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EAR CANDLES (7/13)

Ear candles, also known as “ear cones” or “air candles,” are 10”-15” long cone-shaped hollow candles typically made of wax-impregnated cloth. The tapered end is inserted into the ear canal and the opposite exposed end is lit and burned with the intent to treat a wide variety of ear maladies including cerumen impactions (allegedly through a vacuum effect), otitis media, otitis externa, hearing loss, tinnitus, and Meniere’s disease. Ear candles have also been promoted for relief of sinusitis, headaches, inhalant allergies, “lymph node drainage”, and a host of other conditions. FDA has never cleared or approved a marketing application for ear candles for any of these therapeutic uses.

Historically, ear candles have been sold by mail order, over-the-counter at various health food stores, and more recently through the Internet. They have been advertised and promoted in many types of health-related publications (particularly holistic medicine publications), health food stores, workshops, and the Internet.

An independent clinical study of ear candle use conducted by Daniel R. Seely, M.D. of the Spokane ENT Clinic, Spokane, WA (*Laryngoscope* 1996;106:1226-9) identified 21 ear injuries resulting from ear candle use in a survey of 122 otolaryngologists. The study concluded that ear candles have no benefit in the management of cerumen problems and may, in fact, result in serious injury. Injuries such as burns of the pinna and external auditory canal, partial or complete occlusions of the ear canal with candle wax, and tympanic membrane perforation were identified in the epidemiological survey.

FDA became concerned about the safety issues with ear candles after receiving reports of patient injury caused by the ear candling procedure. Although there are proponents who argue in favor of the use of ear candles, FDA is unaware of any controlled studies or other scientific evidence that support the safety and effectiveness of these devices for any of the purported claims or intended uses as contained in the labeling.

Based on the growing concern associated with the manufacture, marketing, and use of ear candles, FDA has undertaken several successful regulatory actions including product seizures and injunctions since 1996. These actions were based, in part, upon violations of the Food, Drug and Cosmetic Act which pose an imminent danger to health. Specifically, the devices were considered to be misbranded in accordance with Section 502(j) of the Act because:

- Ear candles are dangerous to health when used in the manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling. FDA considers these devices to be dangerous because the use of a lit candle in proximity to the face carries a significant risk of potentially severe burns to the skin/hair, ear canal, tympanic membrane, and middle ear structures.
- The labeling was deemed to be false or misleading [section 502(a)], in that there is no valid scientific evidence to support the efficacy of the intended uses.
- The label of the “device fails to bear adequate directions for use since adequate directions cannot be written for the device’s purported use, Section [502(f)(1)].

Until such time as FDA receives and approves or clears a marketing application for ear candles, they continue to be marketed illegally for these therapeutic uses. Health Canada has taken similar regulatory actions to those of the FDA and maintains that ear candles are sold for unsubstantiated medical intended uses which have no scientific basis for safety and effectiveness. Health Canada and the United States have issued directives prohibiting importation of ear candles. Consumers are advised to avoid these dangerous devices. You may report complaints via FDA’s MedWatch program which is easily accessed through the FDA’s website.