COMSECY-07-0002

January 26, 2007

MEMORANDUM TO: Chairman Klein
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons

FROM: Luis A. Reyes ***/RA/***
Executive Director for Operations

SUBJECT: POTASSIUM IODIDE REPLENISHMENT

The purpose of this memorandum is to inform the Commission of the status of staff efforts to replenish Potassium Iodide (KI) tablets for those States currently providing it for populations within the 10-mile Emergency Planning Zone (EPZ) as directed by the Staff Requirements Memorandum on SECY-06-0142, "Options and Recommendations for Replenishing Expired Potassium Iodide (KI)". In SECY-06-0142, the staff provided an estimate of $1.7 million in FY 2007 and $500K in FY 2008 for replenishment of existing KI stockpiles. At the time SECY-06-0142 was submitted to the Commission, the staff expected that the States would request the same number and dose of tablets as they did with their original order. The staff also estimated that the bulk of the replenishment orders would be filled during the first quarter of FY 2007 before the price increase in the second quarter of FY 2007 when option year 3 of the contract would take effect (approximately $100K cost increase for 13 million tablets). In addition, due to the shelf life of the tablets, the staff estimated that the replenishment request would come 5 years after the original order for the Anbex, Inc. (Anbex)130 mg tablets and 2 years after the original order for the Recip Stockholm AB (Recip) 65 mg tablets.

Due to the impacts of the Continuing Resolution, the staff contacted the States in December 2006 to verify the resources needed to implement the Commission's direction. At that time, the staff identified that all States indicated interest in replenishment of KI stockpiles in FY 2007 and, thus, the $2.3M projected for KI will be needed in FY 2007. During these discussions, some States indicated interest in extending the shelf life of stockpiles rather than full replenishment.

As a result of these and subsequent discussions with States, the staff is pursuing shelf-life extension options with the Food and Drug Administration (FDA). The FDA considers extending the new expiration dating to the previously manufactured lots scientifically sound if there were no significant differences in the formulation, manufacturing process, or packaging materials for

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those lots as compared to current lots. However, FDA regulations and processes typically rely on the manufacturer to apply shelf-life extension to existing product as the manufacturers must verify that existing product was manufactured and packaged in accordance with FDA Good Manufacturing Processes and the approved drug application supplement for the shelf-life extension. Anbex's legal counsel, in a letter dated January 23, 2007, (Enclosure 1) to the Nuclear Regulatory Commission (NRC) states, "It is Anbex's belief there are no significant differences in the formulation, manufacturing process, or packaging materials for those lots as compared to current lots." Based on this statement from Anbex as to the stability of their product lots, the FDA indicated in an email to NRC (Enclosure 2) dated January 24, 2007, that, "the States do not need Anbex's permission in order to extend the expiration date of stockpiled lots by 2 years . . . Assuming the stockpiled lots do not differ significantly in formulation, manufacturing process, or packaging materials from current lots, it would be scientifically sound to extend the expiration dating period to the currently approved 7-year period. In the above cited letter, Anbex confirms this is the case." In response to staff request, the FDA indicated that they intend to send NRC a letter summarizing the email.

The manufacturer of the 65 mg tablets, has provided the necessary documentation on the integrity of their product, Thyro-Safe, and suggested that all purchasers may extend the shelf life. (Enclosure 3)

Based on telephone conferences in January 2007, the staff identified that States, with the exception of New York, continued to express interest in shelf-life extension in addition to replenishment of those tablets that were distributed directly to the public. The staff has placed an order for replenishment of the 65 mg and 130 mg tablets for New York State. In addition to the tablet stockpiles, New York received approximately 3 million doses of 65 mg liquid KI from Health and Human Services (HHS) as part of the joint NRC-HHS distribution. This product does not expire until 2010. Connecticut and Delaware have distributed approximately 75 percent of their stockpiles directly to the public. New Jersey is considering a change to its KI distribution plan to include direct mail of KI tablets to residents of the 10-mile EPZ and may require additional KI to implement this proposed plan. Additionally, both Arizona and Maryland have seen significant increases in populations in their EPZs and indicated that additional KI would be needed for these populations

The staff's current estimate to support States' KI needs in FY07, based on verbal discussions with State representatives, is approximately $600K. This includes replenishment for New York, Connecticut, Delaware, and partial replenishment for the remaining states. California will not require replenishment until FY09 due to the extensions applied to their stockpiled KI. This estimate includes only partial replenishment for Pennsylvania, as Pennsylvania has not yet indicated replenishment plans to the staff. Should Pennsylvania request complete stockpile

replenishment, the cost could increase by approximately $300K. States were requested to notify the NRC by April 30, 2007, of their KI replenishment needs. At that time, the actual FY 2007 costs will be known.

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Enclosures: As stated

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