



FDA News

FOR IMMEDIATE RELEASE

March 28, 2008

Media Inquiries:

Peper Long, 301-827-0599

Consumer Inquiries:

888-INFO-FDA

FDA Seeks Civil Penalties from Calif. Device Maker

The U.S. Food and Drug Administration (FDA) today announced it is seeking a \$2.2 million penalty against a California hearing aid manufacturer for violations of federal law, including manufacturing standards violations and the failure to notify the FDA of a change in an outside supplier or vendor, which may have exposed recipients of the devices to unnecessary health risks.

The hearing aids pose a public health risk due to excessive moisture, exposing patients to the risk of device failure, possible surgery, and the potential for additional hearing loss.

The agency's complaint, originally filed this past November and amended on March 17, seeks penalties against California medical device manufacturer Advanced Bionics, LLC and its president and co-CEO, Jeffrey H. Greiner.

The complaint alleges that Advanced Bionics shipped hearing aids to customers in the United States prior to filing appropriate supplemental information with the Agency, including a notice of changes made to the devices that affected their safety and effectiveness.

On July 7, 2003, Advanced Bionics received FDA approval to market the HiRes90k Implantable Cochlear Stimulator, a cochlear implant hearing aid surgically implanted under the skin behind the ear to treat profound hearing loss in adults and children. The hearing aid is considered a Class III device by the FDA—the most stringent regulatory category for devices.

The complaint alleges that the company failed to comply with the FDA's current Good Manufacturing Practice (GMP) requirements for devices. GMP requires that companies manufacturing medical devices for sale in the United States establish and follow quality systems procedures to assure the safety and quality of their products.

Advanced Bionics' alleged GMP violations include the failure to sufficiently evaluate and select a new vendor as the supplier of a critical device component and the failure to adequately validate the continued safety and effectiveness of the hearing aid by testing lots under actual or simulated use when the unapproved vendor's component was used.

The complaint also states that Advanced Bionics shipped hearing aids in violation of the law between January 2005 and July 2006. Two hearing aids shipped and implanted after a March 2006 recall contained the component from the unapproved vendor.

FDA's complaint states that the company's failure to file the required supplement occurred after a 2001 inspection. At that time, the company was cited for similar failures and made commitments to correct the problems.

Advanced Bionics, LLC, is located in Sylmar, Calif.

#

[RSS Feed for FDA News Releases](#) [\[what is RSS?\]](#)

[Get free weekly updates](#) about FDA press releases, recalls, speeches, testimony and more.

[FDA Newsroom](#)

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

[FDA Website Management Staff](#)