

July 12, 2010

Carmen Bigles, President and CEO
Coqui Radio Pharmaceuticals Corp.
P.O. Box 958
Bayamon, P.R. 00960-0958

SUBJECT: COQUI RADIOPHARMACEUTICAL CORP.'S , ACKNOWLEDGMENT OF
RECEIPT AND REQUEST FOR WITHHOLDING INFORMATION FROM PUBLIC
DISCLOSURE

Dear Mrs. Bigles:

I am acknowledging receipt of your letter dated May 25, 2010. In your letter "PART I OF THE PROPOSED LICENSING STRATEGY FOR COQUI RADIOPHARMACEUTICALS CORP.'S MEDICAL ISOTOPE PRODUCTION FACILITY [MIPF] PERTAINING TO THE FACILITY'S LICENSE CLASS" (Agencywide Documents Access and Management System Accession No. ML101550454) you requested a review and response on three licensing issues. The U.S. Nuclear Regulatory Commission (NRC) staff is currently working on a reply to your questions.

Additionally, you submitted an affidavit dated May 21, 2010, executed by you, Carmen I. Bigles, requesting that Enclosure 1, which accompanied the letter, be withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR), Section 2.390.

The affidavit stated that the submitted information should be considered exempt from mandatory public disclosure for the following reasons:

- i. This information is and has been held in confidence by Coqui.
- ii. This information is of a type that is customarily held in confidence by Coqui, and there is a rational basis for doing so because the information includes sensitive business information pertaining to the costs of constructing and operating the MIPF.
- iii. The information is being transmitted to the NRC voluntarily and in confidence.
- iv. This information is not available in public sources and could not be gathered readily from other publicly available information.
- v. Public disclosure of this information would create substantial harm to the competitive position of Coqui by disclosing the costs of constructing and operating the MIPF. Development and evaluation of this commercial information was achieved at, and disclosure could lead to additional, significant cost to Coqui.
- vi. Public disclosure of the information sought to be withheld is likely to cause substantial harm to Coqui's competitive position and foreclose or reduce the availability of profit making opportunities. The value of the information goes beyond the disclosure of actual information pertaining to Coqui's business, and includes substantial time and work towards developing the MIPF project, and represents significant efforts by Coqui and its associates.
- vii. Coqui's competitive advantage will be lost if its competitors are able to use Coqui's cost estimates to aid their own commercial activities. The value of this information to Coqui would be lost if the information were disclosed to the public. Making such information available to other entities without their having been required to undertake

a similar expenditure of resources would unfairly provide competitors with a windfall, and deprive Coqui of the opportunity to exercise its competitive advantage to seek an adequate return on its large investment.

We have reviewed your application and the material in accordance with the requirements of 10 CFR 2.390 and, on the basis of the statements in the affidavit, have determined that the submitted information sought to be withheld contains proprietary commercial information and should be withheld from public disclosure.

Therefore, the Enclosure 1 marked as proprietary, will be withheld from public disclosure pursuant to 10 CFR 2.390(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the NRC. You also should understand that the NRC may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes your information. In all review situations, if the NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

If you have any questions regarding this matter, I may be reached at 301-415-3281.

Sincerely,

/RA/

Mary Jane Ross-Lee, Chief
Research and Test Reactors Projects Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

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/RA/

Mary Jane Ross-Lee, Chief
Research and Test Reactors Projects Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

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ADAMS Accession No: **ML101650733**

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DATE	6/14/2010	6/28/2010	6/28/2010	7/12/2010

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