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April 13, 2017

Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Lack of timely notice of the meeting of the Antimicrobial Drugs Advisory Committee

Dear Dr. Ostroff:

Public Citizen is writing to express serious concern regarding the Food and Drug Administration's (FDA's) failure to provide timely notice in the Federal Register of today's meeting of the Antimicrobial Drugs Advisory Committee in accordance with the requirements of the agency's regulations at 21 CFR 14.20.

FDA regulations at 21 CFR 14.20(a) require the following:

Before the first of each month, and at least 15 days in advance of a meeting, the Commissioner will publish a notice in the Federal Register of all advisory committee meetings to be held during the month. Any advisory committee meetings for that month called after the publication of the general monthly notice are to be announced in the Federal Register on an individual basis at least 15 days in advance. The Commissioner may authorize an exception to these notice requirements in an emergency or for other reasons requiring an immediate meeting of an advisory committee, in which case public notice will be given at the earliest time and in the most accessible form feasible including, whenever possible, publication in the Federal Register.

FDA regulations at 21 CFR 14.20(b)(10) also stipulate the following:

The Federal Register notice [of an advisory committee meeting] will include-- ...

(10) When a notice is published in the Federal Register less than 15 days before a meeting, an explanation for the lateness of the notice.

On April 7, 2017, the FDA published in the Federal Register a notice of the April 13, 2017 meeting of the Antimicrobial Drugs Advisory Committee, including the establishment of a public docket and a request for comments related to the meeting. The notice indicated the following:

Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 7, 2017.¹

The notice also stated that (a) the docket for the meeting would close on April 12, 2017; (b) comments received on or before April 10, 2017, would be provided to the committee; and (c) comments received after April 10 would be taken into consideration by the agency.

Significantly, the notice did not include any explanation for the lateness of the notice, and, to the best of our knowledge, no notice of the meeting was posted on the FDA's website prior to April 7, 2017. Furthermore, neither the Federal Register notice nor the FDA briefing document for the meeting² indicated that the topic of the meeting represented an emergency or otherwise required an immediate meeting of the committee.

The FDA clearly failed to comply with the requirements of its own regulations at 21 CFR 14.20 in providing notice of today's meeting of the Antimicrobial Drugs Advisory Committee. Although we have decided not to take further action regarding this meeting, we will be closely monitoring the FDA's notices regarding future advisory committee meetings. In the event that the agency fails to provide timely notice of advisory committee meetings in accordance with all regulatory requirements with respect to future advisory committee meetings, we will pursue available legal avenues to ensure compliance.

Thank you for your attention to this matter.

Sincerely,



Michael Carome, M.D.
Director
Public Citizen's Health Research Group

¹ Food and Drug Administration. Antimicrobial Drugs Advisory Committee; notice of meeting; establishment of a public docket; request for comments. 82 FR 17011. April 7, 2017. <https://www.gpo.gov/fdsys/pkg/FR-2017-04-07/pdf/2017-06901.pdf>. Accessed April 13, 2017.

² Food and Drug Administration. FDA briefing document: Developing antibacterial therapies targeting a single bacterial species; meeting of the Antimicrobial Drugs Advisory Committee. April 13, 2017. <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM551632.pdf>. Accessed April 13, 2017.

cc: Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research
Jeffrey E. Shuren, M.D., J.D., Director, Center for Devices and Radiological Health
Janice M. Soreth, M.D., Associate Commissioner for Special Medical Programs