

From: Balazik, Michael
Sent: Thursday, February 08, 2018 9:05 AM
To: Balazik, Michael
Subject: FW: Coquí RadioPharmaceuticals Update

From: Lynch, Steven
Sent: Wednesday, February 07, 2018 4:22 PM
To: Carmen Irene Bigles Raldiris (cbigles@coquipharma.com) <cbigles@coquipharma.com>
Cc: 'IanLTurner@hotmail.com' <IanLTurner@hotmail.com>; Balazik, Michael <Michael.Balazik@nrc.gov>; Adams, Alexander <Alexander.Adams@nrc.gov>; Tran, Linh <Linh.Tran@nrc.gov>
Subject: RE: Coquí RadioPharmaceuticals Update

Good Afternoon,

The U.S. Nuclear Regulatory Commission (NRC) staff is preparing its resource and budget projections for fiscal year (FY) 2020. As of today, Coquí RadioPharmaceuticals (Coquí) has not provided scheduling information related to its proposed license application for a medical isotope facility to the NRC since March 2015 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML15118A936). As such, the NRC staff is not currently preparing or budgeting for the review of a license application for Coquí's proposed medical isotope facility.

As described in the e-mail below, it is important that Coquí communicate accurate and current application scheduling information to facilitate the NRC staff's review of any future license application. The NRC staff is committed to supporting the establishment of a domestic supply of molybdenum-99 and efficiently reviewing license applications for medical isotope production. The NRC staff will resume its preparations for the review of a Coquí license application once current scheduling information is provided to the NRC.

Please feel free to reach out to either me or Michael Balazik with any questions.

Regards,

Steve Lynch, Acting Chief
Research and Test Reactors Licensing Branch
Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission
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From: Balazik, Michael
Sent: Monday, January 29, 2018 1:18 PM
To: 'Carmen Bigles (Coqui)' <cbigles@coquipharma.com>
Cc: 'IanLTurner@hotmail.com' <IanLTurner@hotmail.com>
Subject: Coquí RadioPharmaceuticals Update

Carmen,

Hope all is well. During the 2017 Mo-99 Topical Meeting, Ian Turner presented on the Coqui RadioPharmaceuticals Corp. plans to submit a license application to the NRC in the 3rd quarter of 2018 (slide 13). Several NRC staff attended this meeting, including Steve Lynch who works in the Research and Test Reactors Licensing Branch with me. In order to support NRC staff budget and resource planning estimates, it is important that Coqui communicate accurate and current application scheduling information to the NRC staff. Coqui may choose to communicate this information via pre-application public meeting or updated response to RIS 2013-03, "[Pre-Application Communication and Scheduling for Medical Radioisotope Facilities Intending to Produce Molybdenum-99](#)". Providing this information to the NRC staff in a timely manner will support the familiarization of the staff with Coqui's proposed licensing approach and production technology; the efficient processing and acceptance of any application submission; and the initiation of a technical review without delay. Please contact me with any questions.

Best Regards,

Michael Balazik

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