U.S. FOOD & DRUG ADMINISTRATION

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Re: Docket No. FDA-2019-P-4261

MAR 0 4 2020

Dear Mr. Karst:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on September 10, 2019. Your petition requests that the Agency designate ultramicrosize griseofulvin tablets, 250 milligrams, approved under abbreviated new drug application 204371 held by Mountain LLC as the new reference standard in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).[1]

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

[1] The Orange Book is available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Although your petition refers to the product as ultramicrocrystalline griseofulvin tablets, we refer to the product as ultramicrosize griseofulvin tablets in this response consistent with the drug product's description in the Orange Book.