

May 30, 2002

Dr. David Orloff, Division Director
Center for Drug Evaluation and Research
Department of Health and Human Services
Food and Drug Administration
1451 Rockville Pike Room 6027
Rockville, MD 20852

Dear Dr. Orloff:

Under the Memorandum of Agreement between the Nuclear Regulatory Commission and the Food and Drug Administration (FDA), we are requesting the assistance of the FDA to address a concern received by the NRC regarding the approval of doses of potassium iodide other than 130 mg.

The NRC received the enclosed letter dated April 18, 2002, from Earl P. Freilino II, Director of Homeland Security, Commonwealth of Pennsylvania expressing concern that the presently approved 130 mg KI tablets are inadequate for dosing young children and neonates as directed in the FDA guidelines. The concern is that the tablets cannot be broken down into the appropriate sizes for the various age groups and that, as a result, there is risk of overdose of the young population. The State of Pennsylvania is requesting assistance by FDA to gain approval for doses other than the 130 mg size currently approved.

In that these are drug approval issues, we request that FDA respond directly to Director Freilino. Please provide us a copy of your response.

Should you need any assistance with this matter, please contact Patricia A. Milligan of my staff at 301-415-2223.

Sincerely,

/RA/

Kathy Halvey Gibson, Chief
Emergency Preparedness and
Health Physics Section
Equipment and Human Performance Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Enclosure: As stated

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