



Craig Butler
National Executive Director
Cooley's Anemia Foundation
330 Seventh Avenue
Suite 200
New York, NY 10001

Re: Docket No. FDA-2020-P-0421

Dear Mr Butler:

July 22, 2020


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 January 24, 2020. Your petition asks FDA to require that "all products containing deferiprone be accompanied by a requirement to implement measures that will ensure a comparable level of monitoring and patient and physician support as is currently provided in the current Ferriprox voluntary REMS."

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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 we have reached a decision on your request.

Sincerely,

**Carol
Bennett-S**

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

 Digitally signed by Carol Bennett-S
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ou=FDA, ou=People, cn=Carol Bennett -
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