DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Emcure Pharmaceuticals USA, Inc.
Attention: Nilesh Patel
21/B Cotters Lane
East Brunswick, NJ 08816

DEC 29 2011 2012 JAN -5 A 5:57

Docket No. FDA-2008-P-0303

Dear Mr. Patel:

This is in response to your petition filed on May 19, 2008 requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Griseofulvin Ultramicrosize Oral Suspension, 250 mg/5 mL. The listed drug product to which you refer in your petition is Gris-Peg® (griseofulvin ultramicrosize) Tablets, 250 mg, approved under NDA 050475 held by Pedinol.

Your request involves a change in dosage form from that of the listed drug product (i.e., from oral tablet to oral suspension). The change you request is the type of change that is 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.

In addition, this petition and your waiver request were evaluated with respect to the "Pediatric Research Equity Act of 2007" (PREA). PREA requires that all applications for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain an assessment of the safety and effectiveness of the drug for the claimed indication in relevant pediatric subpopulations unless the requirement is waived or deferred. Your ANDA suitability petition is affected by this Act because it is a petition for a change in dosage form.

The FDA has determined that your proposed change in dosage form is subject to PREA, but has concluded that investigations are not necessary to demonstrate the safety and effectiveness of your proposed product in the pediatric population because studies are impossible or highly impractical (e.g., the number of pediatric patients is so small or is geographically dispersed).

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a dosage form that differs from the dosage form of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form.

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The FDA finds that the change in 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.

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. Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

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,

Keith O. Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research