

EDO Principal Correspondence Control

FROM: DUE: 04/10/02

EDO CONTROL: G20020178
DOC DT: 03/22/02
FINAL REPLY:

Edward F. Jacoby, Jr.
New York State Disaster
Preparedness Commission

TO:
Chairman Meserve

FOR SIGNATURE OF : ** PRI **

CRC NO: 02-0221

Chairman Meserve

DESC: Requests Assistance in Gaining FDA Approval for
Potassium Iodide (KI) Doses in Other than the
130mg Size Currently Approved

ROUTING:
Travers
Paperiello
Kane
Norry
Craig
Burns/Cyr
Virgilio, NMSS
Wessman, IRO
Schum, OEDO
Davis, NMSS

DATE: 03/29/02

ASSIGNED TO: CONTACT:
NRR Collins

SPECIAL INSTRUCTIONS OR REMARKS:

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

Date Printed: Mar 28, 2002 16:50

PAPER NUMBER: LTR-02-0221 **LOGGING DATE:** 03/28/2002
ACTION OFFICE: EDO

AUTHOR: Edward Jacoby, Jr. (NY)
AFFILIATION: NY
ADDRESSEE: CHRM Richard Meserve
SUBJECT: Requests assistance in gaining FDA approval for potassium iodide (KI) doses in other than the 130mg. size currently approved

ACTION: Signature of Chairman
DISTRIBUTION: RF

LETTER DATE: 03/22/2002
ACKNOWLEDGED: No
SPECIAL HANDLING: SECY to Ack

NOTES:
FILE LOCATION: ADAMS

DATE DUE: 04/12/2002 **DATE SIGNED:**

EDO --G20020178



New York State Disaster Preparedness Commission

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Albany, NY 12226-2251

George E. Pataki
Governor

Edward F. Jacoby, Jr.
Chairman

March 22, 2002

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Richard A. Meserve, Chairman
USNRC
One White Flint North
Mail Stop 16C1, 11555 Rockville Pike
Rockville, Maryland 20852-2738

Dear Mr. Meserve:

As you know, New York State recently accepted potassium iodide (KI) from the Nuclear Regulatory Commission (NRC) to augment existing public safety programs that mitigate the threat posed by nuclear power plants. The state is committed to ensuring that, if needed, KI will be available for this purpose. I am writing to request your assistance in gaining FDA approval for doses in other than the 130mg. size currently approved.

As you know, FDA's guidelines, released in December, 2001, provide recommended doses of KI for different risk groups. FDA guidance proscribes that a 130 mg. dose of KI would be appropriate for adults aged 18 – 40 and for adolescents weighing approximately 70kg. This guidance prescribes doses of 65, 32, and 16 mg. for the remaining younger segments of the population, including infants.

Of particular concern is the inability to divide the 130-mg tablets accurately into the doses of 65 mg. recommended for most children and young adults. Accurately dividing the current pill into the even smaller doses prescribed in the FDA guidance is even more unrealistic. During an emergency requiring KI distribution, the need to divide KI tablets into these small doses would present considerable logistical problems. Given the potential that overdosing may produce side effects for this vulnerable segment of the population, the State is very concerned about distribution of solely the adult-sized doses during a disaster. An inability to verify proper dosing could affect public acceptance for the use of KI and could also raise legal concerns for those distributing it. As you know, New York State has already requested KI in the 65 mg. doses consistent with FDA guidance.

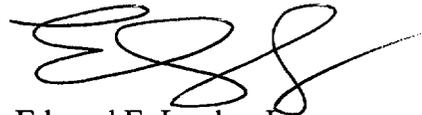
I have been made aware that the NRC's KI contractor has stated that it is able to provide KI in a 65-mg dose size that adheres to the same quality and potency standards under USP guidelines that presently apply to the 130-mg tablets. Doing this, however, would require approval from FDA in order for the product to be marketed as a radiation protection drug. I have also seen other sources for KI in smaller dosages and in a liquid form.

I strongly urge that NRC support an expedited FDA approval of a 65-mg KI tablet of the same approximate size as the existing 130-mg tablet, with an appropriate means of distinguishing between the two tablet sizes through color, shape or packaging. The combination of the 130-mg tablet and tablets at other dosages would provide a viable method of reducing the potential risk of complications from misuse of the drug by the public. Further, I also request your support for prompt FDA approval of the 32mg. and 16 mg. doses and that alternative forms of KI, such as a liquid, be examined and approved as appropriate.

In light of the federal government's current KI stockpiling initiatives, we believe there should be no reason for FDA to delay approval of smaller dose production that would facilitate compliance with the agency's own guidelines.

Thank you in advance for your support of this request.

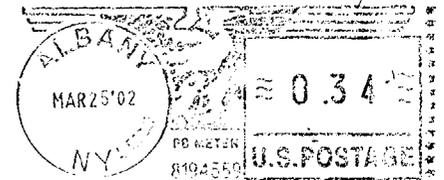
Sincerely,

A handwritten signature in black ink, appearing to read 'E. F. Jacoby, Jr.', with a long horizontal flourish extending to the right.

Edward F. Jacoby, Jr.
Chairman

EFJ:lw

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STATE EMERGENCY MANAGEMENT OFFICE
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