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Date: 11/16/2012 5:01:51 PM

Subject: FW: Inter-Governmental Working Meeting on December 19, 2012

Attachments: Governor.pdf.pdf

From: FDA Commissioner [mailto:commissioner@fda.hhs.gov]

Sent: Friday, November 16, 2012 5:01 PM

Subject: Inter-Governmental Working Meeting on December 19, 2012

Dear Governor,

I am writing to invite you (or your designated representative) to participate in your official capacity in an inter-governmental working meeting on December 19, 2012, to provide your perspective on the U.S. Food and Drug Administration's (FDA's) relationship with the states regarding compounding pharmacies and the best way to provide oversight of this industry going forward. FDA is reaching out to the offices of the governors, state departments of health, and the state boards of pharmacy, recognizing that all three may have a responsibility for the oversight of compounding pharmacies, depending on the state.

As I stated in my testimony before House and Senate Committees this week, the states play a critical role in the oversight of traditional pharmacy compounding, which can include compounding a customized medication in response to a prescription by a licensed practitioner based on the identified medical need of a particular patient for the compounded product, and I believe that the states should continue to do so. However, there is a category of "non-traditional" compounding that requires additional oversight. I testified about the need for federal standards for non-traditional compounding, which is compounding that poses higher risks because of certain factors including the type of activity (e.g., sterile compounding), the amount of product being made, and interstate shipment, among others. FDA would like to hear from its state partners while the agency is working with Congress to consider new authorities over "non-traditional" compounding pharmacies.

During the inter-governmental working meeting, FDA plans to discuss issues regarding the role of the FDA and the states in the oversight of compounding including:

Given existing authorities and resources, are the states currently able to provide the needed oversight of pharmacy compounding and consumer protection?

What should the federal role be in regulating higher-risk pharmacy compounding such as compounding high volumes of drugs for interstate distribution?

Is there a way to rebalance federal and state participation in the regulation of pharmacy compounding that would better protect the public health? What strategies should be developed to further strengthen federal/state communications?

Do you see a role for the states in enforcing a federal standard for "non-traditional" compounding? If so, what role? What factors would affect a decision by your state to take on such responsibility?

The inter-governmental working meeting will take place in the Great Room on the FDA's White Oak Campus located at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. The working meeting will begin at

9 a.m. and will be followed by a separate public meeting in the afternoon. Certain participants from the inter-governmental meeting will be asked to summarize the discussion at the separate public meeting.

The agency intends to promptly issue a *Federal Register* notice to inform stakeholders about the separate public meeting the afternoon of December 19. We will send this notice to you as soon as it becomes available. Detailed information for attendees at meetings on the FDA White Oak campus is available at <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

To attend the inter-governmental working meeting, state representatives are being asked to register online at <http://www.cvent.com/d/mcqddp/1Q> no later than December 12. If you have any questions regarding registration, please contact Steve Morin, Health Programs Coordinator with the FDA Office of Special Health Issues, Office of External Affairs, at Steve.Morin@fda.hhs.gov. For questions regarding logistics, please contact Pat Kuntze, Senior Advisor for Consumer Affairs, Office of External Relations, Office of External Affairs, at Patricia.Kuntze@fda.hhs.gov.

This inter-governmental working meeting is but the first step in establishing a partnership between FDA and the states to build a regulatory framework for compounding pharmacies that adequately protects the public health, and we hope that you or your designated representative will be available to participate.

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs