June 5, 2002

The Honorable George W. Gekas
United States House of Representatives
Washington, D.C. 20515-3817

Dear Congressman Gekas:

I am responding on behalf of the U.S. Nuclear Regulatory Commission (NRC) to your letter of April 23, 2002 concerning the dosage of the potassium iodide being offered to the States by the NRC for children. As you may know, the NRC is providing potassium iodide tablets supplied by a manufacturer approved by the Food and Drug Administration (FDA) to requesting States. FDA approval ensures quality in the manufacture and integrity of the product. Because the FDA is responsible for regulating the production of potassium iodide tablets, it is the appropriate agency to review and respond to your request.

The NRC staff has discussed your request with Dr. David Orloff, Director, Division of Metabolic and Endocrine Drug Products, Office of New Drugs, Center for Drug Evaluation and Research at the FDA, who will be responding directly to you. Dr. Orloff can be reached by telephone at 301-827-6430.

Sincerely,

/RA/

Richard A. Meserve

cc: Deputy Commissioner Lester M. Crawford, FDA
Dr. Orloff, FDA/CDER