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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER**VIA FEDERAL EXPRESS**

NOV - 6 1997

Mr. Charles Anton
President
Comtrad Industries, Incorporated
2820 Waterford Lake Drive, Suite 102
Midlothian, Virginia 23113

Re: Crystal Ear Air Conduction
Hearing Aid

Dear Mr. Anton:

The Food and Drug Administration (FDA) has reviewed promotional materials for the Crystal Ear Hearing Aid. This product is manufactured by Crystal Care, International, distributed by Comtrad Industries (Comtrad), and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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.

FDA has obtained information that Comtrad has sold the Crystal Ear Hearing Aid to a customer without first obtaining evidence of a medical evaluation or of a waiver. Additionally, in a telephone call to Comtrad's sales representatives on November 4, 1997 by this office, your sales representative did not question whether we had obtained a medical evaluation, nor did he 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 requirements or make submission of this information a requirement of sale, prior to agreeing to take an order.

The following regulations 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. Additionally, prospective customers should be given the opportunity to review the User Instructional Brochure.

Because Comtrad has sold, distributed, or used Crystal Ear in violation of the restricted device regulations under section 520(e) i.e., failure to obtain documentation of a medical evaluation or a signed waiver, the Crystal Ear is misbranded within the meaning of section 502(q)(2) of the Act.

The agency has also reviewed a promotional advertisement for the Crystal Ear Hearing Aid which appeared in the November 4, 1997 issue of USA Today. The promotional piece was placed by Comtrad and makes claims that have not been cleared by the agency. Specifically, the ad states in part, "Crystal Ear is powerful – you'll hear low level movie and TV dialogue even when it's overpowered by big special effects!" Such a claim implies that Crystal Ear can reduce or eliminate background noise or help people hear better in noisy environments. The agency has determined that such claims or representations constitute a major change or modification in the intended use of the device which requires the submission of a new 510(k) premarket notification [21 CFR 807.81(a)(3)(ii)]. Since Crystal Ear has not been cleared for the claim of eliminating background noise or for helping people hear better in noisy environments, Comtrad may not make this claim in any of its promotional materials.

By claiming that Crystal Ear can eliminate background noise or help people hear better in noisy environments, Comtrad Industries has misbranded the Crystal Ear within the meaning of 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), and the device were not found to be substantially equivalent to a predicate device.

Additionally, Comtrad has adulterated the Crystal Ear 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 (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

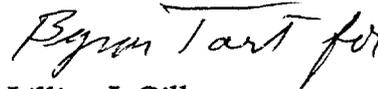
This letter is not intended to be an all-inclusive list of deficiencies associated with your Crystal Ear Hearing Aid. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

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

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. Additionally, we believe Comtrad should take immediate steps to provide adequate

training to your telephone sales representatives regarding the regulatory requirements for obtaining documentation of either a medical evaluation or a signed waiver, prior to taking an order. 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), 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 Baltimore District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Baltimore District Office, 900 Madison Avenue, Baltimore, Maryland 21201-2199.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill".

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