



Patient Affairs Staff

Helping Bring the Patient Voice to FDA



FDA LISTENING SESSIONS

Hosted by the FDA Patient Affairs Staff

WHO ARE THE PATIENT AFFAIRS STAFF?

At the U.S. Food and Drug Administration (FDA), patients are at the heart of what we do and vital to medical product development. The [FDA Patient Affairs Staff \(PAS\)](#) coordinates and supports patient engagement activities across the FDA.

WHAT ARE LISTENING SESSIONS AND HOW CAN YOU PARTICIPATE?

[Listening Sessions](#) are one of [many ways](#) [patients, caregivers, and their advocates](#) can share their experience with a disease or condition by talking directly with FDA staff.

- Listening Sessions are small, informal, non-regulatory, non-public discussions
- Listening Sessions are scheduled for up to 1.5 hours and can be in person at FDA in Silver Spring, MD, on the phone, or a mix of the two
- Listening Sessions are about your disease experiences, not a specific medical product (drug, biologic, or device)
- Companies that develop medical products do not participate
- FDA staff will either ask questions or simply listen to better understand your experience with a disease or condition

HOW DOES FDA BENEFIT FROM LISTENING SESSIONS?

Listening Sessions help FDA understand what is important to you and your patient community when medical products are being developed.

WHAT ARE THE CRITERIA FOR A LISTENING SESSION?

The [Patient Affairs Staff \(PAS\)](#) will work with you to see if a Listening Session is the best way to talk with FDA. Some criteria for Listening Sessions include:

- Of interest to medical product staff in [multiple](#) FDA Centers/programs
- Not on the [same set of agenda topics](#) as a past meeting held or future meeting planned with FDA





HOW TO REQUEST A LISTENING SESSION

WHAT INFORMATION DOES THE FDA NEED FOR YOUR REQUEST?

DISEASE OR CONDITION NAME

List the disease or condition that you plan to discuss with FDA.

DESIRED MEETING GOALS

Describe why you want to meet with FDA. Describe what you hope FDA will learn. Describe what you hope to gain from a Listening Session.

LISTENING SESSION TOPICS

Describe the topics you would like to cover in this Listening Session about the patient's experience living with a disease or condition.

PROPOSED DRAFT MEETING PLAN

Create a draft meeting plan for a 1.5-hour listening session. Please allow 5 minutes for FDA opening remarks and 15 minutes at the end for open discussion between FDA and the patient community. Indicate if you prefer the session to be in person or by teleconference.

HOW DO I REQUEST A LISTENING SESSION?

Follow these steps to start your request for a Listening Session:

1. Go to www.fda.gov/requesttoconnect
2. Complete the form
3. Under the section about the FDA Programs, click: *"Listening Sessions"*
4. In remaining boxes on the form, enter the information from the section above including the name of the disease or condition, what you would like to share during the Listening Session, and what you hope to happen after the listening session
5. Click *"Submit"*

We will review the request for completeness, evaluate the request, and follow up with you. In the meantime, [check out summaries](#) from previous listening sessions!

