



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

March 25, 1999

WARNING LETTER

NWE-16-99W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Martin NMI Howard, President
Willows General Store, Inc.
179 Post Road
Fairfield, Connecticut 06880

Dear Mr. Howard:

During an inspection of your establishment in Fairfield, Connecticut, on October 28, 1998, November 24, 1998 and January 22, 1999, Investigators Stephen Souza and Edward Janik of the U.S. Food & Drug Administration (FDA) and Drug Control Agent Leo Roberge of the state of Connecticut's Department of Consumer Protection determined that your establishment markets the MaxiSound™ Personal Sound Amplifier (MaxiSound™). The MaxiSound™ is a medical device as defined by Section 201(h) of the federal Food, Drug and Cosmetic Act (the Act).

The MaxiSound™ is a hearing aid. A hearing aid, as defined by Title 21, Code of Federal Regulations (21 CFR) §801.420(a), is any wearable instrument or device designed for, offered for the purpose of, or represented as, aiding persons with or compensating for impaired hearing. Representative examples of hearing aid claims in your advertisement taken from the February, 1999 issue of "NAVAL AFFAIRS" include, but are not limited to, the following:

- "My wife was so tired of me asking her to either speak louder or repeat everything she said. We were having arguments over my hearing. Finally, she insisted that I get some help. She told me to buy a hearing aid."
- "MaxiSound can make speech louder, and the sound is crystal clear, pure and natural."

- "It's great to be able to hear the TV clearly again."
- "MaxiSound is made in the USA, and is comparable to other sound enhancement systems that retail for up to \$1000.00."

These devices are misbranded within Section 502(q)(2) of the Act in that they are sold, or used in violation of regulations prescribed in Section 520(e) of the Act. Hearing aids are regulated as restricted devices under section 520(e)(1) of the Act because prior to their purchase, customers must either undergo a medical evaluation designating them as candidates for a hearing aid, or sign a statement waiving the medical evaluation.

Under the provisions of 21 CFR §801.421(a)(1), Hearing Aid Devices, Conditions for Sale, a hearing aid dispenser shall not sell a hearing aid to a prospective user unless the hearing aid dispenser has received a written statement signed by a licensed physician stating that the patient's hearing loss has been medically evaluated within the past six (6) months and that the patient is a candidate for a hearing aid. If the prospective hearing aid user is eighteen (18) years of age or older, the only opportunity for the hearing aid dispenser to waive the medical evaluation required by 21 CFR §801.421(a)(1) is if the hearing aid dispenser:

- (1) informs the prospective user that the exercise of the waiver is not in the user's best health interest;
- (2) does not in any way actively encourage the prospective user to waive such a medical evaluation; and
- (3) affords the prospective user an opportunity to sign a statement indicating that a medical evaluation is in the user's best health interest and that he/she waives the right to such an evaluation.

Furthermore, the insert that accompanies your device must be changed so as not to encourage the customer to just sign the waiver of the medical evaluation. Currently, the manufacturer's insert reads: "You **MUST** read and sign the **WAIVER OF MEDICAL EVALUATION**, then return the signed copy to us in the enclosed postage paid envelope." This gives the appearance that all the user has to do is sign this waiver to fulfill his or her agreement of purchase. This statement fails to comply with the FDA regulations by actively encouraging the prospective user to waive a medical evaluation as required by 21 CFR §801.42(a)(2)(ii).

Additionally, before signing the waiver and before the sale of the hearing aid to the prospective user, Willows General Store, Inc. failed to:

- Provide the prospective user a copy of the Instructional Brochure for the hearing aid as required by 21 CFR §801.42(b)(1);

Warning Letter to Willows General Store, Inc.

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- Review the content of the User Instructional Brochure with the prospective user orally, or in the predominant method of communication used during sale as required by 21 CFR §801.42(b)(2); and
- Afford the prospective user an opportunity to read the User Instructional Brochure as required by 21 CFR §801.421(b)(3).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and /or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Bruce R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely,



John R. Marzilli
District Director
New England District Office