## Stang, Annette

**From:** Milligan, Patricia
**Sent:** Monday, December 23, 2013 1:16 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:** McNamara, Nancy; Stang, Annette; Quinn, Vanessa (Vanessa.Quinn@fema.dhs.gov); Ward, Paul (Paul.Ward@fema.dhs.gov); Lewis, Robert; Morris, Scott
**Subject:** KI Update
**Attachments:** NRC iOSAT memo.signed.FINAL.12.20.13.pdf

Hi,

Attached is the memo from FDA on the shelf life extension for the KI tablets expiring February 2014. In addition, I want to let you know that we have made a change in our KI procurement process. We have entered into an interagency agreement with the Department of Health and Human Services and they will be procuring and shipping the KI tablets. We don't yet have delivery information such as the delivery service/ courier. As soon as we have more details on delivery we will let you know you.

Thanks so much for your patience and understanding. Have a wonderful holiday and happy new year!

*Trish*

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**From:** Milligan, Patricia
**Sent:** Thursday, November 21, 2013 10:57 AM
**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
**Cc:** McNamara, Nancy; Stang, Annette; Quinn, Vanessa (Vanessa.Quinn@fema.dhs.gov); Ward, Paul (Paul.Ward@fema.dhs.gov); Lewis, Robert; Morris, Scott
**Subject:** KI Update

Hi,

I want to bring everyone up to date on the status of KI replenishment.

First let me assure you that we are working to ensure that your KI delivery arrives as soon as possible. As you know, the federal government has faced budget challenges this year. The shutdown added additional challenges and given that the shutdown occurred at the very beginning of the fiscal year, we had yet more challenges. We have worked through those and are on track to purchase KI. The optimist in me would like to tell you that you will have it by the end of Feb. The realist in me urges appropriate caution and likely it will be received in the March-April 2014 timeframe. We are working with FDA and they will be drafting a memo stating that the tablets can be used during the short period between expiration and replenishment without compromise to public health and safety. As soon as we have that memo, we will send it to you. In addition, FEMA has assured the NRC that they will not consider these stockpiles to be out of date should they be inspected during this interim period.

As you know, KI is a very stable substance and it is the "active" ingredient in iodized salt. The FDA recognizes its unique stability and published special guidelines for shelf life extension. These are attached and I have excerpted the following from that document- see page 4. (I highlighted the key points.) Between these guidelines and the upcoming memo from FDA, I think you will be able to address any concerns that may arise regarding the expired KI tablets.

Thank you so much for your understanding and patience. I apologize for any and all problems this may be causing you. Annette and I will keep you up to date on the process over the next few months including when you can expect your delivery. If you haven't done so, please send Annette the up-to-date "ship to " information including a telephone number and contact person.

Don't hesitate to email or call (301-287-3739 is my new phone number) if you have additional questions or concerns.

Have a very happy thanksgiving!

"A. Observations About KI Tablet Stability Based on Historical Data

Potassium Iodide Tablets, USP, is a compendial drug product that is manufactured to meet the recommended tests and specifications listed in the USP monograph. Assay and dissolution are the two specifications with potential relevance to stability, assuming identification and content uniformity testing were performed at release.[11] **Stability studies over many years have confirmed that none of the components of KI tablets, including the active ingredient, has any significant potential for chemical degradation or interaction with other components or with components of the container closure system when stored according to labeled directions.**

To date, the only observed changes during stability testing have been the failure of some batches of KI tablets to meet the USP $S_1$ dissolution specification, Q=75 percent in 15 minutes. Some **tablets tested required slightly longer than the specified time to achieve dissolution, but even in the case of a failure of this sort, the product would remain usable**. In such cases, instructions can be provided to crush the tablets and mix them with a juice or other liquid prior to administration as suggested for emergency pediatric dosing (see Home Preparation Procedures document cited above). In any long-term stability evaluation, appearance should be monitored as a matter of course. In the specific case of KI tablets, a yellowish discoloration would be indicative of stability problems. **Since pure KI is known to be very stable (as long as it is protected from moist air),[12] ongoing evaluation and testing of each batch is probably unnecessary as long as the market package remains intact and continues to be stored under controlled conditions as described in the labeling."**

*Trish*

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