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February 25, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

**RE: "POTASSIUM IODIDE ORAL SOLUTION" 65 MG PER ML
Citizens Petition**

Dear Sir or Madam:

Enclosed for filing, please find the original and three copies of a Citizen's Petition. The enclosed submission is in reference to section 505 of the Federal Food, Drug and Cosmetic Act (21 USC§355), and is a suitability petition requesting permission to file an Abbreviated New Drug Application (ANDA) for Potassium Iodide Oral Solution. The following are included as attachments to the Citizen's Petition:

Attachment 1: Labeling for ThyroSafe™, and

Attachment 2: Labeling for Potassium Iodide Oral Solution, 65 mg per mL

Please contact me by telephone at 301-762-6100, extension 3101, by fax at 301-762-6154, or by e-mail at cfinn@rrdintl.com if you have any questions or require additional information.

Sincerely,

Charles W. Finn, Ph.D.
COO and Chief Development Officer

RRD International, LLC
11 North Washington Street, Suite 310
Rockville, MD 20850
Telephone: 301.762.6100
Fax: 301.762.6154

Enclosure

A Product Development Company



VIA FACSIMILE (301.827.6870)

March 2, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: "POTASSIUM IODIDE ORAL SOLUTION" 65 MG PER ML

Dear Sir or Madam:

We understand that in accordance with 21 CFR 10.30, the petition cannot be maintained as confidential material. Please release this material for public display.

Sincerely,

A handwritten signature in black ink that reads "Charles W. Finn". The signature is written in a cursive style with a large, looped "F" at the end.

Charles W. Finn, Ph.D.
COO and Chief Development Officer

RRD International, LLC
11 North Washington Street, Suite 310
Rockville, MD 20850
Telephone: 301.762.6100
Fax: 301.762.6154



Citizen's Petition

CONFIDENTIAL

February 25, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN'S PETITION

The undersigned submits this Petition under Section 505 of the Federal Food, Drug and Cosmetic Act (21 USC§355), which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR §5.10 to request the Commissioner of Food and Drugs to declare that the drug product, hereinafter described, is suitable for consideration in an abbreviated new drug application.

A. ACTION REQUESTED

By this petition, the undersigned requests permission of the Commissioner of Food and Drugs to file an abbreviated new drug application for a potassium iodide oral solution dosage form containing 65 milligrams (mg) of potassium iodide per milliliter (mL).

B. STATEMENT OF GROUNDS

The Federal Food, Drug and Cosmetic Act as amended in 1984 provides under Section 505(j)(2)(C) that a petition may be filed with the Secretary seeking permission to file an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form or strength differ from that of a listed drug. Such a petition must be granted unless the Secretary finds that investigations must be conducted to show the safety and effectiveness of the drug.

The petitioner requests permission to file an abbreviated new drug application for potassium iodide oral solution, 65 milligrams (mg) per milliliter (mL). The listed drug is available as tablets containing both 130 mg and 65 mg of potassium iodide. The 130 mg tablets are

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currently manufactured by MedPointe Pharm HLC, and the company has received FDA new drug application (NDA) approval for its non-prescription "radiation emergency potassium iodide" drug. The 65 mg tablets are currently manufactured by Recip AB for R&R Registrations and the company has received FDA abbreviated new drug application (ANDA) approval for its non-prescription "radiation emergency potassium iodide" drug.

The agency stated in the Federal Register (Volume 47, No. 125) dated June 29, 1982, "FDA recommends that potassium iodide in doses of 130 milligrams (mg) per day for adults and children above 1 year and 65 mg per day for children below 1 year of age be considered for thyroid blocking in radiation emergencies..." The agency later established recommended doses of potassium iodide (KI) as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment (FDA Guidance Document Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies. U.S. Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research (CDER), December, 2001 (www.fda.gov/cder/guidance/4825fnl.htm)). The recommended doses based on risk group are listed in Table 1. The availability of the proposed KI oral solution will provide a liquid formulation making it easy to administer to young children and infants who are the most vulnerable to the subsequent effects of radiation. Adults could take 2 mL for 130 mg dosage; adolescents and children, 1 mL for 65 mg dosage; children 1 month to 3 years, 1/2 mL for 32 mg dosage; and infants from birth through 1 month, 1/4 mL for 16 mg dosage.

Table 1: Recommended doses of KI for different risk groups.

Group	Predicted Thyroid Exposure (cGy)	KI Dose (mg)	No. of Tablets	
			130 mg	65 mg
Adults > 40 yrs	≥ 500	130	1	2
Adults >18 and ≤40 yrs	≥ 10			
Pregnant or lactating women	≥ 5			
Adolescents >12 and ≤18 years*	≥ 5	65	1/2	1
Children >3 and ≤12 years		32	1/4	1/2
>1 month and ≤3 years				
Birth through 1 month				

*Adolescents approaching adult size (≥ 70 kg) should receive the full adult dose (130 mg).

Source: FDA Guidance Document, 2001

The agency also states (Federal Register, Vol. 50, No. 142, p. 30258, July 24, 1985) that risks of side effects, such as allergic reactions, from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency, are outweighed by the risks of radioiodine induced thyroid nodules or cancer, if the projected dose to the thyroid gland is 25 rems or greater. Because FDA has authorized the non-prescription sale of "radiation emergency potassium iodide," it is legally available to organizations or individuals who, based on their own corporate or personal analysis, choose to have the drug immediately available.

Additionally, it states "This recommendation is made in full recognition of the potential positive side effects of the drug, action by the FDA permitting KI over-the-counter sales, and the authority of State and local health officials to elect to distribute and use the drug based on the specific needs of individual sites."

The proposed product, containing 65 mg potassium iodide per mL, would be identical in active ingredient to the listed drug products. The route of administration of the proposed generic product is a liquid oral dosage form, while the listed drug products are solid oral dosage forms. The bioavailability of KI from a liquid should not be inferior to that from a tablet.

The oral solution would be beneficial in regard to both safety and efficacy. In its most recent guidance on potassium iodide (Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies, December 2001) FDA provides recommendations for consumers to split tablets and create their own oral solutions from the tablets for administration to young children unable to swallow tablets. The availability of an oral solution as described in this petition would eliminate the difficulty of administration of a fraction of a tablet and would provide assurance of uniform dosages upon administration to young children. 2 mL of the proposed drug product will be therapeutically equivalent to the 130 mg tablet ThyroBlock™ marketed by Medpointe Pharm HLC. 1 mL of the proposed drug product will be therapeutically equivalent to the 65 mg tablet ThyroSafe™ marketed by Recip US Inc.

To the best of our knowledge the proposed dosage form will not be violating any patents relating to the composition of the product or the method of manufacture.

We submit that the criteria of Section 505(j)(2)(C) are met and that the requested permission to file an abbreviated new drug application for the dosage form described above should be granted.

C. PEDIATRIC RESEARCH EQUITY ACT OF 2003 REQUEST FOR WAIVER OF PEDIATRIC STUDIES

The petitioner requests a full waiver of the requirement to submit assessments for the proposed dosage form on the basis that studies of this type would be impossible to conduct.

For Potassium Iodide as a thyroid blocking agent in a radiation emergency, the listed product is adequately labeled and acceptable for pediatric use.

D. ENVIRONMENTAL IMPACT

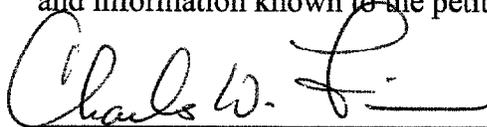
The proposed action is exempt from the requirement of an environmental impact statement under 21 CFR §25.31(c).

E. ECONOMIC IMPACT

No information is required at this time. Information will be provided upon request.

F. CERTIFICATION

The undersigned certifies, that, to the best of its knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Charles W. Finn, Ph.D.
COO and Chief Development Officer

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