

OMB Question: How will FDA handle participants who have hearing loss but try to address it using hearing aids or other techniques? Will those folks use their hearing aids throughout, or will FDA ask them to participate without them?

FDA Response:

During screening, we will ask participants if they regularly wear hearing aids, and suggest that they bring them to the study so that their experience mimics “real world” TV watching as much as possible. They will be asked to remove them for the hearing test but participants who use hearing aids will be welcome to use them while watching the ads and participating in the survey. To maximize the control of the auditory situation in the interview facility, we have chosen to use supra aural headphones that have been highly rated with hearing aid users for their ability to sit comfortably over the ear, even if the participant is using an in-the-ear or behind-the-ear hearing aid.

We plan to ask the following questions in the survey related to participants' hearing aid usage:

**[HEARING AID USE]**

Q37. On an average day, do you use any of the following hearing devices? Check all that apply.

- One or more hearing aids
- Cochlear implant
- Personal FM System
- TV Ears (or a voice clarifying headset)
- Other
- None of the above

**[PROGRAMMER: IF PARTICIPANT CHECKS ONLY “NONE OF THE ABOVE” IN Q37, SKIP Q38 – Q40.]**

**[FREQUENCY OF HEARING AID USE]**

Q38. Think about how much you used any hearing device over the past two weeks. On an average day, how many hours did you use the hearing device?

- None
- Less than 1 hour a day
- 1 to 4 hours a day
- 4 to 8 hours a day
- More than 8 hours a day

**[HEARING AIDS DURING STUDY]**

**[PROGRAMMER: IF PARTICIPANT CHECKS MORE THAN ONE HEARING DEVICE IN Q37, ASK Q39A AND SKIP Q39B. IF PARTICIPANT CHECKS ONLY ONE HEARING DEVICE IN Q37, SKIP Q39A AND ASK Q39B.]**

Q39a. Are you using one of your hearing devices now (during this study)?

Yes  
No

Q39b. Are you using your hearing device now (during this study)?

Yes  
No