



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

June 26, 2019

Mr. John J. Miller, CHP
Radiation Safety Officer
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

SUBJECT: SUSPENSION OF LICENSE AMENDMENT REQUEST

We have reviewed your license amendment request submitted in application and letter dated March 25, 2019. International Isotopes, Inc. (INIS) requested to be licensed to distribute sodium iodide I-131 as an approved radiopharmaceutical. In support of this request, INIS submitted a new drug application to the U.S. Food and Drug Administration (FDA).

Based on our review, we have determined that additional information is needed to continue the review of your license application and a request for additional information was sent to INIS on April 29, 2019, and again on May 15, 2019. As of the date of this letter, INIS has not provided a response to the request for additional information. In addition, FDA has not completed its process for approving INIS' new drug application.

With incomplete documents and the unavailability of adequate information, the NRC staff is unable to continue with the review of your amendment request. Therefore, we have discontinued the review of your amendment request. This is without prejudice to resubmission of your amendment request. When you decide to resubmit your amendment request, please ensure that you have included all the necessary information needed to allow the NRC staff to evaluate your request. Should you have any questions regarding this letter, please contact Roberto J. Torres at (817) 200-1189.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

/RA/

Roberto J. Torres, M.S., Senior Health Physicist
Materials Licensing and Decommissioning Branch

License: 11-27680-01MD
Docket: 030-35486
Control: 611721