DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 24, 2020

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

Sent via email to: cbutler@thalassemia.org

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA require 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 was received by this office on 01/24/2020.

It was assigned docket number FDA-2020-P-0421. 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

Digitally signed by Dynna Bigby
Date: 2020.01.27 11:14:51 -05'00'

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