Closed Telephone Meeting with Check-Cap

Time March 3, 2020 10:00 a.m. to 11:30 a.m. EST

Purpose: To discuss proprietary information related to the use and marketing of the Check-Cap in the United States.

Attendees:

US Nuclear Regulatory Commission	**US Food and Drug Administration**
Donna-Beth Howe, Ph.D	Mark Antonino
Christian Einberg	One more
Lisa Dimmick	
Daniel Dimarco	
Check-Cap	
Alex Ovadia – CEO	
Yoav Kimchy – CTO	
Israel Hershko - VP QnR	
Hogan Lovells consultant to Check-Cap	
Amy Roma	

Agenda

Agenda

Check-Cap proposed the following agenda to help guide the conversation:

I. INTRODUCTIONS

II. OVERVIEW OF CHECK-CAP

A. Clinical Need

B. C-Scan Technology Overview

C. FDA Engagement & Future Plans

D. Capsule Disposal & Nuclear Regulatory Considerations

III. SCOPE OF NRC REQUEST FOR INFORMATION

A. Basis for Request for Information

B. Scope of Information Helpful for NRC Review

IV. NEXT STEPS & TIMELINE

A. Check-Cap Provision of Requested Information

B. NRC Analysis

Meeting Summary

The company presentation followed the order and content of the agenda and the proprietary slides. Most of the discussion centered on the design and functioning of the Check-Cap. Detailed technical information was shared about: the activity of the radioactive material; size of the capsule; how the capsule differentiates between the stomach, small intestine, and large intestine; how it determines when to turn on its main radiation beam; the battery life; and how it signals that it has passed out of the body.

Additional information was shared on the clinical trials, how it functioned, when and how it had to be removed surgically. During the current limited clinical trials, the capsule is retrieved at the end of a procedure. When the company moves on to larger clinical trials, and eventual approved for marketing, the company does not want the patients to have to retrieve the capsules and wants the patients to be allowed to release the capsules into the sewer. The company provided “representative” data and calculation methodology to demonstrate the radiation levels from such a release. To this end, the company will be seeking clarification from the U. S. Nuclear Regulatory Commission (NRC) if this will be permitted under existing NRC regulations.

The discussions included the type of physicians the company is targeting for the marketing of the capsules. These physicians are not currently recognized as authorized users. The company indicated the US distributor and the processes that are expected to occur at the distributor’s site and who will apply to have the device included in the Sealed Source and Device Registry.

The US Food and Drug Administration (FDA) staff was invited to attend the meeting under the provisions of the Memorandum of Understanding (MOU) between NRC and FDA. The MOU permits and encourages the sharing of information on new products regulated by both agencies.