International Isotopes Inc.

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February 15, 2013

Division of Dockets Management, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attention: Johnny Young,
Regulatory Health Project Manager

Re: Suitability Petition (Expedited Review Requested)
Kit for the Preparation of Sodium Iodide I 131 Capsules and Solution USP Therapeutic – Oral

Dear Sir or Madam,

This submission is a suitability petition submitted in part as a continuation of control correspondence #12-1057 that was the subject of an FDA teleconference with Regulatory Health Project Manager, Johnny Young, on December 17, 2012.

On behalf of International Isotopes, Inc (I3), this suitability petition is provided for the submission of an ANDA based on the approved reference listed drug, NDA 021305, HICON™ Kit for the Preparation of Sodium Iodide I 131 Capsules and Solution USP Therapeutic – Oral

International Isotopes, Inc is submitting a request for a change in:

1) the strength of the sodium iodide I-131 active pharmaceutical ingredient that is provided as the active component of a therapeutic oral solution intended for direct administration to a patient, and
2) as a solution component of a kit used to prepare I-131 therapy capsules containing physician prescribed amount of I-131 radioactivity.

The sodium iodide I-131 drug substance being proposed for the generic product is identical in chemical and radiological properties to that contained in the reference listed drug, but this petition requests an increase in strength. The concentrated sodium iodide I 131 solution provided in the reference listed drug (HICON™ NDA 21305) is formulated in sodium phosphate buffer with disodium ethylenediamine tetracetic acid and sodium thiosulfate added as a stabilizer and antioxidant. The proposed generic drug will be formulated in dilute (0.05N) sodium hydroxide with 0.02 M added sodium thiosulfate, which has been documented to effectively preserve radiochemical purity and identity of the iodide I-131 active moiety. Both the proposed generic drug and the HICON™ product are intended for dispensing as a final dosage form oral solution (by dilution) or for further compounding by a licensed practitioner in the form of final dosage form capsules for administration of prescribed doses to the patient.

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International Isotopes Inc.

Radioactive iodine (I-131) has been routinely available for over 50 years being used as a therapeutic agent for treatment of a wide variety of thyroid disorders. The dose of I-131 administered to patients varies with the extent and type of disease and is directly dependent on thyroid uptake. A therapy dose can range from a few mCi to hundreds of mCi as determined by extent of thyroid uptake, the type and extent of disease and the intended radiation adsorbed dose. The proposed change in strength will not impact the quantity of I-131 to be administered to the patient.

The reference listed drug, HICON (NDA 21305), originally provided for 3 different fixed strengths of Sodium Iodide I 131 solution (250 mCi/mL, 500 mCi/mL and 1000 mCi/mL). The NDA holder has since discontinued both lower concentrations and presently distributes only the 1000 mCi/mL strength in fixed volumes of 0.25 mL, 0.5 mL and 1.0 mL. Each mL of the 1000 mCi/mL NaI-l31 solution contains 37 GBq of 1-131, < 2.0 mg of disodium edetate dihydrate, as a stabilizer, < 4.4 mg of sodium thiosulfate pentahydrate as an antioxidant, and < 40 mg of disodium phosphate anhydrous as a buffer to control the pH of the solution is 7.5 to 9.0.

In addition to the I-131 vial, the kit also includes a package of ten small (No.2) hard gelatin capsules filled with 300 mg of dibasic sodium phosphate; and 10 empty large (No.1) hard gelatin capsules.

This suitability petition seeks FDA agreement for a change in strength for the concentrated sodium iodide I 131 solution provided in the Kit from 250 – 1000 mCi/mL (at time of calibration) to 500 – 3500 mCi/mL (at time of calibration). This change in strength will permit the preparation of physician prescribed doses of I-131 in fewer capsules than the reference listed drug and will reduce the time and manipulations required by the operator to prepare multiple capsules.

We respectfully request expedited review of this suitability petition. If you have any questions or comments regarding this submission, please contact me at (208) 524-5300.

Sincerely,

Steve Laflin
President and CEO
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International Isotopes Inc.

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