

**COLLEEN CAROL CASEY  
MATERIALS LICENSING BRANCH  
UNITED STATES NUCLEAR REGULATORY COMMISSION**  
REGION III  
2443 WARRENVILLE ROAD STE 210  
LISLE, ILLINOIS 60532-4352  
OFFICE: (630)-829-9841 FAX: (630) 515-1078

<b>CONVERSATION RECORD</b>		
	TIME	DATE
<b>ACTUALLY FAXED? YES.</b>	<i>C33 [Signature] 4:20pm</i>	<b>June 14, 2007</b>
<b>NAME OF PERSON(S) CONTACTED</b>	<b>ORGANIZATION</b>	<b>TELEPHONE NO.</b>
Robert Reyes, R.Ph.,	Brogan Pharmaceuticals	219-644-3693 <i>Fax No. 219-644-3682</i>
<b>SUBJECT</b>		
License No.: PENDING	Control No.: 316072	

**SUMMARY**

We have reviewed your application dated February 28, 2007, your facsimile dated March 16, 2007, and your letter dated April 24, 2007, requesting a new byproduct materials license and find that we need additional information as follows:

1. Item 5.B. of your letter dated April 24, 2007, requests only non-volatile forms of iodine-131. However, other sections of this letter make reference to the potential use of volatile materials, which will not be authorized under this license. **Please respond by stating that you are withdrawing all references to the potential use of volatile materials in the April 24, 2007, letter.**
2. Under the section of your letter dated April 24, 2007, marked "General Rules for the Safe Use of Radioactive Materials," item 2 states that "eating, drinking.....are not permitted in the manufacturing facility where radioactive materials are used or stored." **Please clarify this statement by removing the language "in the manufacturing facility" so that it is clear that these activities are not permitted anywhere that radioactive materials are used or stored.**
3. The section of your letter dated April 24, 2007, describing your training program for individuals working in or frequenting restricted areas failed to address the assessment of training, the names and qualifications of instructors and the method and frequency of training. **Please revise this section to include the assessment of training, the names and qualifications of instructors and the method and frequency of training.**
4. In order to name you and Brett Dines to this license as authorized users and you as RSO, I'll need to verify your previous employment at Cardinal Health. Your letter dated April 24, 2007, states that Rosalyn Jamison will verbally verify your employment there but you have not provided me with a phone number to reach her at. **Please provide Ms. Jamison's phone number and I will attempt to contact her and obtain written verification of your previous employment.**

Also, for future reference, when submitting the training and experience information for proposed authorized personnel, please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

5. Please submit a letter, currently dated and signed by you, as proposed RSO, stating that you accept the position as RSO for this license and that you understand the duties and responsibilities associated with this position.
6. Your website states that you manufacture radiopharmaceuticals and distribute them. This license application does not request such authority, it is for research and development activities only. Please explain and clarify your intentions for this license.
7. I will be conducting a pre-licensing site visit of you and your facilities, etc. in the next few weeks. Please describe your general availability from approximately June 25, 2007 through July 13, 2007.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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**ACTION REQUIRED**

Submit the requested information by referencing control number **316072** to facilitate proper handling. Upon receipt of your response we will reactivate placement of your request in our database and resume our review. Address your written response to my attention at the above address. As we cannot issue a new license at this time we are voiding this request in order to enable you to prepare a quality response without time constraints. This is done without prejudice to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address.

PLEASE NOTE THAT A "VOID" IS AN ADMINISTRATIVE PROCEDURE THAT PUTS YOUR AMENDMENT REQUEST "ON HOLD" (TAKES IT OUT OF OUR ACTIVE CASEWORK DATABASE) UNTIL YOU REACTIVATE IT VIA SUBMISSION OF A WRITTEN RESPONSE. IT "BUYS" YOU TIME TO PREPARE A QUALITY RESPONSE AND IS GENERALLY REGARDED AS A "GOOD THING."

**PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9841 or (800) 522-3025.**

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NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Colleen Carol Casey



June 14, 2007

TRANSMISSION VERIFICATION REPORT

TIME : 06/14/2007 17:01  
NAME : USNRC RIII  
FAX : 6308299782  
TEL :  
SER. # : 000A7J925774

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 6/14/07

NUMBER OF PAGES: 3  
(including this page)

SEND TO: RIBT. REYES, R. PL.

LOCATION: BROGAN PHARMACEUTICALS

FAX NUMBER: 219-644-3682  VERIFY BY CALLING SENDER

FROM: (SENDER) COLLEEN CAROL CASEY

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-829-9782

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE Please call me to discuss this if you have questions,  
(0.2001) ...



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MESSAGE *Please call me to discuss this if you have questions,  
(I will be out of town on business 6/18-22/07.)*  
*Colleen Carol Casey*

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.