



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 12, 2019

Kurt R. Karst
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Suite 1200
Washington, D.C. 20005-5929

Sent via email to: kkarst@hpm.com

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting 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 was received by this office on 09/10/2019.

It was assigned docket number FDA-2019-P-4261. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Supervisory Administrative Proceedings Specialist
Dockets Management Staff
FDA/Office of Operations (OO)