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BY ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

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

Dear Sir or Madam:

In light of FDA's October 2020 final guidance, "Referencing Approved Drug Products in ANDA Submissions," in which FDA states that applicants may submit controlled correspondence to ask FDA to designate a new reference listed drug or select a reference standard ("RS"), Petitioner requests withdrawal of the above-referenced citizen petition. Because the controlled correspondence pathway is available, Petitioner will request that FDA designate as a new RS Pyrimethamine Tablets, 25 mg, approved under abbreviated new drug application (ANDA) 207127 and held by Cerovene Inc due to market unavailability of the current RS. As such, a formal response to Docket No. FDA-2020-P-1369 is no longer necessary.

Sincerely,

Kurt R. Karst