

January 18, 2007

Mr. Alan Morris, President
Anbex, Inc.
Box 284, 35246 US 19 N.
Palm Harbor, FL 34684

SUBJECT: SHELF-LIFE EXTENSION OF ANBEX IOSAT 130 MG TABLETS

Dear Mr. Morris:

Per our phone conversation of January 17, 2007, the U.S. Nuclear Regulatory Commission (NRC) hereby requests written confirmation from Anbex of the approval of a 2-year extension to the expiration period of all IOSAT purchased by NRC and held in State stockpiles.

By letter dated February 21, 2005, Anbex approved such an extension for all IOSAT held by California (enclosed). During our discussion, you stated that the IOSAT product delivered to the States and stockpiled in accordance with the storage requirements specified by the package insert all meet the same exacting standards. Therefore, the shelf-life extension granted to California could reasonably be applied to any State desiring to extend their existing stockpiles of IOSAT 130 mg tablets. You further stated that there was no variability in the production process of the different lots of IOSAT purchased by NRC for delivery to the States.

NRC is reassured to hear that there is not a problem with IOSAT 130 mg tablets. We request a letter to NRC that states, as in the California letter, that all products produced by Anbex after January 2000, which includes all IOSAT purchased by NRC for delivery to the States is subject to monitoring and testing as required by the Food and Drug Administration (FDA) to assure that it meets or exceeds appropriate FDA specifications. The letter should further state that "to correctly calculate the new expiration date for all IOSAT purchased by NRC and held in State stockpiles, please add 2 years to the expiration date which is printed on the package."

If you have any questions regarding this letter, please contact Patricia Milligan, of my staff, at 301-415-2223.

We look forward to your reply by January 22, 2007, on this urgent issue.

Sincerely,

R/A

Eric J. Leeds, Director
Division of Preparedness and Response
Office of Nuclear Security and Incident Response

Enclosure: Letter to California from Anbex

cc: Vanessa Quinn, DHS
Dan Wilcox, DHS

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