

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

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

**DISTRIBUTION**

EPHP Reading File

P. Milligan

K. Gibson

ADAMS Accession Number: ML021350304

OFFICE	IEHB/DIPM	IEHB/DIPM		
NAME	PMILLIGAN	KGIBSON		
DATE	5/ 29 /2002	5/30/2002		

OFFICE RECORD COPY