

# OMB/Lively Meeting Agenda

July 29, 2022

10:00 a.m.

## Welcome and Introductions

- OMB
- Lively

## Lively - Company and Mission

## Policy Discussion

- Lively views of FDA proposed regulations generally
  - Performance standards - output and gain limitations
  - Defining mild-to-moderate hearing loss and self-assessment tests
  - Insertion depth
  - Pre-emption of state regulation

## Q&A

## Attendees:

- Adam Karp, CEO and Co-Founder
- Christina Callahan, Head of Clinical Audiology
- Steve Lehman, General Counsel
- Harvey Abrams, Senior Advisor and Head of Research Audiology
- Paul Martin, Advisory Board Member
- Jennifer Walsh, Consultant, Foley & Lardner LLP