



DEPARTMENT OF HEALTH & HUMAN SERVICES

7FI-35

Public Health Service

M 1957N

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 6 1998

WARNING LETTER
VIA EXPRESS

Mr. Marshall Oreck
Executive Vice President
Oreck Corporation
100 Plantation Road
New Orleans, Louisiana 70123

Dear Mr. Oreck:

We have received and reviewed your letter of July 6, from Adam W. Chase, of Adams, Johnston & Oreck, which responded to our June 18 letter. As stated in our previous letter of May 15, 1997, your Oreck Celoc Hypo-Allergenic Air Machine is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. This device is considered a medical recirculating air cleaner, and is classified as a class II medical device. The reference for this is 21 CFR 880.5045 (copy enclosed). The law requires that manufacturers of medical devices obtain marketing clearance for their products from the Food and Drug Administration (FDA) before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. The kind of information you need to submit in order to obtain this clearance can be obtained by contacting our Division of Small Manufacturers Assistance (DSMA) at 1-800-638-2041 or through the Internet at <http://www.fda.gov>. The FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the

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product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Ms. Carolyn Niebauer, Chief, General Hospital Devices Branch at the letterhead address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting DSMA.

If you have any questions regarding the contents of this letter, please feel free to contact Ms. Leslie E. Dorsey at (301) 594-4618, extension 115.

Sincerely yours,


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

Enclosure