



Lorna Speid, Ph.D.
Founder and President
Putting Rare Diseases Patients First!
13243 Kingsfield Court
San Diego, CA 92130

January 11, 2021

Re: Docket No. FDA-2020-P-1674

Dear Dr. Speid:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition (Petition), in which you request that the Agency:

1. “[A]dd Sickle Cell Disease, a Tropical Disease that impacts a majority African American population in the US, to the Neglected Tropical Disease Priority Review Voucher List”;
2. “[A]djust the title of the list so that it is more in line with the WHO List; the WHO list does not include the word *Infectious*”;
3. “Alternatively,. . . create a new Priority Review List for diseases like Sickle Cell Disease that impact patients from predominantly under-served, and marginalized populations.”

(Petition at 1).

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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ou=FDA, ou=People, cn=Carol Bennett -S,
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research