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U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

dis91b

Telephone: [718] 965-5300 [Ext 5053]

December 9, 1996

WARNING LETTER

Certified Mail Return Receipt Requested

Mr. Drew E. O'Connell, President
Cirrus Air Technologies LLC
98 Forest Avenue
Locust Valley, New York 11560

Re: 21-NYK-97

Dear Mr. O'Connell:

During an inspection of your firm located in Locust Valley, New York, on November 21, 22, 25, 1996 our investigator determined that your firm manufactures both *Children's earplanes* and *earplanes* which are contract manufactured by [REDACTED] located at [REDACTED] and distributed by [REDACTED], located at [REDACTED]. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection found that the above-named devices are adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that they are Class II devices under Section 513(f)(1) and do not have approved applications for premarket approval in effect pursuant to Section 515(a)(2) or approved applications for investigational device exemptions under Section 520(g) and preamendment status has not been documented.

The above-named devices are also misbranded within the meaning of Section 502(o) of the Act, in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment which did not list as required by Section 510(j), and notices or other information respecting the devices was not provided to the FDA as required by Section 510(k).

The above-stated inspection also revealed that the *Children's earplanes and earplanes* are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulations, as specified in Title 21, Code of Federal Regulations, (CFR), Part 820, as follows:

1. Failure to maintain a Device Master Record that includes the location of device specifications, packaging and labeling specifications, including methods and processes used and quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used. Specifically there is neither a Device Master Record nor documentation which refers to the specification setter for both the *Children's earplanes and earplanes*.
2. Failure to have written manufacturing specifications and processing procedures established, implemented, and controlled to assure the device conforms to its original design or any approved changes in that design, as well as procedures for specification changes to be approved and documented by a designated individual(s) with the approval date and the date the change becomes effective. Specifically there is no documentation to show that a change in the devices' component specifications were made in the silicone rubber used to produce a softer earplane.
3. Failure to maintain, review, evaluate and investigate complaint files that involve the possible failure of a device to meet any of its performance specifications. Specifically, there was no follow-up investigation regarding six complaints received between August 1996 and November 1996 involving the possible failure of the *earplanes* to meet its functions including relieving ear discomfort, clogging and/or popping.

The above inspection also revealed that you are the owner or operator of an establishment that is not exempt under section 510(g) of the Act or Subpart D of this part in that you are engaged in the manufacturing, preparation, propagation, compounding assembly or processing of devices intended for human use that are not registered and there is no submission of a listing of information for these devices in commercial distribution. For your convenience, enclosed are forms FDA 2891 "Initial Registration of Device Establishment," FDA 2892 "Device Listing," a copy of the FDA Booklet "Everything You Always wanted to Know about Medical Device Requirements . . . and Weren't Afraid to ask," a copy of the CDRH publication "Medical Device Establishment Registration Information and Instructions" and, a copy of 21 CFR Part 807 "Establishment Registration and Device Listing for Manufactures of Devices." If your firm is claiming preamendment status, a copy of the "Documentation Required for Preamendment Status" is also enclosed.

Both the labeling and product literature that is associated with these devices makes health claims that both *Children's earplanes and earplanes* "regulate the air flowing into and out of the ear thereby alleviating ear pain . . . ," "recommended for travelers who must fly with colds, allergies or sinus conditions," and "relieves painful ear discomfort, clogging, popping and hearing loss." The Office of Device Evaluation of the Center for Devices and Radiological Health and Evaluation requires that clinical data be submitted to substantiate the claims made for these devices.

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. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If causes are determined to be systems problems, you must promptly initiate permanent corrective actions. 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. Additionally, no pending applications for premarket approval (PMA's) or export approval requests will be approved and no Premarket notifications [Section 510(k)'s] will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations 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 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Include 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 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, attention: Anita Fenty, Compliance Officer.

Very truly yours,



Alonza Cruse
Acting District Director
New York District Office
Food and Drug Administration

Enclosure

cc:

