



**PUBLIC PROTECTION CABINET
KENTUCKY LICENSING BOARD FOR SPECIALISTS IN HEARING INSTRUMENTS**

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**Medical Device Reporting:
Filing an FTC or FDA Complaint**

To report illegal or misleading advertising, or report a problem with a hearing device:

The U.S. Federal Trade Commission (FTC) accepts complaints about fraud and unfair business practices related to health products. Go to <http://bit.ly/FTCCConsumerComplaint> to learn more and/or file a complaint.

To report allegations of regulatory misconduct:

The U.S. Food and Drug Administration (FDA) accepts allegations of regulatory misconduct, which may include failure to register and list a medical device, marketing unapproved products, failure to follow quality system requirements, or misleading promotion. Go to <http://bit.ly/FDARegulatoryMisconductReporting> to learn more and/or file a complaint.

To report adverse events with medical devices:

The U.S. FDA encourages individuals and providers to use the MedWatch form to report adverse events that they observe or suspect for medical products, including serious drug side effects, product use error, product quality problems, and therapeutic failures for a variety of FDA-regulated products. Go to <http://bit.ly/FDAMedWatchReporting> to learn more and/or file a complaint.

Be prepared with any filing to provide details on the specific complaint, including product and manufacturer information, the date of the occurrence, adverse outcomes, and any other relevant information.

If you have filed a complaint with the FTC or FDA, please notify the International Hearing Society (IHS) regarding the details of your complaint by completing the IHS intake form, <http://bit.ly/IHSNotification-FederalReporting>. IHS will review the information and determine the most appropriate course of action. To contact IHS with questions about reporting, email advocacy@ihsinfo.org or call 734-522-7200.

To report a complaint against a Kentucky Hearing Instrument Specialist:

The Kentucky Board for Specialists in Hearing Instruments accepts complaints regarding licensed Specialists in Hearing Instruments in Kentucky. Go to <https://bit.ly/2XtouYZ> to file a complaint.