

November 10, 2005

Kirksy E. Whatley, Director
Office of Radiation Control
Department of Public Health
P.O. Box 303017-3017
Montgomery, AL 36130-3017

Dear Mr. Whatley:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

A 65 mg dosage form of KI was subsequently approved by the Food and Drug Administration (FDA). In a letter dated January 23, 2004 the NRC informed the Governor-designated State Liaison Officers that the FDA had approved the 65 mg tablets and that the NRC would be making these available to the States and Federally-recognized Tribal Governments for their populations within the 10-mile EPZ. When the current KI contract was put into effect, only 130 mg and 65 mg tablets were approved by the FDA. No dosage form suitable for children who could not swallow pills was available.

On January 12, 2005, the FDA approved ThyroShield™ (Potassium Iodide Oral Solution, USP) 65 mg/mL for use in children. The oral solution is the first to be developed specifically for children, although it is suitable for adult use. One milliliter of the solution contains 65mg of potassium iodide in a black raspberry-flavored solution, providing easy, emergency-ready dosing for individuals ranging from infants to adults. The black raspberry taste is designed to make it more palatable to children, as current adult-dose tablets are bitter. Also, while tablets must be broken into pieces to provide a child's dose, ThyroShield™ is designed for simple administration of the liquid KI utilizing a graduated eyedropper. ThyroShield™ is provided in one ounce (30 mL) bottles that provide up to 30 pediatric doses of KI per bottle. Dosing instructions are based on the child's age and weight and are included in the consumer product information sheet that accompanies the bottles. As with the tablet form of KI, ThyroShield™ should be taken as soon as possible after being directed to do so by public officials in the event of a nuclear emergency. While ThyroShield™ is designed for children, it was not initially packaged in such a way as to child proof access to the product. That will be remedied such that no liquid KI will be shipped to States until that condition is met.

The Department of Health and Human Services (DHHS) Office of Public Health Emergency Preparedness (OPHEP) and the NRC are making available, at this time, to all eligible States and Federally-recognized Tribal Governments, the opportunity to request an order of the FDA approved pediatric formulation of (liquid) potassium iodide (KI). HHS/NRC will supply sufficient ThyroShield™ for each child under 10 years of age in the 10-mile EPZ(s).

If you are interested in this offer and would like to either add to your current KI stockpiles or to request KI for the first time, you may request the HHS/NRC to provide KI by writing to Nader Mamish, Director, Emergency Preparedness Directorate, Mail Stop O6-H2, U.S. NRC, Washington, D.C. 20555. Your letter must include the following information: The nuclear power plant (NPP) site(s); the number of 30 mL (30 cc) Bottles of ThyroShield™ you are requesting; the pediatric population under 10 years of age in the NPP's 10-mile EPZ for which you are responsible; the contact person authorized to receive the KI; and the 'Ship to' address for

KI delivery. Upon receipt of this information, the NRC will validate the data and make arrangements for HHS's contractor to ship KI directly to your designated contact/address. You may also fax your request to 301-415-2968. If your State has not yet requested its initial supply of KI tablets, you may also do so at this time.

We request that a single submittal for KI be provided by each State and Federally-recognized Tribal Government no later than January 30, 2006. If decisions about emergency planning and the use of KI are the responsibility of local, rather than State authorities, we request that the State consolidate the local requests and forward the consolidated request covering all NPPs within the State to the NRC.

The following information is enclosed to this letter for your consideration and use: FDA guidance on use of KI (Enclosure 1); FEMA guidelines for KI program implementation (Enclosure 2); NRC Statements of Consideration published in support of the final KI rule (Enclosure 3); and NRC Disclaimer (Enclosure 4). Additional information about NRC's KI policy can be found on NRC's web site at: <http://www.nrc.gov/what-we-do/emerg-preparedness/protect-public/potassium-iodide.html>. If you have any questions about the purchase of KI or require assistance in this matter, please contact Patricia Milligan, Office of Nuclear Security and Incident Response, Division of Preparedness and Response, by telephone at 301-415-2223 or by e-mail at pxm@nrc.gov.

Thank you for your consideration of this important issue.

Sincerely,

/RA/

Janet R. Schlueter, Director
Office of State and Tribal Programs

November 10, 2005

Bernard Bevill
Arkansas Department of Health
Division of Radiation Control
and Emergency Management
4815 West Markham Street, Mail Slot #30
Little Rock, AR 72205-3867

Dear Mr. Bevill:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Aubrey Godwin, Director
Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, AZ 85040

Dear Mr. Godwin:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

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November 10, 2005

James D. Boyd, Commissioner
California Energy Commission
1516 Ninth Street, MS-34
Sacramento, CA 95814

Dear Commissioner Boyd:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

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November 10, 2005

Edward L. Wilds, Jr., Ph.D., Director
Department of Environmental Protection
Division of Radiation
79 Elm Street
Hartford, CT 06106-5127

Dear Dr. Wilds:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Harry W. Otto, Ph.D., FAIC
Department of Natural Resources & Environmental Control
Division of Water Resources
P.O. Box 1401
Dover, DE 19903

Dear Dr. Otto:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

William A. Passetti, Chief
Bureau of Radiation Control
Florida Department of Health
4052 Bald Cypress Way, SE, Bin C21
Tallahassee, FL 32399-1741

Dear Mr. Passetti:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Jim Sommerville, Acting Chief
Department of Natural Resources
Environmental Protection Division
Program Coordination Branch
2 Martin Luther King Jr., Street
Suite 1452 - East Tower
Atlanta, GA 30334

Dear Mr. Sommerville:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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Daniel K. McGhee,
Iowa Department of Public Health
Bureau of Radiological Health
Lucas State Office Building
321 East 12th Street
Des Moines, IA 50319

Dear Mr. McGhee:

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Gary N. Wright, Director
Illinois Emergency Management Agency
Division of Nuclear Safety
1035 Outer Park Drive, 5th Floor
Springfield, IL 62704

Dear Mr. Wright:

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November 10, 2005

Thomas A. Conley, CHP, RRPT, Chief
Radiation and Asbestos Control Section
Kansas Department of Health and Environment
Bureau of Air and Radiation
1000 SW Jackson, Suite 310
Topeka, KS 66612-1366

Dear Mr. Conley:

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A 65 mg dosage form of KI was subsequently approved by the Food and Drug Administration (FDA). In a letter dated January 23, 2004 the NRC informed the Governor-designated State Liaison Officers that the FDA had approved the 65 mg tablets and that the NRC would be making these available to the States and Federally-recognized Tribal Governments for their populations within the 10-mile EPZ. When the current KI contract was put into effect, only 130 mg and 65 mg tablets were approved by the FDA. No dosage form suitable for children who could not swallow pills was available.

On January 12, 2005, the FDA approved ThyroShield™ (Potassium Iodide Oral Solution, USP) 65 mg/mL for use in children. The oral solution is the first to be developed specifically for children, although it is suitable for adult use. One milliliter of the solution contains 65mg of potassium iodide in a black raspberry-flavored solution, providing easy, emergency-ready dosing for individuals ranging from infants to adults. The black raspberry taste is designed to make it more palatable to children, as current adult-dose tablets are bitter. Also, while tablets must be broken into pieces to provide a child's dose, ThyroShield™ is designed for simple administration of the liquid KI utilizing a graduated eyedropper. ThyroShield™ is provided in one ounce (30 mL) bottles that provide up to 30 pediatric doses of KI per bottle. Dosing instructions are based on the child's age and weight and are included in the consumer product information sheet that accompanies the bottles. As with the tablet form of KI, ThyroShield™ should be taken as soon as possible after being directed to do so by public officials in the event of a nuclear emergency. While ThyroShield™ is designed for children, it was not initially packaged in such a way as to child proof access to the product. That will be remedied such that no liquid KI will be shipped to States until that condition is met.

November 10, 2005

Michael E. Henry, Senior Environmental
Scientist - Permits Division
Office of Environmental Compliance
P.O. Box 4313
Baton Rouge, LA 70821-4312

Dear Mr. Henry:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

A 65 mg dosage form of KI was subsequently approved by the Food and Drug Administration (FDA). In a letter dated January 23, 2004 the NRC informed the Governor-designated State Liaison Officers that the FDA had approved the 65 mg tablets and that the NRC would be making these available to the States and Federally-recognized Tribal Governments for their populations within the 10-mile EPZ. When the current KI contract was put into effect, only 130 mg and 65 mg tablets were approved by the FDA. No dosage form suitable for children who could not swallow pills was available.

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November 10, 2005

Cristine McCombs, Director
Massachusetts Emergency Management Agency
400 Worcester Road
Framingham, MA 01702-5399

Dear Ms. McCombs:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

A 65 mg dosage form of KI was subsequently approved by the Food and Drug Administration (FDA). In a letter dated January 23, 2004 the NRC informed the Governor-designated State Liaison Officers that the FDA had approved the 65 mg tablets and that the NRC would be making these available to the States and Federally-recognized Tribal Governments for their populations within the 10-mile EPZ. When the current KI contract was put into effect, only 130 mg and 65 mg tablets were approved by the FDA. No dosage form suitable for children who could not swallow pills was available.

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November 10, 2005

Thomas Snyder, Director
Maryland Department of the Environment
Air and Radiation Management Administration
1800 Washington Boulevard, Suite 705
Baltimore, MD 21230-1720

Dear Mr. Snyder:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Liane Shekter Smith, Chief
Waste and Hazardous Materials Division
Hazardous Waste and Radiological Protection Section
Michigan Department of Environmental Quality
Post Office Box 30241
Lansing, MI 48909-7741

Dear Ms. Smith:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Patricia Bloomgren, Director
Minnesota Department of Health
Environmental Health Division
P. O. Box 64975
St. Paul, MN 55164-0975

Dear Ms. Bloomgren:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

H. Floyd Gilzow
Deputy Director for Policy
Department of Natural Resources
P.O. Box 176
Jefferson City, MO 65102

Dear Mr. Gilzow:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Robert W. Goff, Director
Division of Radiological Health
State Department of Health
P.O. Box 1700
Jackson, MS 39215-1700

Dear Mr. Goff:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Beverly O. Hall, Chief
Radiation Protection Section
Division of Environmental Health
Department of Environment & Natural Resources
3825 Barrett Drive
Raleigh, NC 27609-7221

Dear Ms. Hall:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Robert E. Leopold, Administrator
Nebraska Department of Health and Human Services
P.O. Box 95007
Lincoln, NE 68509-5007

Dear Mr. Leopold:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Bruce Cheney, Director
Division of Fire Safety & Emergency Management
Department of Safety
Bureau of Emergency Management
33 Hazen Drive
Concord, NH 03305

Dear Mr. Cheney:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Bradley M. Campbell, Commissioner
Department of Environmental Protection
P. O. Box 402
Trenton, NJ 08625-0402

Dear Commissioner Campbell:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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On January 12, 2005, the FDA approved ThyroShield™ (Potassium Iodide Oral Solution, USP) 65 mg/mL for use in children. The oral solution is the first to be developed specifically for children, although it is suitable for adult use. One milliliter of the solution contains 65mg of potassium iodide in a black raspberry-flavored solution, providing easy, emergency-ready dosing for individuals ranging from infants to adults. The black raspberry taste is designed to make it more palatable to children, as current adult-dose tablets are bitter. Also, while tablets must be broken into pieces to provide a child's dose, ThyroShield™ is designed for simple administration of the liquid KI utilizing a graduated eyedropper. ThyroShield™ is provided in one ounce (30 mL) bottles that provide up to 30 pediatric doses of KI per bottle. Dosing instructions are based on the child's age and weight and are included in the consumer product information sheet that accompanies the bottles. As with the tablet form of KI, ThyroShield™ should be taken as soon as possible after being directed to do so by public officials in the event of a nuclear emergency. While ThyroShield™ is designed for children, it was not initially packaged in such a way as to child proof access to the product. That will be remedied such that no liquid KI will be shipped to States until that condition is met.

The Department of Health and Human Services (DHHS) Office of Public Health Emergency Preparedness (OPHEP) and the NRC are making available, at this time, to all eligible States and Federally-recognized Tribal Governments, the opportunity to request an order of the FDA approved pediatric formulation of (liquid) potassium iodide (KI). HHS/NRC will supply sufficient ThyroShield™ for each child under 10 years of age in the 10-mile EPZ(s).

If you are interested in this offer and would like to either add to your current KI stockpiles or to request KI for the first time, you may request the HHS/NRC to provide KI by writing to Nader Mamish, Director, Emergency Preparedness Directorate, Mail Stop O6-H2, U.S. NRC, Washington, D.C. 20555. Your letter must include the following information: The nuclear power plant (NPP) site(s); the number of 30 mL (30 cc) Bottles of ThyroShield™ you are requesting; the pediatric population under 10 years of age in the NPP's 10-mile EPZ for which you are responsible; the contact person authorized to receive the KI; and the 'Ship to' address for

KI delivery. Upon receipt of this information, the NRC will validate the data and make arrangements for HHS's contractor to ship KI directly to your designated contact/address. You may also fax your request to 301-415-2968. If your State has not yet requested its initial supply of KI tablets, you may also do so at this time.

We request that a single submittal for KI be provided by each State and Federally-recognized Tribal Government no later than January 30, 2006. If decisions about emergency planning and the use of KI are the responsibility of local, rather than State authorities, we request that the State consolidate the local requests and forward the consolidated request covering all NPPs within the State to the NRC.

The following information is enclosed to this letter for your consideration and use: FDA guidance on use of KI (Enclosure 1); FEMA guidelines for KI program implementation (Enclosure 2); NRC Statements of Consideration published in support of the final KI rule (Enclosure 3); and NRC Disclaimer (Enclosure 4). Additional information about NRC's KI policy can be found on NRC's web site at:<http://www.nrc.gov/what-we-do/emerg-preparedness/protect-public/potassium-iodide.html>. If you have any questions about the purchase of KI or require assistance in this matter, please contact Patricia Milligan, Office of Nuclear Security and Incident Response, Division of Preparedness and Response, by telephone at 301-415-2223 or by e-mail at pxm@nrc.gov.

Thank you for your consideration of this important issue.

Sincerely,

/RA/

Janet R. Schlueter, Director
Office of State and Tribal Programs

cc: Jill Lipoti, Ph.D., Assistant Director
Radiation Protection Programs & Release Prevention
Division of Environmental Safety & Health

November 10, 2005

Peter Smith, President
New York State Energy Research and Development Authority
17 Columbia Circle
Albany, NY 12203-6399

Dear Mr. Smith:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

A 65 mg dosage form of KI was subsequently approved by the Food and Drug Administration (FDA). In a letter dated January 23, 2004 the NRC informed the Governor-designated State Liaison Officers that the FDA had approved the 65 mg tablets and that the NRC would be making these available to the States and Federally-recognized Tribal Governments for their populations within the 10-mile EPZ. When the current KI contract was put into effect, only 130 mg and 65 mg tablets were approved by the FDA. No dosage form suitable for children who could not swallow pills was available.

On January 12, 2005, the FDA approved ThyroShield™ (Potassium Iodide Oral Solution, USP) 65 mg/mL for use in children. The oral solution is the first to be developed specifically for children, although it is suitable for adult use. One milliliter of the solution contains 65mg of potassium iodide in a black raspberry-flavored solution, providing easy, emergency-ready dosing for individuals ranging from infants to adults. The black raspberry taste is designed to make it more palatable to children, as current adult-dose tablets are bitter. Also, while tablets must be broken into pieces to provide a child's dose, ThyroShield™ is designed for simple administration of the liquid KI utilizing a graduated eyedropper. ThyroShield™ is provided in one ounce (30 mL) bottles that provide up to 30 pediatric doses of KI per bottle. Dosing instructions are based on the child's age and weight and are included in the consumer product information sheet that accompanies the bottles. As with the tablet form of KI, ThyroShield™ should be taken as soon as possible after being directed to do so by public officials in the event of a nuclear emergency. While ThyroShield™ is designed for children, it was not initially packaged in such a way as to child proof access to the product. That will be remedied such that no liquid KI will be shipped to States until that condition is met.

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Thank you for your consideration of this important issue.

Sincerely,

/RA/

Janet R. Schlueter, Director
Office of State and Tribal Programs

cc: John P. Spath, Program Manager
Radiological Waste Policy and Nuclear Coordination
New York State Energy Research and Development Authority

November 10, 2005

Carol A. O'Claire, Branch Chief
Radiological Branch
Ohio Emergency Management Agency
2855 West Dublin-Granville Road
Columbus, OH 43235-2206

Dear Mr. O'Claire:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

A 65 mg dosage form of KI was subsequently approved by the Food and Drug Administration (FDA). In a letter dated January 23, 2004 the NRC informed the Governor-designated State Liaison Officers that the FDA had approved the 65 mg tablets and that the NRC would be making these available to the States and Federally-recognized Tribal Governments for their populations within the 10-mile EPZ. When the current KI contract was put into effect, only 130 mg and 65 mg tablets were approved by the FDA. No dosage form suitable for children who could not swallow pills was available.

On January 12, 2005, the FDA approved ThyroShield™ (Potassium Iodide Oral Solution, USP) 65 mg/mL for use in children. The oral solution is the first to be developed specifically for children, although it is suitable for adult use. One milliliter of the solution contains 65mg of potassium iodide in a black raspberry-flavored solution, providing easy, emergency-ready dosing for individuals ranging from infants to adults. The black raspberry taste is designed to make it more palatable to children, as current adult-dose tablets are bitter. Also, while tablets must be broken into pieces to provide a child's dose, ThyroShield™ is designed for simple administration of the liquid KI utilizing a graduated eyedropper. ThyroShield™ is provided in one ounce (30 mL) bottles that provide up to 30 pediatric doses of KI per bottle. Dosing instructions are based on the child's age and weight and are included in the consumer product information sheet that accompanies the bottles. As with the tablet form of KI, ThyroShield™ should be taken as soon as possible after being directed to do so by public officials in the event of a nuclear emergency. While ThyroShield™ is designed for children, it was not initially packaged in such a way as to child proof access to the product. That will be remedied such that no liquid KI will be shipped to States until that condition is met.

November 10, 2005

David J. Allard, Director
Bureau of Radiation Protection
Pennsylvania Department of
Environmental Protection
Rachel Carson State Office Building
P.O. Box 8469
Harrisburg, PA 17105-8469

Dear Mr. Allard:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Doreen Hagan, President
Prairie Island Indian Community
5636 Sturgeon Lake Road
Welch, MN 55089

Dear Ms. Hagan:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Henry J. Porter, Assistant Director
Division of Waste Management
Bureau of Land and Waste Management
South Carolina Department of Health
and Environmental Control
2600 Bull Street
Columbia, SC 29201

Dear Mr. Porter:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

L. Edward Nanney, Director
Tennessee Department of Environment
And Conservation
Division of Radiological Health
L & C Annex
401 Church Street 3rd Floor
Nashville, TN 37243-1532

Dear Mr. Nanney:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Roger Mulder, Director
Pantex Program
State Energy Conservation Office
Comptroller of Public Accounts
P.O. Box 13528
Austin, TX 78701

Dear Mr. Mulder:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

Michael M. Cline, State Coordinator
Virginia Department of Emergency Services
Management
10501 Trade Court
Richmond, VA 23236-3713

Dear Mr. Cline:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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November 10, 2005

David O'Brien
Commissioner of Public Service
Department of Public Service
112 State Street
Montpelier, VT 05620-2601

Dear Commissioner O'Brien:

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

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On January 12, 2005, the FDA approved ThyroShield™ (Potassium Iodide Oral Solution, USP) 65 mg/mL for use in children. The oral solution is the first to be developed specifically for children, although it is suitable for adult use. One milliliter of the solution contains 65mg of potassium iodide in a black raspberry-flavored solution, providing easy, emergency-ready dosing for individuals ranging from infants to adults. The black raspberry taste is designed to make it more palatable to children, as current adult-dose tablets are bitter. Also, while tablets must be broken into pieces to provide a child's dose, ThyroShield™ is designed for simple administration of the liquid KI utilizing a graduated eyedropper. ThyroShield™ is provided in one ounce (30 mL) bottles that provide up to 30 pediatric doses of KI per bottle. Dosing instructions are based on the child's age and weight and are included in the consumer product information sheet that accompanies the bottles. As with the tablet form of KI, ThyroShield™ should be taken as soon as possible after being directed to do so by public officials in the event of a nuclear emergency. While ThyroShield™ is designed for children, it was not initially packaged in such a way as to child proof access to the product. That will be remedied such that no liquid KI will be shipped to States until that condition is met.

The Department of Health and Human Services (DHHS) Office of Public Health Emergency Preparedness (OPHEP) and the NRC are making available, at this time, to all eligible States and Federally-recognized Tribal Governments, the opportunity to request an order of the FDA approved pediatric formulation of (liquid) potassium iodide (KI). HHS/NRC will supply sufficient ThyroShield™ for each child under 10 years of age in the 10-mile EPZ(s).

If you are interested in this offer and would like to either add to your current KI stockpiles or to request KI for the first time, you may request the HHS/NRC to provide KI by writing to Nader Mamish, Director, Emergency Preparedness Directorate, Mail Stop O6-H2, U.S. NRC, Washington, D.C. 20555. Your letter must include the following information: The nuclear power plant (NPP) site(s); the number of 30 mL (30 cc) Bottles of ThyroShield™ you are requesting; the pediatric population under 10 years of age in the NPP's 10-mile EPZ for which you are responsible; the contact person authorized to receive the KI; and the 'Ship to' address for

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We request that a single submittal for KI be provided by each State and Federally-recognized Tribal Government no later than January 30, 2006. If decisions about emergency planning and the use of KI are the responsibility of local, rather than State authorities, we request that the State consolidate the local requests and forward the consolidated request covering all NPPs within the State to the NRC.

The following information is enclosed to this letter for your consideration and use: FDA guidance on use of KI (Enclosure 1); FEMA guidelines for KI program implementation (Enclosure 2); NRC Statements of Consideration published in support of the final KI rule (Enclosure 3); and NRC Disclaimer (Enclosure 4). Additional information about NRC's KI policy can be found on NRC's web site at: <http://www.nrc.gov/what-we-do/emerg-preparedness/protect-public/potassium-iodide.html>. If you have any questions about the purchase of KI or require assistance in this matter, please contact Patricia Milligan, Office of Nuclear Security and Incident Response, Division of Preparedness and Response, by telephone at 301-415-2223 or by e-mail at pxm@nrc.gov.

Thank you for your consideration of this important issue.

Sincerely,

/RA/

Janet R. Schlueter, Director
Office of State and Tribal Programs

cc: William Sherman, State Nuclear Engineer
Vermont Department of Public Service

November 10, 2005

Matt Steuerwalt
Office of the Governor
Executive Policy Division
P.O. Box 43113
Olympia, WA 98504-3113

Dear Mr. Steuerwalt :

The purpose of this letter is to announce the availability of an additional dosage form of liquid potassium iodide for use in children under the age of 10 years to protect the thyroid gland from uptake of radioactive iodine.

On December 20, 2001, the U.S. Nuclear Regulatory Commission (NRC) informed the Governor-designated State Liaison Officer, and Federally-recognized Tribal Governments with populations in the 10-mile Emergency Planning Zone (EPZ) that NRC emergency planning regulations had been amended. The amended regulations require that States consider including the prophylactic use of potassium iodide (KI) as a supplement to evacuation and sheltering for the general public in the plume exposure pathway EPZ (66 FR 5427, January 19, 2001). In the letter, the NRC also made an offer to fund an initial supply of KI for States and Federally-recognized Tribal Governments that choose to incorporate KI for the general public in their emergency plans. At the time of this initial offer, KI was only available in 130 mg tablets.

A 65 mg dosage form of KI was subsequently approved by the Food and Drug Administration (FDA). In a letter dated January 23, 2004 the NRC informed the Governor-designated State Liaison Officers that the FDA had approved the 65 mg tablets and that the NRC would be making these available to the States and Federally-recognized Tribal Governments for their populations within the 10-mile EPZ. When the current KI contract was put into effect, only 130 mg and 65 mg tablets were approved by the FDA. No dosage form suitable for children who could not swallow pills was available.

On January 12, 2005, the FDA approved ThyroShield™ (Potassium Iodide Oral Solution, USP) 65 mg/mL for use in children. The oral solution is the first to be developed specifically for children, although it is suitable for adult use. One milliliter of the solution contains 65mg of potassium iodide in a black raspberry-flavored solution, providing easy, emergency-ready dosing for individuals ranging from infants to adults. The black raspberry taste is designed to make it more palatable to children, as current adult-dose tablets are bitter. Also, while tablets must be broken into pieces to provide a child's dose, ThyroShield™ is designed for simple administration of the liquid KI utilizing a graduated eyedropper. ThyroShield™ is provided in one ounce (30 mL) bottles that provide up to 30 pediatric doses of KI per bottle. Dosing instructions are based on the child's age and weight and are included in the consumer product information sheet that accompanies the bottles. As with the tablet form of KI, ThyroShield™ should be taken as soon as possible after being directed to do so by public officials in the event of a nuclear emergency. While ThyroShield™ is designed for children, it was not initially packaged in such a way as to child proof access to the product. That will be remedied such that no liquid KI will be shipped to States until that condition is met.

November 10, 2005

Paul S. Schmidt, Manager
Division of Public Health
Radiation Protection Section
Department of Health and Family Services
P.O. Box 2659
Madison, WI 53701-2659

Dear Mr. Schmidt:

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November 10, 2005

Dan Hill, Chief
Radiological Health Program
Office of Environmental Health Services
DHHR Bureau for Public Health
Capitol & Washington Streets
1 Davis Square, Suite 200
Charleston, WV 25301-1798

Dear Mr. Hill:

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Sincerely,
/RA/

Janet R. Schlueter, Director
Office of State and Tribal Programs

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