DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 2006

1591 '06 OCT -5 P2:13

Dale A. Malone
Banner & Witcoff, Ltd
28 State Street
28th Floor
Boston, Massachusetts 02109-1775

Re: 2006P-0165

Dear Mr. Malone:

This is in response to your citizen petition dated April 11, 2006, and filed by the Food and Drug Administration (FDA) on April 18, 2006. In your letter, you describe possible violations with FDA sunlamp product requirements and our policy on lamp compatibility. Your petition requested that FDA initiate "administrative proceedings for the purpose of investigating and enjoining the unlawful sale and distribution of ultraviolet suntanning lamps that are misbranded as defined by 21 U.S.C. § 352(a)" and impose "penalties prescribed by 21 U.S.C. § 333(g)."

Thank you for providing this information to the FDA. Information from regulated industry is often very helpful to us in identifying problems with marketed products and possible violations of the laws that we enforce. We take such reports seriously, and we will evaluate this matter to determine what follow-up action is appropriate. The type and extent of any follow-up is dependent upon the nature of the problem, the possible impact on the public health, and the availability of our resources.

While FDA does not provide information on ongoing investigations, information can be obtained pursuant to a Freedom of Information Act (FOIA) request, once an investigation is closed. Written requests for information may be sent to the following address:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions regarding this response to your petition, please contact Manual Karos at 240-276-3318.

Sincerely,

Linda Kahan

Linda Kahan
Deputy Director
Center for Devices
and Radiological Health

2006P-0165

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