



January 30, 2018

Dr. William Dunn
Federal Drug Administration
c/o Federal Drug Administration
White Oak Campus Bldg 22, Ste 4338
10903 New Hampshire Ave
Silver Springs, MD 20993
Re: Support for fast track approval of OTIVIDEX

Dear Dr. Dunn,

The Vestibular Disorders Association (VeDA) supports the approval of OTIVIDEX for the treatment of Meniere's disease.

VeDA is the leading international organization people turn to for help with vestibular (inner ear and brain) disorders. We are an authoritative resource, publishing information that is clear, reliable, and scientifically objective. VEDA supports people with vestibular disorders by connecting them to health care specialists and support networks. VEDA promotes awareness for vestibular disorders through testimony and advocacy.

The FDA has already granted fast track designation to OTIVIDEX due to the importance of this treatment for Meniere's patients. We agree that this drug should be made available to patients as quickly as possible.

I know firsthand the dramatic impact Meniere's disease can have on both patients and family members. My mother, Eileene Haslam, has had Meniere's disease for over 30-years. I have seen her transform from a competent and outgoing individual to someone who is most often fearful and depressed. She uses a walker on the few occasions she ventures out, and grasps onto walls to get around her home. She also has severe hearing loss, making phone conversations limited, further isolating her from her family and friends. She recently told me that she simply, "no longer (has) the will to do anything."

The National Institutes of Health estimates that about 615,000 people in the U.S. have Ménière's disease, and that 45,500 new cases are diagnosed each year. In my position as Executive Director of VeDA, I have heard from countless Meniere's patients with the same story. Without an FDA approved treatment, these people will continue to suffer.

You have the power to offer hope to hundreds of thousands of patients faced with an incurable chronic illness. VeDA urges you to make OTIVIDEX available to these patients as quickly as possible.

Thank you for your time and consideration.

Sincerely,

Cynthia Ryan, MBA, Executive Director

VESTIBULAR DISORDERS ASSOCIATION