

Appendix II: Patient Listening Sessions

Satisfaction Survey

OMB Control No. 0910-0697

Expiration Date: 12/31/2023

PRA Burden Statement - According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control for this information collection is 0910-0697 and the expiration date is 12/31/2023. The time required to complete this information collection is estimated to average 75 minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestion for reducing burden to PRAStaff@fda.hhs.gov.

Your participation/nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-responders), this information collection fully complies with all aspects of the Privacy Act and data will be kept secure to the fullest extent allowed by law.

Background

Introduction and context: Patient Affairs would like to better understand the experiences and perspectives of the patients and caregivers who participate in FDA Patient Listening Sessions.

Objectives: We are trying to understand what aspects of the current Listening Session design work well and where there may be opportunities for improvement in order to maximize the usefulness of Patient Listening Sessions to both FDA staff and patients, caregivers, or their advocates. The survey can be used to measure participant's satisfaction in participating in an FDA Patient Listening Session.

Method of distribution: We will distribute this survey after the completion of each Patient Listening Sessions, both internally and externally requested. The survey will be distributed via email to those who participated on each Patient Listening Session. Participants can respond to the survey by email or if they prefer to submit the survey anonymously, to the National Organization for Rare Disorders (NORD) (our collaborative partner through a Memorandum of Understanding) who will then in turn share the survey response with the Office of Patient Affairs.

Satisfaction Survey: Patient/caregiver participants in FDA Patient Listening Sessions

1. On a scale of 1 to 5, did you feel like the FDA heard your perspective during the Listening Session? *1 = not well heard, 5 = very well heard. Why?*

2. On a scale of 1 to 5, How valuable did you find the Listening Session to be? *1 = not valuable, 5 = very valuable. Why?*

3. On a scale of 1 to 5, How comfortable did you feel with sharing your experience with FDA? *1 = not comfortable, 5 = very comfortable. Why?*

4. What could be improved in the preparation for a Listening Session?

5. Was there anything else you would like to share with the FDA Division Staff about your experience with this condition?