decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(4) Technical data. Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard “Specification of Hearing Aid Characteristics,” ANSI S3.22–2003 (Revision of ANSI S3.22–1996) (Includes April 2007 Erratum). The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005–3993, or are available for inspection at the Regulations Staff, CDRH (HFZ–215), FDA, 1350 Piccard Dr., rm. 150, Rockville, MD 20850, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

- (i) Saturation output curve (SSPL 90 curve).
- (ii) Frequency response curve.
- (iii) Average saturation output (HF-Average SSPL 90).
- (iv) Average full-on gain (HF-Average full-on gain).
- (v) Reference test gain.
- (vi) Frequency range.
- (vii) Total harmonic distortion.
- (viii) Equivalent input noise.
- (ix) Battery current drain.
- (x) Induction coil sensitivity (telephone coil aids only).
- (xi) Input-output curve (ACG aids only).
- (xii) Attack and release times (ACG aids only).

(5) Statement if hearing aid is used or rebuilt. If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) Statements in User Instructional Brochure other than those required. A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

- (i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and
- (ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

Food and Drug Administration, HHS

§ 801.430

(a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter.

(b) Data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency as set forth in paragraph (f) of this section.

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

VerDate Mar<15>2010 18:34 May 10, 2012 Jkt 226074 PO 00000 Frm 00045 Fmt 8010 Sfmt 8010 Q:\21\21V8.TXT ofr150 PsN: PC150