

From: LeMoine, Leigh
To: Veldran, Katherine <KatherineVeldran@gov.sc.gov>
Date: 12/1/2012 11:15:02 AM
Subject: RE: Follow-up Invitation: Dec. 19 Compounding Pharmacies Meeting: Governors

Hi, can we talk about this on Monday? I had been told by Christian and Josh this wasn't an invitation but policy request that you had been sent as well and were handling and that I could close out my records. If that's not the case, just want to know appropriate way to respond as NH will not be participating.

Thanks,
Leigh

From: Veldran, Katherine
Sent: Friday, November 30, 2012 1:36 PM
To: Haltiwanger, Katherine; LeMoine, Leigh
Subject: RE: Follow-up Invitation: Dec. 19 Compounding Pharmacies Meeting: Governors

At this time there is no action on my part.
Please advise.
KV

From: Haltiwanger, Katherine
Sent: Friday, November 30, 2012 1:35 PM
To: LeMoine, Leigh; Veldran, Katherine
Subject: FW: Follow-up Invitation: Dec. 19 Compounding Pharmacies Meeting: Governors

KV, just wanted to pass along. I think you are handling this with DHEC and LLR... thanks.

From: Marchand, Heidi [<mailto:Heidi.Marchand@fda.hhs.gov>]
Sent: Thursday, November 29, 2012 6:12 PM
To: Marchand, Heidi
Subject: Follow-up Invitation: Dec. 19 Compounding Pharmacies Meeting: Governors



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

November 29, 2012

Dear Governor:

I am writing in follow-up to the email that Dr. Margaret A. Hamburg, Commissioner, Food and Drugs sent to you on November 16, 2012 inviting you (or your designated representative) to participate in an inter-governmental working meeting on December 19, 2012 on pharmacy compounding issues. Dr. Hamburg reached 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.

At the December 19 meeting, the Food and Drug Administration (FDA) plans to discuss the role of the FDA and the states in the oversight of compounding including issues regarding the current capacity of the states to provide needed oversight of compounding, what the federal and state roles should be in regulating higher-risk pharmacy compounding, and how best to strike the balance between federal and state regulation. 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 which will begin at 3 p.m.

Since we extended the invitations to participate in the meeting, several states have requested that FDA help to defray some of the costs associated with travel to and participation in the meeting. We have carefully considered those requests, and I am pleased to announce that FDA will be able to pay for the travel and per diem expenses for up to two representatives from each state to attend the one-day meeting, which would include payment for an overnight stay of one (1) night. We are hopeful that defraying these travel costs will allow for robust participation.

If you or your representative(s) would like to take advantage of this travel stipend, please contact Rachel Trevino in the Office of Financial Services at Rachel.Trevino@fda.hhs.gov. In addition, please make sure to register online at <http://www.event.com/d/mcqddp/1Q> no later than December 12. You will need to register first before FDA can book your travel arrangements. 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.

In preparation for the meeting, we sent out a list of questions for you to contemplate and come ready to discuss. These include:

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 re-balance 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?

In addition to these questions, it would be helpful if attendees would come prepared with an understanding of the extent to which compounded sterile products from outsourcers are used by health care facilities in your state. We are asking that the state boards of pharmacy and departments of health discuss with health care facilities in their states the extent of such outsourcing for sterile products. Here are some questions that may be helpful in your discussions with them:

To what extent do these facilities utilize products from large scale compounding pharmacies?

What types of products do they obtain from large scale compounding pharmacies (e.g., convenience dosage forms, sterile admixtures, custom-compounded products or other)?

To what extent are these types of product used by hospitals, outpatient surgical/procedural clinics (e.g., GI, interventional radiology, surgery), dialysis, nursing homes and other longer-care facilities such as rehab, home health care services, hospice?

Would abrupt loss of supply cause shortages? Would it cause care disruption? How severe? Are alternative suppliers or preparation methods available for these products?

We look forward to hearing your perspectives and working with you to address this very important issue.

Sincerely,

Heidi C. Marchand, Pharm.D.
Assistant Commissioner
Office of Special Health Issues/Office of External Affairs
heidi.marchand@fda.hhs.gov