U.S. FOOD & DRUG ADMINISTRATION

January 4, 2023

Randall Henri Steinmeyer
[redacted]

Sent via email to: [redacted]

Re: Citizen Petition – Docket Number FDA-2022-P-1632

Dear Mr. Steinmeyer:

This is an interim response to the petition dated July 19, 2022, filed by the Food and Drug Administration (FDA) on July 20, 2022. In the petition, you requested FDA "revoke the Association for the Advancement of Blood and Biotherapies (AABB) authority to regulate … commercial DNA testing laboratories," "transfer" AABB's authority to the American Society of Crime Laboratory Directors, and "halt the sale of the so-called motherless paternity tests."

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Daniel Schieffer of our Office of Policy at daniel.schieffer@fda.hhs.gov or (301) 796-3350.

Sincerely yours,

Ellen J. Flannery -S
Digitally signed by Ellen J. Flannery -S
Date: 2023.01.04 09:50:55 -05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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