Health Canada | Santé Canada
Deputy Minister | Sous-ministre
Ottawa, Canada
K1A 0K9

May 16, 2025

Ms. Luciana Nechita
Chief Executive Officer
Speech-Language & Audiology Canada
[redacted]

Dear Ms. Nechita:

Thank you for your correspondence of May 2, 2025, inviting me to meet with you to discuss the recent licensing of Class II medical devices marketed as over-the-counter (OTC) hearing aids in Canada. I appreciate Speech-Language & Audiology Canada's commitment to expanding access to hearing health solutions and its emphasis on ensuring public safety, consumer education and product efficacy.

Unfortunately, I will not be able to accept your kind invitation.

Health Canada regulates the sale, advertisement for sale and importation for sale of medical devices through the *Medical Devices Regulations* (the Regulations) of the *Food and Drugs Act*. The Department is committed to enabling access to safe and effective medical devices in Canada.

I agree that appropriate regulatory oversight in combination with proper consumer education is key in supporting the health and safety of Canadians. Licensed hearing aids, including licensed hearing aid and hearing test features, meet all applicable regulatory requirements with respect to safety, effectiveness and quality under the Regulations. The provinces and territories decide how licensed medical devices are accessed in their jurisdictions, including whether a prescription is required for such devices. It is Health Canada's understanding that the regulatory restrictions vary throughout Canada. If you have not already done so, you may wish to reach out to provincial/territorial regulatory bodies or health authorities to discuss existing regulations and restrictions on access to hearing aids within their jurisdictions.

Should the Department become aware of issues associated with these licensed hearing aids, please be assured that officials will investigate and ensure that applicable regulatory requirements are met.

Should you have any additional questions regarding the licensing of medical devices in Canada, please contact Mr. Bruce Randall, Director General, Medical Devices Directorate, Health Products and Food Branch, by email at **bruce.randall@hc-sc.gc.ca**, or by telephone at 343-553-4570.

Again, thank you for writing, and please accept my best wishes.

Yours sincerely,

Greg Orencsak
Deputy Minister of Health