

**NRC-Exubrion Publicly-Noticed Meeting on September 12, 2019:
Options for Exubrion Therapeutics, Inc.'s Continued Discussions on the
Use of Sn-117m in Dogs for the Treatment of Osteoarthritis**

There are two options being considered for Exubrion Therapeutics, Inc.'s (Exubrion) continued discussions for the use of Sn-117m in dogs for the treatment of osteoarthritis. These options are described below:

1. One option follows the same process used in 2018 whereby a licensee would request authorization from the NRC for use of this treatment. This license amendment request would be received by an NRC regional office, who would then send a Technical Assistance Request (TAR) to the medical team at U.S. Nuclear Regulatory Commission (NRC) Headquarters for guidance on veterinary release criteria. The NRC medical team would then perform a TAR acceptance and completeness review. Once accepted, the NRC medical team would conduct its formal review and provide a TAR response back to the NRC regional office. Typically, TAR responses are not made publicly available.
2. The second option follows a similar process that is used in other parts of the agency whereby Exubrion would 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. This option would involve Exubrion filing a notice of intent to submit followed by a pre-submittal meeting with the NRC. Once the application is received, the NRC would perform an acceptance review and issue an acceptance letter. The NRC would then review the application and issue requests for information (RAIs) as needed; this stage may involve a public meeting to discuss the RAIs and proposed RAI responses. Next, the NRC would develop a draft Safety Evaluation (SE) or guidance document, which could be provided to Exubrion for comment. When completed, the final SE or guidance document would be posted on the Veterinary Toolkit on the NRC's public Web site.