4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-P-0025]

Determination That GRIFULVIN V (Griseofulvin Microcrystalline) Tablets, 250 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for griseofulvin microcrystalline tablets, 250 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which

authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, is the subject of ANDA 062279, held by OrthoNeutrogena, and approved on June 2, 1980. GRIFULVIN V is indicated

for the treatment of certain ringworm infections (tinea corporis, tinea pedis, tinea cruris, tinea barbae, tinea capitis, and tinea unguium) when caused by a certain genera of fungi.

GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Arthur Y. Tsien of Olsson Frank Weeda Terman Bode Matz PC submitted a citizen petition on behalf of a client, dated January 7, 2011 (Docket No. FDA-2011-P-0025), under 21 CFR 10.30, requesting that the Agency determine whether GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, from sale. We have also independently reviewed relevant literature and data for possible postmarketing adverse event reports. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, may be approved by

the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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