



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 10, 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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA take the following three actions described below:

- 1) 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 PGx information.
- 2) As required by the First Amendment and the practice of medicine provision of the Federal Food, Drug, and Cosmetic Act (FDC Act), FDA should 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.
- 3) 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. FDA should also 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.

This petition was received by this office on 01/09/2020 and it was assigned docket number FDA-2020-P-0152. 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
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)