



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

November 15, 2019

MEMORANDUM TO: Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

FROM: Irene Wu, Project Manager */RA/*
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 NOVEMBER 6, 2019, PRE-SUBMITTAL PUBLIC
MEETING WITH EXUBRION THERAPEUTICS

On November 6, 2019, a public meeting was held at the U.S. Nuclear Regulatory Commission (NRC) Headquarters in Rockville, Maryland. The purpose of the public meeting was to discuss Exubriion Therapeutics, Inc. (Exubriion) intent to submit a hypothetical license amendment containing generic release procedures and instructions following the treatment of osteoarthritis in dogs with Synovetin OA™, a radioactive colloid containing Sn-117m. This meeting was held in response to Exubriion's request (in a letter dated September 20, 2019, Agencywide Documents Access and Management System (ADAMS) Accession No. ML19267A301) for a pre-submittal meeting to discuss the structure and sequence of the process going forward and the necessary content of the hypothetical license amendment. NRC staff provided an overview of the process, tentative schedule, regulatory requirements associated with the release of animals containing radioactive material, and information which staff would need to complete this review. NRC staff and Exubriion staff and its contractors engaged in discussion throughout NRC's slide presentation. Specific issues that were discussed in greater detail included the need for more justification for how the 2 mrem in any one hour public dose limit will be met following dog release; more measurement data or models, peer-reviewed journal articles, or other basis to provide justification for any non-conservative assumptions used to demonstrate public dose limits are met; and figures to show distances and geometries for measurements. Following this discussion, the public was provided an opportunity to comment. Dr. Dennis Law, a veterinarian, encouraged NRC to move forward with this effort because there are many dogs who could benefit from this treatment.

There were 22 participants in the public meeting. Participants represented the NRC, Exubrion, contractors to Exubrion, and the public. A list of meeting attendees and the meeting agenda are attached. NRC's slide presentation is available in ADAMS under Accession No. ML19308C187.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

SUBJECT: SUMMARY OF NOVEMBER 6, 2019, PRE-SUBMITTAL PUBLIC MEETING WITH EXUBRION THERAPEUTICS

DATE: November 15, 2019

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K. Tapp, NMSS

**ADAMS Accession Nos.: PKG ML19319A423; Meeting Summary ML19319A465;
NRC Slide Presentation ML19308C187; Meeting Notice ML19309D594**

***via email**

OFFICE	NMSS/MSST/MSEB/PM	NMSS/MSST/MSEB/TL	NMSS/MSST/MSEB/BC
NAME	IWu	LDimmick	CEinberg
DATE	11/13/19	11/13/19	11/13/19

OFFICIAL RECORD COPY

Meeting Attendees

Pre-Submittal Meeting with Exubion Therapeutics, Inc.
November 6, 2019
NRC One White Flint North, O-11B4
9:00 AM – 1:00 PM

	Name	Organization
1	Irene Wu	NRC
2	Katie Tapp	NRC
3	Betsy Ullrich	NRC
4	Vincent Holahan	NRC
5	Chris Einberg	NRC
6	Kevin Williams	NRC
7	Ian Irvin	NRC
8	Lisa Dimmick	NRC
9	Donna-Beth Howe	NRC
10	Sarah Lopas	NRC
11	Vered Shaffer	NRC
12	Colleen Casey	NRC
13	Peter Selover	Exubion Therapeutics
14	John Donecker	Exubion Therapeutics
15	Steve Fox	Exubion Therapeutics
16	Nigel Stevenson	Exubion Therapeutics
17	Eric Schreiber	Exubion Therapeutics
18	Martin Manco	Exubion Therapeutics
19	Matthew Arno	Foxfire Scientific, Inc.
20	Chad Smith	F.X. Massé Associates
21	Dennis Law	Public
22	Roland Benke	Renaissance Code Development

Meeting Agenda

Pre-Submittal Meeting with Exubriion Therapeutics, Inc.
November 6, 2019, 9:00 AM to 1:00 PM

NRC One White Flint North, O-11B4
11555 Rockville Pike
Rockville, MD

<u><i>Time</i></u>	<u><i>Topic</i></u>	<u><i>Speaker</i></u>
9:00 AM	Introductions and Opening Remarks	NRC
	NRC Presentation	NRC
	NRC and Exubriion Discussion	NRC and Exubriion
	Public Comments	Public
	Adjourn	NRC