

FDA TALK PAPER

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LAMP'S LABELING FOUND TO BE FRAUDULENT

FDA's Aug. 27 Enforcement Report carried a "Health Fraud Notice" listing the Vita-Lite Fluorescent Lamp sold by the Duro-Test Corporation of North Bergen, N.J., as a "gross deception of the consumer" because of its labeled claims.

The following may be used in answering questions:

FDA occasionally publishes a Health Fraud Notice as part of its "Tipped Off" program to warn prospective purchasers about deceptive medical devices. Such listings are likely to be used by state and local consumer units, the Better Business Bureaus and others who receive inquiries from potential buyers. The listings "do not preclude further legal or regulatory action by FDA," according to the notice.

Vita-Lite is a full-spectrum fluorescent lamp designed to simulate natural sunlight. But it is sold as having proven health benefits, claiming that it "improves visual acuity... reduces fatigue... enhances calcium absorption... makes people feel better... helps fight winter blues"... and "could be of value in reducing contamination by microorganisms."

FDA cautions consumers that these claims are unsubstantiated and misleading because there is little or no clinical data derived from well-controlled scientific investigations to support use of such full-spectrum fluorescent lights for these therapeutic purposes. Much more research is required before firms could justify medical claims for nonprescription use of full-spectrum lamps. There is no recognized, conclusive evidence to

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establish full-spectrum light's possible therapeutic or health benefits in general -- though Duro-Test in its "technical literature" cites popular magazines, non-referenced articles and testimonial letters.

Light therapy as a treatment for winter depression is still experimental, and should not be attempted without professional clinical supervision. Some recent studies on "winter blues" and seasonal affective disorder (SAD) suggest no advantage to full-spectrum lights like Vita-Lite compared to ordinary cool-white fluorescent bulbs or standing in the sun.

Vita-Lite also makes claims for increased sexual potency in male turkeys, fewer dental caries in hamsters and "significantly different" growth of vital organs in rats -- claims which might make unwary consumers think they could gain similar dental or sexual dividends.

FDA hopes by such notices to alert the public and help consumers make informed choices.

At an Aug. 28 hearing, New Jersey's U.S. District Court denied Duro-Test's petition for a temporary restraining order (TRO) to prevent distribution of the Aug. 27 Enforcement Report containing the Health Fraud Notice on Vita-Lite. Duro-Test subsequently withdrew without prejudice its request for a court hearing on the motion for a preliminary injunction. The firm and FDA are currently discussing possible labeling revisions in an attempt to resolve the matter without further litigation.

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