

December 18, 1998

DOCKETED  
USNRC

NOTE TO: Chairman Jackson  
Commissioner Dicus  
Commissioner Diaz  
Commissioner McGaffigan  
Commissioner Merrifield

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FROM: Peter Crane *Peter Crane*

DOCKET NUMBER

PETITION RULE PRM 50-63A  
(62 FR 66038)

1 DEC 98 11:37

SUBJECT: COSTS OF POTASSIUM IODIDE

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On December 8, 1998, in my private capacity, I attended a public meeting on potassium iodide in Painesville, Ohio. The meeting was called by the Ohio Department of Health to present its current thinking on the potassium iodide issue to counties and the public. In the past year, Ohio has circulated a first and then a second draft of its proposed new policy on potassium iodide. Its approach is two-track: stockpiling for the general population near nuclear plants, coupled with predistribution for those who affirmatively request the drug. They reason that people who are well enough informed to ask for the drug can be depended on to understand its limitations as well as its benefits. The Ohio officials explained that their policy focuses primarily on ensuring that the drug is available in an emergency to children and pregnant women.

At one point, there was discussion of how the anticipation of greater demand for potassium iodide had driven up the price of the drug. The Ohio officials responded that they had found a Swedish supplier offering the drug at half the cost and with twice the shelf life. At my request, Susan Hiatt of the Ohio Citizens for Responsible Energy followed up, and last night, I received an e-mail from Mr. Harvey Brugger of the Ohio Department of Health, attaching mail he had received from the Swedish company. The correspondence is attached. You will see that this Swedish company is offering a million 10-pill blister packs at \$.70 apiece, and 5 million at \$.60 apiece, with a guaranteed shelf life of up to 10 years. It is also offering to take the responsibility of securing approval from the Food and Drug Administration.

My purpose in writing this note is information, not advocacy, but I will not hide my belief that six-tenths to seven-tenths of a cent per child per year is not an exorbitant price to pay to bring the protection of American children up to world standards.

This note is written in my private capacity, at home, on my own time. I would ask the Secretary to add it to the docket file of PRM-50-63A as a comment and forward a copy to Ms. Carol Gallagher for posting on the NRC rulemaking website.

Attachment: E-mail from Mr. Harvey Brugger, Ohio Department of Health, December 17, 1998  
(with attachments)

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Subject: KI supplier in Sweden -Reply -Forwarded

Date: Thu, 17 Dec 1998 15:26:14 -0500

From: Harvey Brugger <HBRUGGER@GW.ODH.State.OH.US>

To: pgcrane@erols.com

CC: susan.hiatt@hamradio.org

Peter,

In response to Ms. Hiatt's request, I am forwarding information to you regarding our contacts with the Swedish company that provides KI. Two letters are appended to this message directly. (They should also appear as Wordperfect 6.1 attachments in the mail forwarded to Ms. Hiatt, which is also attached.)

Harvey

ATTACHMENT 1

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From: <allan.skolfman@recip.se>

To: ODH OMIS.DPM1 (COSTROVE)

Date: 11/3/98 10:04am

Subject: Potassium Iodide -your e-mail dated october 30, 1998

Dear Ms.Ostrove,

Thank you very much for your above message which we duly have taken care of. We would like to give you the following information:

1. Our product is registered in Europe.
2. All formal export rights from Sweden can be obtained.
3. In many countries registration is not a necessity as the authorities have the responsibility for the storage and the distribution of the tablets.
4. Potassium Iodide tablets are generally not to be found at pharmacies demanding a regular registration procedure.
5. Does the product have to be registered in the United States as the state of Ohio is having the responsibility for the handling of the product? If so is the case we will arrange for any authorisation needed, including the FDA. This may, however, take a considerable time to accomplish and also be associated with costs.
6. The availability of the product is totally dependent upon the volumes to be shipped. Consequently we would like to have your input in order to present the most adequate answer to you.
7. Pricing. This is also totally dependent upon volumes. However below please find our general price list.

100,000 packs (blister of 10 tablets)	-USD 1.15 per pack
500,000       "               "	-   "   0.90   "   "
1,000,000     "               "	-   "   0.70   "   "
5,000,000     "               "	-   "   0.60   "   "

8. Shipping costs. Generally we are selling at Ex Works (Incoterms 1990). However we are always open for discussion. in order to facilitate your ordering procedure.

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9. Payment conditions. Generally Irrevocable Letter of Credit.  
For US customers we may consider Cash on Delivery or Stand  
by Letter of Credit.

10. Ordering address:  
RECIP AB  
Branningevagen 12  
120 54 ARSTA  
Sweden

11. We have, as you may know, furnished not only Sweden with our  
product but also other European countries as well as Latvia  
and Belarus. A number of countries are just about to change from the old  
200mg product to the new one of 65mg. A  
positive interest has been shown from international organi-  
sations.

12. As can be seen from our pamphlet our product does follow  
the WHO recommendations. We can also guarantee a shelf-life  
of up to 10 years. (Some of our batches have been tested  
even up to 12-14 years).

We hope that the above information will be of assistance to you.

If there are additional questions to be answered by us, please do not  
hesitate to contact us whenever you want.

Telephone number: Switchboard +46 8 6025200 direct +46 8 6025329  
Telefax number: " +46 8 818703 " +46 8 6025302

We look forward to hearing from you.

With kind regards,

Allan Skolfman  
Export Manager

CC: ODH\_REMOTE.SMTP("hans-henrik.bark@recip.se", "thoma...

ATTACHMENT 2

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M E M O R A N D U M

TO: Harvey B. Brugger, Supervisor  
FROM: Dwain C. Baer, Health Physicist III  
SUBJECT: Potassium Iodide [KI] Manufacturers  
DATE: October 30, 1998



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Based on the research conducted by Connie Ostrove and myself, the only company which manufactures and distributes tablet KI specifically for use as a thyroid protection product is Carter-Wallace Laboratories, located on Half Acre Road in Cranbury, New Jersey 08512. Current cost per case of 100 bottles [fourteen tablets per bottle] is \$250.00 [17.8 cents per tablet]. This cost has increased over 80% from last year, based on the anticipated increase of sales.

Roxane Laboratories, located at 1809 Wilson Road in Columbus, Ohio 43228-8601, produces a liquid solution labeled for use as an expectorant. However, the Food and Drug Administration [FDA] has approved this product for use as a thyroid protection method during a nuclear power plant radiological release. Roxane has never produced tablet KI for use as an expectorant, or for use as a thyroid protective method.

Several other companies within the United States were researched for thyroid blocking KI. However, all of the companies researched market KI for expectorants of various bronchitis problems only, and have not been approved by the FDA for thyroid blocking usage.

A company in Sweden called Recip AB, Branningevagen, has provided a cost estimate via e-mail. A pack of ten KI tablets can cost as much as \$1.15 per pack [11.5 cents per tablet] plus the cost of shipping to the United States, and the cost of any authorization which may be required.

cc: Connie Ostrove, Librarian  
R.A.S./KI File

Date: Mon, 14 Dec 1998 13:00:09 -0500  
From: Harvey Brugger <HBRUGGER@GW.ODH.STATE.OH.US>  
To: susan.hiatt@hamradio.org  
Cc: dbaer@GW.ODH.STATE.OH.US, rsuppes@GW.ODH.STATE.OH.US,  
shelmer@GW.ODH.STATE.OH.US  
Subject: KI supplier in Sweden -Reply

Susan,

I am attaching two Wordperfect 6.1 documents. Since their preparation, one additional contact with the Swedish supplier, Recip AB, indicates their disinclination to provide KI tablets at any different dosage that they currently manufacture. However, this is not necessarily an impediment. In fact, for purposes of public distribution, the Export Manager, Mr. Allan Skolfman, indicated that the 65 mg size may be more useful. Their tablet can be divided at score lines in order to comply with World Health Organization recommendations for dosages to children.

On a cost basis, comparing the Swedish Product with the Carter-Wallace product follows:

Carter Wallace Product

130 mg tablets packaged in a bottle of 14 tablets with a shelf life of 5 years cost \$2.50 per bottle.

Recip AB (Swedish) Product

65 mg tablets packaged in a blister pack of 10 tablets with a shelf life of 10 years cost \$1.15 per package in the quantities contemplated.





If one were not contemplating the subdivision of a bottle or packet, then it would be cheaper using the Swedish product to dispense one product per person.

Emergency workers and institutionalized are given a ten day supply plus extra tablets equivalent to a 14 day supply. If a five day supply without extra tablets would suffice, then they could be given one blister packet. Even if they were given two packets, in order for them to take two 65 mg tablets per day for 10 days, it would still be cheaper to use the Swedish product.

On strictly a comparison of cost/mg/year, the Swedish product is also cheaper: \$1.77 E-4 versus \$2.75 E-4

Harvey

Harvey

 <u>Part 1.2</u>	<b>Name:</b> POTASSIU.SWE <b>Type:</b> unspecified type (application/octet-stream) <b>Encoding:</b> x-uuencode
 <u>Part 1.4</u>	<b>Name:</b> SUPPLY.KI <b>Type:</b> unspecified type (application/octet-stream) <b>Encoding:</b> x-uuencode
 <u>Part 1.6</u>	<b>Name:</b> POTASSIU.SWE <b>Type:</b> unspecified type (application/octet-stream) <b>Encoding:</b> x-uuencode
 <u>Part 1.8</u>	<b>Name:</b> SUPPLY.KI <b>Type:</b> unspecified type (application/octet-stream) <b>Encoding:</b> x-uuencode