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*PRACTICE WITHIN THE DISTRICT OF COLUMBIA IS LIMITED TO MATTERS AND PROCEEDINGS BEFORE FEDERAL COURTS AND AGENCIES.

January 23, 2007

Patricia A. Milligan, RPh., CHP
Senior Advisor for Emergency Preparedness
Office of Nuclear Security and Incident Response
6 H2, NSIR/DPR/DDEP
One White Flint North
Rockville, Maryland

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.