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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Refer to: 1122336  
OC Track No. 69079

Public Health Service  
Food and Drug Administration  
Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4040

May 20, 1997

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Raymond N. Owens, President  
Sun Box Company  
19217 Orbit Drive  
Gaithersburg, Maryland 20879

Dear Mr. Owens:

On March 11, 1997, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the products known as SunSquare, SunRay, SunRay II, and SunLight Jr. light boxes, which are made and marketed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices, as they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may be offered 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 products for sale. The type of information you must submit to obtain this clearance is described in the enclosed materials. 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 products are adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. Your products are adulterated under the Act because you did not obtain pre-market approval based on information developed by you that demonstrates your devices are safe and effective. Your products are misbranded under the Act because you did not submit information that

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demonstrates your devices are substantially equivalent to other devices that are legally marketed, and because you have not registered or listed your devices with the FDA.

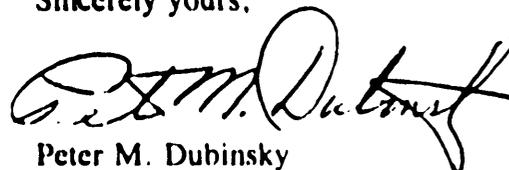
This serious violation of the law may result in the FDA taking regulatory action without further notice. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. 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 and to prevent their recurrence. 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. Please direct your response to Gerald W. Miller, Compliance Officer, U.S. Food and Drug Administration, 101 West Broad Street, (Suite 400), Falls Church, Virginia 22046-4200.

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 pre-market clearance for your devices 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 our Division of Small Manufacturers Assistance at 1-(800)-638-2041 or through the Internet at <http://www/fda/gov>.

If you have any specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Gerald W. Miller, Compliance Officer, at the U.S. Food and Drug Administration, 101 West Broad Street (Suite 400), Falls Church, Virginia 22046-4200, phone (703)-235-8440, extension 504.

Sincerely yours,



Peter M. Dubinsky  
Acting Director, Baltimore District

Enclosure