



**DEPARTMENT OF HEALTH & HUMAN
SERVICES**

Food and Drug
Administration Rockville,
MD 20857

May 11, 2020

Kurt R. Karst
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700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005-5929

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate ANDA 207127 (Pyrimethamine Tablets, 25 mg) held by Cerovene, Inc. ("Cerovene") as a RS for purposes of FDA evaluation of ANDAs for Pyrimethamine Tablets, 25 mg was received by this office on 05/08/2020.

It was assigned docket number FDA-2020-P-1369. 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,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)