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

November 4, 2020

Re: Docket No. FDA-2020-P-1369

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 May 8, 2020. Your petition requests that the FDA designate abbreviated new drug application (ANDA) 207127 (Pyrimethamine Tablets, 25 mg), held by Cerovene, Inc., as a reference standard for purposes of evaluating ANDAs for Pyrimethamine Tablets, 25 mg.

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 Bennett -S

Digitally signed by Carol Bennett -S
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Date: 2020.11.03 15:16:28 -05'00'

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