

From: Milligan, Patricia
Sent: Friday, March 21, 2014 5:51 PM
To: Tangney, Cynthia
Cc: Gutowski, Teresa; Bouchelle, Timothy (PSC/AMS); Bergeron, Brenda; Hackett, William J; Dake, Sylvia; Fontneau, Sean; Sandgren, Peter; Stang, Annette
Subject: RE: KI Update

Hi Cindy

When we first discussed this in March and April 2013, (see attached email) we agreed that we would send you the vendor information and you could discuss with the vendor your needs for special packaging when the contract was awarded. In the past the NRC has not paid for any special packaging and we have never been involved in any negotiations with the vendor on behalf of a State for special packaging. The NRC requires that the tablets be blister packed and the distributor sends out the tablets in a manner that meets their FDA approved packaging. Apparently Anbex had prior approval from FDA to repackage the tablets in a manner that is different from their approved packaging.

DHHS is the agent for NRC and they are the ones who will receive and resend the tablets. Annette sent you the contact information for HHS. I understand that the manufacturer is not allowed to repackage their product as it has to be packaged in the FDA approved packaging for import. Have you spoken with Tim Humphries from HHS to see if they would be able to repackage in accordance with your needs and bill CT directly?

<

We were aware that some States would have to change their public education materials to address the change to 65 mg tablets. NRC did notify you and other States (see emails dated March 8 and 19, 2013) that NRC would no longer be supplying 130 mg tablets but would be instead supplying 65 mg tablets. And included in a follow up email to you, we provided specific answers to your questions and included a photograph of the new tablets and the packaging. All of the emails related to the KI replenishment for the 2014 replenishment cycle are entered into the NRC ADAMS system in accordance with NRC policy.

In November 2013, NRC sent out an email to inform impacted States of the status of the KI replenishment and that the tablets would likely be delivered in the March-April timeframe due to the many budget challenges faced by the federal government. A short time later we sent out the FDA memo on tablet shelf life extension and then we have followed up with additional status updates pointing to an April delivery. We have tried very hard to be proactive in our communications on these important changes recognizing the impact such changes have on the states and their programs.

I am happy to discuss this next week. Please let me know when you are available.

Thanks and have a good weekend.

Trish

From: Tangney, Cynthia [Cynthia.Tangney@ct.gov]
Sent: Friday, March 21, 2014 3:27 PM
To: Milligan, Patricia
Cc: Gutowski, Teresa; Bouchelle, Timothy (PSC/AMS); Bergeron, Brenda; Hackett, William J; Dake, Sylvia; Fontneau, Sean; Sandgren, Peter
Subject: RE: KI Update

Thanks Trish,

In past correspondence, you had mentioned that we would be able to negotiate with the vendor, but we needed to wait for a p.o. number and POC so we could negotiate with the vendor. We were then

directed to DHHS. We have been trying to work out the packaging issue through DHHS, but haven't made a lot of progress. Now you are sending us a status update to expect delivery in less than a month.

Are you saying that we still have time to negotiate the packaging?

The packaging means a great deal to us in CT because our distribution plans are very thorough. Now, we will need to open the box, rip off the required number of pills, provide separate literature (labor intensive) and we still need to determine how we would accomplish that. There isn't a lot of time left to plan.

There is also the dosage change and that means changing all of our public information and fact sheets that we hand out with the pills. In the past, we went through Anbex, and they were able to package a set of pills with our information right inside a cellophane package. This was an ideal packaging system.

These are our major issues. We need to know if we can still negotiate with the vendor on packaging. Who will pay for the cost difference if there is one? Anbex also gave us a 7 year expiration date in the past, while this one is six years.

Can we get on a conference call sometime next week and work out the details?

Thanks,

Cindy

From: Milligan, Patricia [<mailto:Patricia.Milligan@nrc.gov>]
Sent: Friday, March 21, 2014 2:23 PM
To: Tangney, Cynthia; Rose, Dan (DEMA; Mike Griffen; James.Langenbach@doh.state.nj.us; jeffrey.winegar@doh.state.nj.us; Irwin, William; Corbett, Pamela; Fisch, Theodore <TFisch@dhss.ny.gov> (TFisch@dhss.ny.gov); gus.savastano@state.ma.us; Hintz, Pamela; Wilson, Tom; Lipp, David; Helmer, Stephen; Snee, Michael
Cc: Bouchelle, Timothy (PSC/AMS); Gutowski, Teresa; Bergeron, Brenda; Hackett, William J; Dake, Sylvia; Fontneau, Sean; Sandgren, Peter
Subject: RE: KI Update

Hi Cindy

I am not sure I understand the packaging problem. NRC has never customized orders for states. Any customization was done by direct interaction between State and vendor without NRC engagement or knowledge for that matter.

The shipments are not yet on their way. The email I sent below was simply designed to be a status update.

Can you please let me know what the problems are?

Thanks so much.

Trish

From: Tangney, Cynthia [Cynthia.Tangney@ct.gov]
Sent: Friday, March 21, 2014 1:55 PM
To: Rose, Dan (DEMA; Mike Griffen; James.Langenbach@doh.state.nj.us; jeffrey.winegar@doh.state.nj.us; Irwin, William; Corbett, Pamela; Fisch, Theodore

<TFisch@dhses.ny.gov> (TFisch@dhses.ny.gov); gus.savastano@state.ma.us; Hintz, Pamela; Wilson, Tom; Lipp, David; Helmer, Stephen; Snee, Michael
Cc: Milligan, Patricia; Bouchelle, Timothy (PSC/AMS); Gutowski, Teresa; Bergeron, Brenda; Hackett, William J; Dake, Sylvia; Fontneau, Sean; Sandgren, Peter
Subject: RE: KI Update

Hello and Good Afternoon,

I have a few questions for my REP colleagues.

Does anyone else have any distribution plan issues resulting from the new dosage and/or packaging for this shipment of KI?

Did anyone else have a chance to negotiate packaging before we were notified the shipment was on its way?

Anyone have a good general public distribution plan to share??

I would appreciate any input you can provide.

Thanks very much, and have a great weekend.

Cindy Tangney
REP Program Supervisor
CT DEMHS
860-256-0874

From: Milligan, Patricia [<mailto:Patricia.Milligan@nrc.gov>]
Sent: Tuesday, March 18, 2014 12:00 PM
To: Tangney, Cynthia; Rose, Dan (DEMA; Mike Griffen; James.Langenbach@doh.state.nj.us; jeffrey.winegar@doh.state.nj.us; Irwin, William; Corbett, Pamela; Fisch, Theodore
<TFisch@dhses.ny.gov> (TFisch@dhses.ny.gov); gus.savastano@state.ma.us; Hintz, Pamela; Wilson, Tom; Lipp, David; Helmer, Stephen; Snee, Michael
Cc: Nancy McNamara; Stang, Annette; Quinn, Vanessa (Vanessa.Quinn@fema.dhs.gov); Ward, Paul (Paul.Ward@fema.dhs.gov)
Subject: KI Update

Hello,

I was hoping to be writing this under spring skies rather than after yet another winter storm. I hope that everyone is surviving this winter and remember the first day of spring is this Friday!

We are on track to have the KI delivered to you by no later than the third week of April. We will notify you in advance of the actual ship dates so that you can get prepared for receipt of the shipment. Annette will send emails with the projected ship dates. If you have any changes in your "ship to" location now is the time to let us know.

Again, thanks for your patience.

Trish

Patricia A. Milligan, CHP, RPh
Senior Level Advisor for Preparedness and Response
Office of Nuclear Security and Incident Response
US Nuclear Regulatory Commission
Three White Flint North
MS 3WFN-09D-14
11601 Landsdown St.
North Bethesda, MD 20852
301-287-3739