June 8, 2020

Jeffrey N. Gibbs, Director
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, NW, Suite 1200
Washington, DC 20005-5929
Sent via email to: jgibbs@hpm.com

Re: Citizen Petition – Docket Number FDA-2020-P-0152

Dear Mr. Gibbs:

This is an interim response to the petition filed with the Food and Drug Administration (FDA) on January 9, 2020. In the petition, you requested that FDA:

- Issue a revised Safety Communication clarifying that laboratories and software providers may communicate information about gene-drug interactions as part of genetic test reports to the extent such information is supported by adequate evidence and is not contraindicated by information in drug labels with impact of genetic variants on drug response (PGx) information.
- Permit clinical laboratories to include medication-specific information in PGx test reports that is (1) included in FDA-approved drug labels or (2) that is supported by adequate evidence of PGx gene-drug associations without clearance or approval of a premarket submission.
- Conduct any future policy development related to PGx tests in compliance with the Administrative Procedure Act (APA), which allows for the participation of stakeholders through notice-and-comment rulemaking.
- Hold a public hearing before the Commissioner pursuant to 21 C.F.R Part 15, because this is a matter pending before FDA and a hearing is in the public interest.

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 Jean Olson of our Office of Policy at (301) 796-6579.

Sincerely,

Ellen J. Flannery -S Digitally signed by Ellen J. Flannery -S Date: 2020.06.08 18:22:03 -04'00'

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