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.

SECY, please track.

Enclosures: As stated

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January 23, 2007

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Dear Ms. Milligan:

As you know, this firm and I represent Anbex, Inc. in legal and business matters. I have reviewed the request from Mr. Eric J Leeds, requesting that Anbex authorize the Nuclear Regulatory Commission (NRC) to relabel Iosat® potassium iodide tablets manufactured and purchased by the NRC prior 2004, to extend the shelf life from five years to seven years.

This request is apparently based upon the approval by the Food and Drug Administration (FDA) in January of 2004 of Anbex's supplement to its Abbreviated New Drug Application (ANDA), to permit Anbex to label product manufactured after that date to bear a seven-year shelf life.

By electronic mail to Mr. Alan Morris, President of Anbex, you indicated that FDA advised you that there may be instances in which it is "scientifically sound" to relabel a product with a new expiration date, where FDA has approved a new extended expiration dating period for product manufactured in the future. You indicated that, according to FDA, it might be scientifically sound for the states to extend the expiration date on product that they have stockpiled if Anbex determines that there are no significant differences in the formulation, manufacturing process, or packaging materials for those lots as compared to current lots.

It is Anbex's belief that there are no significant differences in the formulation, manufacturing process, or packaging materials for those lots as compared to current lots. However, I cannot advise Anbex to provide the letter that you have requested without first receiving assurances directly from FDA that Anbex may proceed in that manner and receiving from the states appropriate evidence that

the conditions under which the product has been held since leaving Anbex's control have been consistent with Iosat® labeling.

Further, I have reviewed the contract under which the NRC purchased Iosat® tablets between 2002 and 2004. The price negotiated and agreed to by the NRC and Anbex reflected *both parties' understanding that the product being purchased would have a shelf life of five years.* A product with a seven-year expiration date would likely have been a more expensive product at the time.

NRC's request that Anbex authorize relabeling of the product purchased under the 2002 contract is effectively a request to renegotiate the contract. Assuming that FDA confirms that Anbex may relabel the product in question, Anbex would be happy to renegotiate the contract and to extend the expiration date for NRC's stockpiled Iosat® tablets at a mutually agreeable price or, alternatively, to negotiate a contract to replace the stockpiled product with product labeled with an extended shelf life.

Please feel free to contact me at the address on this letterhead, or by telephone at (202) 518-6325 or by e-mail at nhalpern@ofwlaw.com.

Sincerely,

Naomi J. L. Halpern

Naomi J. L. Halpern
Counsel to Anbex, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Roy Zimmerman, Director
Office of Nuclear Security and Incident Response
US NRC MS T-4D22A
Washington, D.C. 20555

FEB 15 2007

Reference Number: OGD #07-0163

Dear Mr. Zimmerman:

This is in response to a February 5, 2007 e-mail request and other e-mail exchanges from Patricia Milligan, Senior Advisor for Emergency Preparedness, US Nuclear Regulatory Commission. The communications were regarding the appropriateness of the States that had obtained Iosat® Tablets (Potassium Iodide Tablets, USP) extending the expiration dating period of these stockpiled lots to 7 years.

We understand that certain state governments have received from the Nuclear Regulatory Commission (NRC) Iosat® Tablets (Potassium Iodide Tablets USP) manufactured by Anbex, Inc. for stockpiling in the event of a radiation emergency. This drug product is manufactured under the approved Abbreviated New Drug Application (ANDA) 18-664. We understand that the stockpiled lots bear a 5 year expiration dating period. As it is known to the NRC that Anbex, Inc. has received approval from the Office of Generic Drugs (OGD) to apply a 7 year expiration dating period to this drug product, NRC requests advice from FDA as to whether it would be appropriate for the stockpiled lots that have a 5 year expiration date to have the expiration extended another 2 years.

When the expiration dating period of a drug product that is subject to an ANDA is extended by the manufacturer either due to FDA approval or under a protocol that had been approved by FDA, the extended expiration dating period is considered to apply to new lots manufactured after the extended expiration dating period has been implemented. The FDA does not have any regulation or policy regarding the application of an extended expiration dating period to lots that were manufactured prior to the implementation of the extended expiration dating period. However, FDA does not object to such a practice as long as adequate records are kept and doing so is scientifically sound. It would be considered to be scientifically sound if the lots having the expiration date extended had no significant difference in formulation, manufacturing process or packaging materials from current lots. The letter to Patricia Milligan at NRC from counsel to Anbex, Inc. dated January 23, 2007 indicates that this is the case.

Given the above information, it is our opinion that it would be scientifically valid and, therefore, appropriate for the stockpiled lots of Iosat® Tablets to have their expiration date extended by an additional 2 years. The States should ensure that the lots have been properly stored as recommended on the drug product label and also maintain an adequate record of the expiration date extension. This opinion is based strictly on scientific considerations. Any issues related to contractual agreements between the parties are outside the scope of these comments.

If you have any additional questions, please contact Mr. Michael Smela at 301-827-5775.

Sincerely,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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2006-06-19

Regarding extended expiry dating period for Thyrosafe

FDA has approved an extension of the expiration dating period to 72 months according to ANDA 76-350/S-007.

Thyrosafe batchnumber	Expiry date as printed on package	Shelf life when packaged	Extended expiry date
TF202A	08/2004	2 years	08/2008
TF301A	01/2005	2 years	01/2009
TF401A	01/2007	3 years	01/2010
TF402A	04/2007	3 years	04/2010
TF501A	12/2007	3 years	12/2010

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Enclosure 3