



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

WARNING LETTER

Food and Drug Administration
2098 Galther Road
Rockville MD 20860

VIA FEDERAL EXPRESS

DEC 30 1996

Mr. Michael W. Nehr, M.S.
President
Crystal Care, International, Incorporated
1919 Vandervort Road
Lutz, Florida 33549

Re: Crystal Ear CE 100 Air
Conduction Hearing Aid,
K942189

Dear Mr. Nehr:

The Food and Drug Administration (FDA) has reviewed an infomercial for the Crystal Ear CE 100 (Crystal Ear), which was broadcast on various U.S. television stations between November and December, 1996. The Crystal Ear is manufactured by Crystal Care, International, Incorporated (Crystal Care) and is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Crystal Ear has been cleared under section 510(k) of the Act and is intended to amplify sound pressure waves and transmit the signal to the external ear through the medium of air to compensate for impaired hearing.

The Agency has obtained information, and has independently confirmed, that Crystal Care's infomercial was broadcast on various television stations throughout the United States. Representative examples of broadcasts are as follows: station WOCD-TV (Albany, NY), 11/15/96 at 11:30 A.M.; 11/18/96 at 8:30 A.M.; 11/18/96 at 2:00 P.M.; WTJC-TV (Dayton, OH), 11/14/96 at 4:00 P.M.; 11/15/96 at 11:30 A.M.; and 11/17/96 at 4:30 P.M.. Other stations included: WAAP-TV (Greensboro, NC), KUBD-TV (Denver, CO), WTLK-TV (Atlanta, GA), WRB-TV (Orlando, FL).

At least two portions of the videotape make claims that the device can improve hearing in noisy environments. One patient who was interviewed stated that Crystal Ear can eliminate background noise. A hairdresser indicated that it was difficult to carry on a conversation because of the noise from blow dryers and ringing telephones, but after trying Crystal Ear, she was able to speak and hear without difficulty, and another patient implied that Crystal Ear can improve hearing in restaurants by eliminating background noise. Crystal Ear has not been cleared for the claim of eliminating background noise or to improve hearing in noisy environments.

The Agency has determined that making or implying user benefit in a noisy environment is a significant modification in the intended use of the device and requires the submission of a new 510(k).

The Agency has determined that making or implying user benefit in a noisy environment is a significant modification in the intended use of the device and requires the submission of a new 510(k). Such claims misbrand the Crystal Ear hearing aid under section 502(o) of the Act in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii).

In another section of the videotape, Gary Collins, the narrator, makes the statement, "The vast majority of people with mild or moderate hearing loss can be helped with Crystal Ear." In your July 27, 1994 letter to the Agency, Crystal Care made a commitment to recommend Crystal Ear only for those patients who have mild hearing loss in Classes A through B i.e., 40 dBHL ISO or less. Claims that Crystal Ear can help people with moderate hearing loss further misbrands your device under section 502(o) of the Act.

The Crystal Ear hearing aid is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f) and does not have an approved application for premarket approval in effect pursuant to section 515(a) or an approved application for an investigational device exemption under section 520(g).

Additionally, your representations in the video that the Crystal Ear is an assisted listening device is inaccurate. Your device was cleared as an air conduction hearing aid and any other representation is misleading.

Finally, we note that a section of the videotape references FDA's approval of the device and compliance with GMP's (Good Manufacturing Practices). References to FDA or GMP's, in advertisements or other promotional materials for medical devices, is prohibited by the Act and represents misbranding under section 502(a). The reference for this may be found under 21 CFR 807.97, "Any representation that creates an impression of official approval because of complying with the premarket notification regulations is misleading and constitutes misbranding." References to FDA or GMP's create an impression of FDA approval.

This letter is not intended to be an all-inclusive list of deficiencies associated with your device. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter also may be reflected in other promotional or advertising materials used by your firm. You are responsible for

investigating and reviewing all materials to assure compliance with applicable regulations.

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

Additionally, in a telephone call to Crystal Care's sales representatives on December 20, 1996, your sales representative did not question whether we had obtained a medical evaluation, nor did she inform us that in the absence of such an examination, we could sign a waiver. It was clear that your sales representative did not adequately discuss these issues prior to agreeing to take an order. Although Crystal Care could discuss these issues in a video, this would not meet the intent of the regulations prior to the sale of the hearing aid.

We are taking this opportunity to remind you of your responsibility in relation to the conditions for sale that are mandated by 21 CFR 801.421(a)(1)(2). The manufacturer or distributor 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 6 months and that the patient is a candidate for a hearing aid. The only exception is when the dispenser provides the prospective user, who is 18 years of age or older, an opportunity to waive the medical evaluation requirement and (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.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should also include steps being taken to address any misleading information currently in the market place and to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

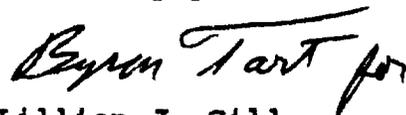
Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302),

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Office of Compliance, Center for Devices and Radiological Health,
2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Florida District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Florida District Office (HFR-SE200), 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health