

## Torres, RobertoJ

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**From:** John J. Miller [jjmiller@intisoid.com]  
**Sent:** Wednesday, September 09, 2009 4:27 PM  
**To:** Torres, RobertoJ  
**Subject:** 11-27680-01 Amendment

Roberto,

I would like to revise some additional language in 11-27680-01 as part of the application to amend the license.

Currently Block 9 F., G, & H. reads:

**F., G., and H.      Receipt, handling, and processing of radiochemicals for persons authorized to receive the licensed material pursuant to the specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. Not to be distributed as a radiopharmaceutical or**

Blocks F. and G. pertains to Lu-177 and I-131 respectively.

Block H. is generic, we use this occasionally to distribute isotopes to source manufacturers or researchers .

I would suggest separating Blocks F. and G. from Block H.

Block 9 H. could read:

**Receipt, handling, and processing of radiochemicals for distribution to persons authorized to receive licensed materials pursuant to the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. Not intended for use in humans or animals.**

Because Block 9 F., G., is used to distribute to:

**Receipt, handling, and processing of radiochemicals for distribution to persons authorized to receive licensed materials pursuant to the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. May be distributed as a radioactive drug substance for the preparation of a final drug product to pharmacies, licensed pharmacists or licensed physicians license by the U.S. Nuclear Regulatory Commission or an Agreement State.**

The purpose of changing the language of Block 9 F. and G. (specifically 9 G) is so that there is no confusion as to what the intended use of I-131 is when it is distributed to radiopharmacies. The Drug Master File for the I-131 solution defines the product as a Drug Substance. The FDA definition for "Component" is **§ 210.3**

**Definitions** (b)(3) *Component* means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. The FD&C Act authorized licensed pharmacists and physicians to compound drugs using bulk drug substances;

b) COMPOUNDED DRUG.—

(1) LICENSED PHARMACIST AND LICENSED PHYSICIAN.—A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

I don't believe this would change our licensing category, we certainly are not considered a pharmacy. After discussion with the FDA and an explanation of our process we have registered with the FDA as "re-packager"

Please let me know if this email will suffice or if I should send a formal letter requesting this language change as part of our application to amend the license.

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