



Conference of Radiation Control Program Directors, Inc.

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February 14, 2007

William F. Kane

Deputy Executive Director for Reactor and Preparedness Programs

Office of the Executive Director of Operations

U. S. Nuclear Regulatory Commission

Washington, DC 20555

Dear Mr. Kane:

On behalf of the Conference of Radiation Control Program Directors, Inc. (CRCPD) Board of Directors I am writing to seek resolution of a critical issue regarding the replenishment of Potassium Iodide (KI) stockpiles within state Radiological Emergency Preparedness programs requested under the 2001 rule change. Many states have expressed their dissatisfaction in the way this initiative is progressing and have requested the CRCPD to intervene on their collective behalf. While I am certain that you are aware of the progress of this initiative, I would like to take the time to outline the recent history from the perspective of the state programs.

On October 26, 2006, NRC sent a letter to each of the contacts within the states that are actively participating in the KI initiative. That letter outlined the procedure to request replenishment of state stockpiles of KI. The letter also indicated that this would be a one time only purchase offered by the NRC. Since that time, many states have been working diligently to meet the requirements for that offer. However, in the past month state organizations responsible for the stockpile and distribution of KI have been informed that appropriations to support this initiative have not been approved. As a result, many states will not be able to receive supplies to replenish stockpiles that will become outdated this year. In fact, doses that number in the millions will expire by the end of March 2007 with no reasonable expectation that replacements will arrive in time to satisfy state preparedness and response requirements.

In response to this dilemma, NRC staff has been working with the manufacturer and the FDA to reach an agreement regarding the extension of the expiration date on current stockpiles. The FDA has approved a request from Anbex to relabel Iosat potassium iodide tablets manufactured prior to 2004, extending the shelf life from five years to seven years. Mr. Eric J. Leads of your staff requested that Anbex extend that approval to the products purchased by the NRC. Patricia Milligan, also of your staff, received a response to that request on January 23, 2007 from the legal firm representing the manufacturer. In that letter, Anbex clearly states that while there are no "significant differences in the formulation, manufacturing process or packaging materials," they will not authorize extension until states prove storage has been maintained according to manufacturer specifications. The attorney for Anbex further clarified their position stating that any request to authorize shelf life extension also is a request to renegotiate the purchase contract. In short, Anbex will extend the shelf life for a price.

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Further attempts have been made by NRC staff to resolve the extension issue with the FDA. State agencies have been provided with several e-mails from Ms. Milligan and Michael Smela (FDA) that seem to indicate that there is a way to extend the shelf life without the manufacturer's approval. Ms. Milligan indicates in her correspondence that this is "relatively easy" to accomplish. The states do not agree.

During a conference call between the NRC and state agencies held in January, states were led to believe that the FDA would approve shelf life extension in writing and on department letterhead with specific instructions on the steps required to accomplish that objective. That letter has not been developed nor is it expected at this point. In addition, the methodology outlined in Mr. Smela's e-mail represents his opinions and beliefs (specific language from the e-mail) and not those of the FDA as a whole. While this may seem "relatively easy" to staff at the NRC and FDA, it does not seem that way from the state perspective. The information provided to the states to extend the shelf life carries no weight with regard to legal authority for the extension. We and state organizations do not feel that the NRC and FDA have provided sufficient legal authority under which to carry out this extension process.

The Commission has made a commitment to its state partners and stakeholders to replenish supplies of KI. Funding for that is not available. The NRC made a commitment to pursue shelf life extension. Official documentation and guidance on that process is unavailable. We support the states' position with regard to this critical issue. The NRC needs to take responsibility for their commitment to this initiative and provide definitive solutions and guidance for states to follow to meet their Emergency Preparedness directives and obligations. Therefore, we request that the NRC work in conjunction with the FDA toward issuing an official guidance statement that will authorize state agencies to legally extend the shelf life of current stockpiles. The timely issuance of an official position is critical to the level of preparedness at the state level and their ability to protect the health and safety of the public.

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We urge NRC to act quickly before millions of doses of KI in state stockpiles and in medicine cabinets throughout the country reach their expiration date of March 2007. In less than a month, the NRC and the states will be required to explain to the public why we have allowed this to occur. Since state programs have been assured of a process to alleviate the KI expirations issue, the states did not proactively pursue the expiration extensions independently. If you have any questions or would like to discuss this issue further, please feel free to contact me directly at 803/545-4599.

Sincerely,



T. Pearce O'Kelley
Chairperson
Conference of Radiation Control Program Directors, Inc.

cc: Charles Miller
Janet Schlueter
Kathleen Schneider
CRCPD Board of Directors