrochloride Tablets for Oral Solution are provided with this petition in Attachments 1 and 2, respectively.

C. Pediatric Use Information

As the package insert of Bristol-Myers Squibb Company's Glucophage® contains adequate information for the pediatric population, no additional studies are required.

D. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR §25.31.

E. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

F. Certification

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,



Nicholas M. Fleischer, R.Ph., Ph.D.
Director of Biopharmaceutics
THE WEINBERG GROUP INC.

NMF/kh

Enclosure

cc Gary Buehler, Director, Office of Generic Drugs

