

OFFICE OF THE SECRETARY  
CORRESPONDENCE CONTROL TICKET

Date Printed: Feb 14, 2013 15:22

PAPER NUMBER: LTR-13-0141

LOGGING DATE: 02/13/2013

ACTION OFFICE: EDO/Chrm

To: Leads, NRR

cys: OEDO  
FSME  
NMSS  
OGC  
Merckle, OEDO

AUTHOR: Carmen I Bigles Raldiris

AFFILIATION:

ADDRESSEE: CHRM Allison Macfarlane

SUBJECT: Provides a copy of her letter to The Honorable Steven Chu, Secretary of Energy, concerning American Medical Isotopes Production Act of 2012.

ACTION: Information

DISTRIBUTION: RF, SECY to Ack.

LETTER DATE: 02/08/2013

ACKNOWLEDGED No

SPECIAL HANDLING:

NOTES: Please check with staff responsible for licensing COQUI Radio Pharmaceuticals Corp. to see if this can be made public. - Yes, per S. Lynch, NRR.

FILE LOCATION: ADAMS

DATE DUE:

DATE SIGNED:

# COQUI RADIO PHARMACEUTICALS CORP.

## MEDICAL ISOTOPE PRODUCTION FACILITY

- 1172 South Dixie Highway, Suite 335 • Coral Gables, FL 33146 •
- E-mail [cbigles@coquipharma.com](mailto:cbigles@coquipharma.com) • [www.coquipharma.com](http://www.coquipharma.com) •

February 8, 2013

The Honorable Steven Chu  
Secretary of Energy  
U.S. Department of Energy  
1000 Independence Avenue, SW  
Washington, DC 20585-1000

**Re: American Medical Isotopes Production Act of 2012**

Dear Secretary Chu:

Thank you for taking the time to read this letter. As you are aware the American Medical Isotopes Production Act of 2012 ("ACT") was approved as part of the 2013 National Defense Authorization Act for Fiscal Year 2013 (H. R. 4310). The ACT provides that the Secretary of the Department of Energy ("DOE") shall carry out a technology neutral program to evaluate and support projects for the production of significant quantities of molybdenum-99 ("MO-99") without the use of highly enriched uranium (HEU) for the United States.

As part of the program pursuant to the ACT the DOE shall provide assistance for the development of fuels, targets, and processes for domestic MO-99 production that do not use HEU. In addition to the above the DOE shall establish a uranium lease and take-back program to make low enriched uranium (LEU) available through lease contracts, for irradiation for the production of MO-99 for medical use ("Lease and Take-Back").

*EMC*  
Our company Coquí Radio Pharmaceuticals Corp. (the "Company") has the specific goal of establishing a dedicated Medical Isotope Production Facility ("MIPF") in order to secure a significant continuous domestic supply of the radioisotope MO-99 for U.S. Citizens. The Company will use LEU technology and irradiation techniques that have been successfully demonstrated, proven and implemented in several countries around the world and whose end products have obtained the approval of the Food and Drug Administration (FDA). Our proposed MIPF would use technology that is in line with the very core of the ACT's mandated Lease and Take-Back program.

Since our Company's business model would make use of the Lease and Take-Back program we would need to include the costs in our business plan. Although we understand that the program has still not been implemented the DOE could use data for its costs incurred in the supply and take back of fuel for research reactors. Thus, our Company respectfully requests from the DOE information pertaining the estimated costs of the Lease and Take-Back program ("Cost Estimate").

Steven Chu, Secretary of Energy

February 8, 2013

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In addition to this petition, since the ACT provides that DOE shall carry out a technology neutral program to evaluate and support projects for MO-99 production in the United States we also respectfully request that the DOE consider supporting the Company in its efforts to create a MIPF to produce significant quantities of MO-99 via LEU irradiation techniques that have been proven successful and commercially scalable.

Please note that at this time the Company has not received any support in the form of DOE funding or otherwise unlike many other unproven or emergent technologies that have received substantial funding from DOE. Thus, now that the ACT has been approved and because our Company is the only party that to our knowledge has submitted a pre-application to the Nuclear Regulatory Commission (NRC) for technology that can make use of the Lease and Take-Back program, it makes sense for the DOE to, as part of a technology neutral program, also include support for the technology hosted by the Company. Support for this type of facility is best provided for the design and NRC licensing stage of the MIPF as this would make it more commercially viable to private investment.

Our proposed technology and MIPF offers proven solutions to stave off the impending MO-99 crises that U.S. patients may suffer. Thus, we humbly request from the DOE that it provide assistance with the Cost Estimate for the Lease and Take-Back program and that the DOE keep us informed of any potential Funding Opportunity Announcements (FOA's) or cooperative agreements to support, as part of a technology neutral program, LEU reactor based irradiation techniques for the production of MO-99.

Respectfully Submitted,



Carmen I. Bigles Raldiris

President,

Coquí Radio Pharmaceuticals Corp.

CC. The Honorable Allison Macfarlane,  
Chairman of the NRC

Daniel B. Poneman,  
Deputy Secretary of Energy

Parrish Staples, National Nuclear Security Administration  
Director of European and African Threat Reduction

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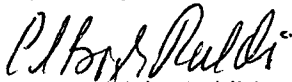
The Honorable Allison Macfarlane,  
Chairman of the NRC  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

**Re: American Medical Isotopes Production Act of 2012 CC communication.**

Dear Chairman Macfarlane:

I trust you are well when you receive this letter. For your records I am copying you on the letter that we submitted to The Honorable Steven Chu.

Respectfully,



Carmen I. Bigles Raldiris  
President,  
Coquí Radio Pharmaceuticals Corp.

**Coquí RadioPharmaceuticals Corp.**

1172 South Dixie Hwy. Suite 335

Coral Gables, Florida 33146

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**The Honorable Allison Macfarlane**  
**Chairman of the NRC**  
**U.S. Nuclear Regulatory Commission**  
**Washington, D.C. 20555-0001**