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BY ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Citizen Petition

The undersigned ("Petitioner") submits this Citizen Petition pursuant to the Federal Food, Drug, and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. §§ 10.25(a) and 10.30 with regard to the FDA-designated Reference Standard ("RS") for Ultramicrocrystalline Griseofulvin Tablets, 250 mg. The current RS, approved under New Drug Application ("NDA") 050475, is commercially unavailable. For this reason, Petitioner requests that the Food and Drug Administration ("FDA") take action to maintain a pathway for Abbreviated New Drug Application ("ANDA") submissions. Petitioner requests that FDA designate an additional (or new) RS for Ultramicrocrystalline Griseofulvin Tablets, 250 mg, and amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") to reflect ANDA 204371 as a RS for the drug.

I. ACTION REQUESTED

Petitioner requests that FDA designate ANDA 204371 (Ultramicrocrystalline Griseofulvin Tablets, 250 mg) held by Mountain LLC as a RS for purposes of FDA evaluation of ANDAs for Ultramicrocrystalline Griseofulvin Tablets.

II. STATEMENT OF GROUNDS

FDC Act § 505(j) allows the marketing of generic versions of previously approved drug products based on FDA approval of an ANDA. To obtain ANDA approval, the applicant must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product has the same active ingredient(s) in the same strength, dosage form and route of administration, has essentially identical labeling, and is bioequivalent.

A "listed drug" includes a new drug product that has an effective approval under FDC Act § 505(j), that has not been withdrawn or suspended under FDC Act §§ 505(e)(1) through (5) or (j)(5), and that has not been withdrawn from sale for reasons of safety or effectiveness. See 21 C.F.R. § 314.3. Listed drugs are identified in FDA's Orange Book. An RLD is the listed drug identified by FDA as the drug product on which an ANDA applicant should rely in seeking approval of an application. The product designated by FDA as the "reference standard," in the Orange Book, must be used to conduct the in vivo bioequivalence testing required for FDA approval. However, where there is a "limited or no quantities of the reference standard in distribution" a potential ANDA applicant may request designation of a new RS through the submission of a citizen petition. FDA, *Draft Guidance for Industry, Referencing Approved Drug Products in ANDA Submissions*, at 9 (Jan. 2017).

Despite diligent efforts to obtain sufficient quantities of the present RS—GRIS-PEG (ultramicrosize griseofulvin) Tablets, 250 mg (NDA 050475)—the drug product is not commercially available and appears to have been discontinued from marketing. As such, Ultramicrocrystalline Griseofulvin Tablets, 250 mg, is shielded from additional generic competition.

There is a sound basis for selecting an ANDA—and preferably ANDA 204371—as a new RS. Ultramicrocrystalline Griseofulvin Tablets, 250 mg, held by Mountain LLC (ANDA 204371), is believed to lead the U.S. market in terms of the number of tablets sold, and should therefore be more readily accessible and more appropriate for RS designation.

In an effort to introduce further competition, FDA should designate one of the following ANDAs listed in the Orange Book as the new (or an additional) RS for Ultramicrocrystalline Griseofulvin Tablets, 250 mg, and preferably ANDA 204371.

GRISEOFULVIN, ULTRAMICROSIZE							
TABLET;ORAL							
GRIS-PEG							
AB	+	VALEANT PHARMS INC	125MG		N050475	001	
AB	+!		250MG		N050475	002	
GRISEOFULVIN, ULTRAMICROSIZE							
AB		MOUNTAIN	125MG		A204371	001	Jan 09, 2014
AB			250MG		A204371	002	Jan 09, 2014
AB		SANDOZ INC	125MG		A202805	001	Dec 26, 2018
AB			250MG		A202805	002	Dec 26, 2018
GRISEOFULVIN,ULTRAMICROSIZE							
AB		SIGMAPHARM LABS LLC	125MG		A202545	001	Oct 22, 2012
AB			250MG		A202545	002	Oct 22, 2012

Accordingly, the undersigned requests that FDA designate in the Orange Book Ultramicrocrystalline Griseofulvin Tablets, 250 mg, approved under one of the above-cited ANDAs (and, in particular, ANDA 204371) as a new RS.

III. ENVIRONMENTAL IMPACT

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

IV. ECONOMIC IMPACT

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. Petitioner hereby commits to promptly provide this information, if so requested.

V. CERTIFICATION

Petitioner certifies that, to the best knowledge and belief of Petitioner, 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 is unfavorable to the petition.

Sincerely,

Kurt R. Karst

KRK/eam