



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

October 1, 2019

MEMORANDUM TO: Christian Einberg, Chief  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs **/RA by Lisa Dimmick for/**  
Office of Nuclear Material Safety and Safeguards

FROM: Irene Wu, Project Manager  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety and Safeguards

SUBJECT: SUMMARY OF SEPTEMBER 12, 2019, PUBLIC TELECONFERENCE  
WITH EXUBRION THERAPEUTICS TO DISCUSS OPTIONS FOR  
CONTINUED DISCUSSIONS ON THE USE OF SN-117M IN DOGS  
FOR THE TREATMENT OF OSTEOARTHRITIS

On September 12, 2019, a public teleconference was held at the U.S. Nuclear Regulatory Commission (NRC) Headquarters in Rockville, Maryland. The purpose of the public teleconference was to discuss options with Exubrion Therapeutics, Inc. (Exubrion) for continued discussions on the use of Sn-117m in dogs for the treatment of osteoarthritis. This teleconference was held in response to Exubrion's request (in a letter dated August 7, 2019, Agencywide Documents Access and Management System (ADAMS) Accession No. ML19221B309) to have an in-person meeting to discuss the changes made to its proposed pre-screening process, proposed owner interview checklist to be used as part of the pre-screening process, and the proposed guidance for veterinary staff to customize the release instructions for a particular dog. The NRC staff began the meeting by providing an overview of the interactions to date between Exubrion and the NRC followed by a presentation of the two options being considered for continuing these discussions. These options are either (1) to follow the same process used in 2018 whereby a licensee would request authorization from the NRC for use of this treatment, which would involve a Technical Assistance Request to the medical team at NRC Headquarters for guidance on veterinary release criteria, or (2) to request approval for a hypothetical license amendment from a hypothetical licensee, which then licensees could use as a template when they prepare and submit a license amendment request to the NRC.

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Following NRC's presentation, Exubrion and its contractors asked questions about the two options. Some specific questions asked by Exubrion and its contractors regarding the two options were how much interaction they would have with the NRC headquarters staff, what documents would be made publicly available, when in the process would the documents be reviewed by the NRC's Office of the General Counsel, and how long each process would take. Exubrion and its contractors also raised their concern that NRC still had not asked all of its questions regarding Exubrion's proposed pre-screening process, proposed owner interview checklist, and proposed guidance for veterinary staff. At the end of the teleconference, the NRC staff indicated that if Exubrion wanted to proceed with the first option, they could just inform the medical team at NRC Headquarters that a license amendment request for use of this treatment was sent to an NRC regional office. If Exubrion wanted to proceed with the second option, Exubrion would have to send in a letter indicating its notice of intent to submit a hypothetical license amendment for a hypothetical licensee.

There were 14 participants in the public teleconference meeting. Participants represented the NRC, Exubrion, and contractors to Exubrion. A list of meeting attendees and the meeting agenda are attached. The meeting handout with a description of the two options being considered is available in ADAMS Accession No. ML19253B171.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

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DATE: October 01, 2019

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**ADAMS Accession Nos.: PKG ML19273A954; Meeting Summary ML19273A957;  
Meeting Handout ML19253B171; Meeting Notice ML19253C426** **\*via email**

OFFICE	NMSS/MSST/MSEB/PM	NMSS/MSST/MSEB/TL	NMSS/MSST/MSEB/BC
NAME	IWu	LDimmick	Lisa Dimmick for: CEinberg
DATE	09/26/19	10/01/19	10/01/19

**OFFICIAL RECORD COPY**

### **Meeting Attendees**

Teleconference with Exubrion Therapeutics

September 12, 2019

1:00 p.m. to 3:00 p.m. ET

	<b>Name</b>	<b>Organization</b>
1	Donna-Beth Howe	NRC
2	Christian Einberg	NRC
3	Lisa Dimmick	NRC
4	Vincent Holahan	NRC
5	Ian Irvin	NRC
6	Irene Wu	NRC
7	Robert Gallagher	NRC
8	Penny Lanzisera	NRC
9	Peter Selover	Exubrion Therapeutics
10	John Donecker	Exubrion Therapeutics
11	Eric Schreiber	Exubrion Therapeutics
12	Martin Manco	Exubrion Therapeutics
13	Matthew Arno	Foxfire Scientific, Inc.
14	Chad Smith	F.X. Massé Associates

## Meeting Agenda

Teleconference with Exubrion  
September 12, 2019, 1:00 p.m. to 3:00 p.m. ET

<u><b>Time</b></u>	<u><b>Topic</b></u>	<u><b>Speaker</b></u>
1:00 p.m. to 3:00 p.m. ET	Discussion of Options	NRC/Exubrion