DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

December 8, 2014

International Isotopes, Inc.
Attention: Steve Laflin
4137 Commerce Circle
Idaho Falls, ID 83401

Docket No. FDA-2013-P-0219

Dear Mr. Laflin:

This is in response to your petition filed on February 21, 2013, with the U.S. Food and Drug Administration (FDA or Agency) requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Sodium Iodide I-131 Oral Solution, 500-3500 mCi/mL at the time of calibration. The listed drug product to which you refer in your petition is Hicon Kit® (sodium iodide I-131) Oral Solution-Therapeutic, 1000 mCi/mL at time of calibration, approved under NDA 021305, held by Jubilant Draximage.

Your request involves a change in strength from that of the listed drug product (i.e., from 1000 mCi/mL at time of calibration to 500-3500 mCi/mL at time of calibration). The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents FDA's determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, FDA will approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency finds that the change in strength for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, dosage form, and route of administration of the proposed drug product are the same as that of the listed drug product. In addition, the proposed change is consistent with dosing recommendations in the labeling of the listed drug. The FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioequivalence requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioequivalence requirements under section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for this drug product to the Office of Generic Drugs, Office of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Kathleen Uhl -A

Digitally signed by Kathleen Uhl -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kathleen Uhl -A, 0.9.2342.19200300.100.1.1=1300138540
Date: 2014.12.08 11:27:32 -05'00'

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research