



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

February 21, 2013

Steve Laflin
President and CEO
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

Dear Mr. Laflin:

Your petition to the Food and Drug Administration requesting FDA to declare the proposed generic drug product Sodium Iodide I 131 Capsules and Solution USP Therapeutic – Oral suitable for consideration in an Abbreviated New Drug Application (ANDA) with an amended strength ranging from 500 mCi/mL to 3500 mCi/mL, was received by this office on 2/21/2013. It was assigned docket number FDA-2013-P-0219/CP1, and it was filed on 2/21/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)