DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Alan R. Bennett
Ropes & Gray LLP
One Metro Center
700 12th Street, NW
Washington, DC 20005

Joan McPhee
Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600

Coleen Klasmeier
Paul E. Kalb
Sidley Austin LLP
1501 K Street, NW
Washington, DC 20005

Re: Docket No. FDA-2013-P-1079

Dear Mr. Bennett, Ms. McPhee, Ms. Klasmeier, and Mr. Kalb:

I am writing in response to your citizen petition received on September 3, 2013, and submitted on behalf of members of the Medical Information Working Group (MIWG).[1] Your petition requests that the Food and Drug Administration (FDA or Agency) (1) respond fully and in a constitutionally permissible manner to the four specific requests in your July 2011 petition and (2) comprehensively review, and modify as necessary in view of constitutional and statutory limitations, the regulatory regime governing manufacturer communications to protect and promote public health. This petition follows your petition received on July 5, 2011, requesting that the Agency clarify its regulations and policies governing certain communications and activities related to investigational new drugs and investigational devices and off-label uses of marketed drugs and devices. The agency provided an interim response to the July 2011 petition on December 29, 2011, which indicated that the agency was continuing to consider the issues raised by that petition.

[1] The petition was submitted on behalf of the following companies: Allergan, Inc.; Bayer Healthcare Pharmaceuticals Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Eli Lilly and Company; Genentech, Inc.; GlaxoSmithKline LLC; Johnson & Johnson; Novartis Pharmaceutical Corporation; Novo Nordisk, Inc.; Pfizer, Inc.; Purdue Pharma L.P.; and Sanofi US.

Specifically, the 2011 petition requests clarification in the following areas:

1. Manufacturer responses to unsolicited requests
2. Scientific exchange
3. Interactions with formulary committees, payors, and similar entities
4. Dissemination of third-party clinical practice guidelines

In both petitions, you maintain that currently there is a lack of clarity regarding the sharing of truthful and non-misleading scientific information about unapproved new uses of marketed drugs and devices.

The Agency is actively reviewing and analyzing the specific requests made in your petitions, including your request that we review and revise the regulatory regime governing manufacturer communications. Because we have not completed our consideration of your requests, we have not yet reached a final determination on your petitions. At the same time, the agency also continues to develop approaches to a variety of topics, including topics that relate to the subjects of your petition requests. As you are aware, since the submission of your first petition, we have issued several documents for public comment on related subjects. For example, in December 2011, we made available for public comment a draft guidance for industry titled *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Unsolicited Requests Guidance).[2] In the *Federal Register* of December 28, 2011(76 FR 81508), we published a notice seeking comments on various issues associated with scientific exchange to help in our further consideration of that subject. We are evaluating comments on the Unsolicited Requests Guidance and the scientific exchange *Federal Register* notice and determining our next steps for these topics.

Today we have posted on the FDA Drugs guidance website, a revised draft guidance for industry entitled *Distributing Scientific and Medical Publications on Approved New Uses – Recommended Practices*.[3] In the *Federal Register* of March 3, 2014, FDA will publish a notice announcing the availability of this guidance for public comment. This revised draft guidance describes the recommended practices for drug or medical device manufacturers, or their representatives, to follow when distributing to health care professionals or health care entities scientific and medical publications that discuss unapproved new uses of approved drugs or approved or cleared medical devices. In particular, this revised draft guidance not only addresses journal articles, but also separately clarifies FDA's current recommendations for manufacturer dissemination of medical and scientific textbooks that may address unapproved new uses of legally marketed drugs and devices, and adds a new section that includes specific recommendations for manufacturers who choose to disseminate clinical practice guidelines. The

[2] Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf.

3 Available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

public comment period for this draft guidance will open on March 3, 2014. We also expect to address issues related to interactions with formulary committees, payors, and similar entities after providing an opportunity for public comment.

While we continue to pursue policy development in these related areas, we are still considering all the specific requests made in your petitions, including your request that we review the regulatory regime governing manufacturer communications. We are providing this interim response in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). Because the petition raises complex issues requiring extensive review and analysis by Agency officials, and because we continue to be actively engaged in addressing these issues, we are not providing a final response at this time.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research