DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

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Re: Docket Nos. FDA-2011-P-0512 and FDA-2013-P-1079

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

I am writing to provide the Medical Information Working Group with an update on FDA's June 2014 response to your citizen petitions. Please note that we are also placing a copy of this letter in the above-referenced dockets.

In our response, we discussed our intention to issue guidance that addresses unsolicited requests, distributing scientific and medical information on unapproved new uses, and manufacturer discussions regarding scientific information more generally by the end of this calendar year, as well as a draft guidance document on health care economic information. Our current goal is to issue guidance that addresses manufacturer dissemination of information regarding unapproved uses during the first part of 2015 followed by guidance that addresses HCEI. We are also currently reviewing comments received on four related draft guidance that FDA issued earlier this year:

1. Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices;
2. Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics;
3. Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices; and
4. Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.

We appreciate the comments we have received on these guidance and are considering all the perspectives reflected in the comments as we work on all these guidance. Please be assured that these guidance are one of FDA's highest priorities in the coming year.

Sincerely,

Leslie Kux
Associate Commissioner for Policy