



April 24, 1998

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 425-486-8788
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 98-11

Mr. Larry W. Dennison, Co-Owner
Coyote Found Candles
31 Workman St.
P.O. Box 1412
Port Townsend, WA 98368

WARNING LETTER

Dear Mr. Dennison:

We are writing to you because on March 2 & 5, 1998, Engineer Prabhu P. Raju from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the products known as "Air Candles" which are made and marketed by your firm. These air candles are labeled as: *AIR CANDLES 1/2" BEESWAX (30 pack)*; *AIR CANDLES 1/2" PARAFFIN (30 pack)*; *AIR CANDLES 3/4" PARAFFIN (20 pack)*; and *4 Pack Air Candles 1/2 " Paraffin*.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices because 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 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.

Review of the labeling for this device collected during the inspection, reveals that the Air Candles are misbranded within the meaning of Section 502(a) in that the labeling for the device, namely, (1) the insert brochure entitled "CANDLING"; (2) the candling pamphlet entitled, "CANDLING, Here is your Guide to a Safe, Natural, Economical, and Easy Solution for your better Health" and, (3) the candling guide entitled, "CANDLING, Here is your Guide to a Safe, Natural, Economical, and Easy Solution for your better Health" represent or suggest that the devices are adequate and effective for a number of conditions. Among other statements, the Air Candles are purported to: help with various ear disorders; remove excess wax, infections, and residuals of past infections; correct ear infections in children; stop parasites from growing in the ear; control fungus infection of the outer ear, reduce tinnitus, sinus problems, sore throat, ear ache, swimmer's ear, some chronic headaches, allergies and hearing difficulty; and to relieve the discomfort of menstrual cramping.

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Our records do not show that you obtained marketing clearance before you began offering your products for sale. The kind of information you need to submit in order 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 products 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 premarket approval based on information developed by you that shows your devices are safe and effective. Your products are misbranded under the Act because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed. The Air Candles are not exempted from premarket approval under the conditions found in the attached enclosure.

Furthermore, the inspection revealed that the Air Candles are in violation of additional misbranding provisions of the Act. These violations would include Sections 502(f)(1) and 502(j). Section 502(f)(1) concerns the labeling which fails to bear adequate directions for use for the purposes for which the Air Candles are intended. That is, the labeling does not bear adequate directions for lay use in the medical treatment of the conditions listed in the above described literature. Section 502(j) states that the Air Candles are a danger to health when used in the dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling.

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.

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 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 Thomas S. Piekarski, Compliance Officer, at the above address.

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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 our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Ronald L. Swann at (301) 594-4613 ext. 109.

Sincerely,

A handwritten signature in cursive script, appearing to read "Roger L. Lowell".

Roger L. Lowell
District Director

Enclosure:
Premarket Notification