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By Certified Mail

April 11, 2006

Division of Dockets Management  
United States Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Citizen's Petition Under 21 C.F.R. 10.30**

Dear Sirs,

The undersigned submits this petition under Section 331 of the Federal Food, Drug and Cosmetic Act to request the Commissioner of Food and Drugs to (i) initiate administrative proceedings against International Tan Makers, Inc., a Massachusetts corporation having a principal place of business at 320 Charger Street, Revere, Massachusetts 02151; (ii) issue a cease distribution and notification order (pursuant to 21 C.F.R. §810.10); and (iii) impose upon International Tan Makers the penalties prescribed by 21 U.S.C. §333(g), for the reasons set forth in this petition.

**A. Action Requested**

Petitioner requests that the Commissioner initiate administrative proceedings for the purpose of investigating and enjoining the unlawful sale and distribution by International Tan Makers of ultraviolet suntanning lamps that are misbranded as defined by 21 U.S.C. §352(a); and to impose appropriate remedies against, and to require corrective actions by, International Tan Makers, including:

1. Issuance of a cease distribution and notification order; and,
2. Imposition of the penalties prescribed by 21 U.S.C. §333(g).

**B. Statement of Grounds**

This petition pertains to the marketing, sales and distribution of ultraviolet suntanning lamps, Class I devices as defined by 21 U.S.C. §360c. International Tan Makers, Inc., a Massachusetts corporation having a principal place of business at 320 Charger Street, Revere, Massachusetts 02151, is a distributor of suntanning lamps and related products, and markets, sells and distributes the devices involved in this petition in interstate commerce throughout the United States. More specifically, International Tan Makers markets, sells and distributes replacement suntanning lamps to the owners of

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BOSTON, MA  
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suntanning beds and booths, including salon owners and operators, and individuals.

The Food and Drug Administration's "Policy on Lamp Compatibility" (published on September 2, 1986), notes that the amended performance standard for sunlamp products (21 C.F.R. §1040.20) requires that the User Instructions supplied with replacement lamps (i.e., "an ultraviolet lamp not accompanying a sunlamp product") must contain a clear identification by brand name and model designation of all lamp models for which replacement lamps are promoted. This so-called "lamp compatibility" statement is a certification that the marketed lamp meets the detailed technical requirements set forth in the Policy on Lamp Compatibility. As stated in the preamble to the amendments to the standard (published in the federal register issue of September 6, 1985), "*the promotion of incompatible lamps will be considered as marketing a falsely certified product.*"

International Tan Makers has for many years marketed, sold and distributed a series of replacement suntanning lamps under its trademark, Euro Bronze Magnifier®. Prior to 2005, International Tan Makers purchased the lamps sold under the Euro Bronze Magnifier brand from Light Sources, Inc. These replacement lamps were sold to salon owners and operators, and to individuals, along with a sheet of User Instructions as required by 21 C.F.R. §1040.20. That User Instructions sheet listed compatibility information for thirteen (13) different lamp models sold under the Euro Bronze Magnifier brand. On information and belief, the manufacturer of the thirteen Euro Bronze Magnifier models, Light Sources, Inc., prepared and filed the required spectrophotometric testing data to support the claimed compatibility under 21 C.F.R. §1040.20(f)(2)(iii).<sup>1</sup> A copy of the User Instructions sheet for the Euro Bronze Magnifier lamps manufactured for International Tan Systems by Light Sources, Inc., is attached at Tab 1.

In early 2005, International Tan Makers ceased purchasing its Euro Bronze Magnifier lamps from Light Sources, Inc., and instead sourced these products from a distributor, ETS, for whom the lamps were manufactured by Osram Sylvania, Inc. International Tan Makers retained the same model names, and the same identifying model numbers, for each of the thirteen Euro Bronze Magnifier lamps it had previously sourced from Light Sources, Inc.

Since that time, International Tan Makers has marketed, sold and distributed its Euro Bronze Magnifier lamps as replacement lamps to tanning salon owners and operators, and to individuals. Such lamps have been accompanied by a User Instructions

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<sup>1</sup> Petitioner takes no position here regarding the accuracy of the data submitted to FDA by Light Sources, Inc. Regardless of their accuracy, it is clear that the *different* lamps now sold by International Tan Makers under the same model numbers and tradenames have *vastly* different spectral characteristics than certified by their distributor.

sheet (attached at Tab 2) that listed, as previously, purported compatibilities between the thirteen Euro Bronze Magnifier lamps and the lamps they are marketed to replace. However, on information and belief, *no compatibility testing data whatsoever has been submitted to the Food and Drug Administration to support the alleged compatibility.* Rather, International Tan Makers has simply continued to distribute the same compatibility claims it had made previously, even though it now sells *different* lamps made by a *different* manufacturer.

Indeed, comparison of the production specifications of the International Tan Makers products to those lamps (also manufactured by Osram Sylvania<sup>2</sup>) to which compatibility is claimed amply demonstrates that at least six of the thirteen Euro Bronze Magnifier lamps now being marketed, sold and distributed by International Tan Makers are, in fact, incompatible with the lamps they are being promoted to replace. In some instances, replacement of the listed lamp with the allegedly compatible Euro Bronze Magnifier product would result in moderate overexposure to users. ***In many more instances, however, replacement with the allegedly compatible International Tan Makers product would result in gross overexposure to users.***

Petitioner has obtained production specification data for the following lamps listed on the User Instructions sheet now being distributed by International Tan Makers. In each instance, the difference in spectral performance between the two lamps exceeds the maximum ( $\pm 10\%$ ) permitted by the standard:

<u>Int'l Tan Makers Model</u>	<u>Competitive Lamp</u>	<u>Difference<sup>3</sup></u>	<u>Compatible?</u>
Euro Bronze Magnifier 7.0 Plus F59T12/BL/BP	Bellarium S	-14%	NO
	Crystal Sun S	-14%	NO
	Diamond Sun S	-16%	NO
	EuroSun S3	-12%	NO
	EverGlo	-12%	NO

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2 Because all of the production specifications set forth herein are from the same manufacturer (Osram Sylvania), manufacturing variations within each production model would be expected to be comparable. Moreover, the large differences between the production specifications of the International Tan Makers products and many of the lamps claimed to be compatible to those models far overshadow any reasonable manufacturing variation.

3 The difference in time, in minutes, to erythema ( $T_E$ ) as measured pursuant to FDA's Policy on Lamp Compatibility. A negative difference indicates that the International Tan Makers replacement lamp is more powerful, causing erythema more quickly, than the original lamp.

<u>Int'l Tan Makers Model</u>	<u>Competitive Lamp</u>	<u>Difference</u>	<u>Compatible?</u>
Euro Bronze Magnifier 7.0 Plus F59T12/BL/BP ( <i>continued</i> )	CosmoLux ESP	+31%	NO
	Accelerator	-16%	NO
Euro Bronze Magnifier 7.0 Plus F71T12/BL/BP	Bellarium Plus	-50%	NO
	Bellarium S	-49%	NO
	Crystal Sun S	-49%	NO
	Diamond Sun S	-49%	NO
	EuroSun S3	-47%	NO
	Everglo	-47%	NO
	Velocity	-44%	NO
Euro Bronze Magnifier 7.0 Plus F72T12/BL/HO	Diamond Sun S	-49%	NO
	Crystal Sun S	-49%	NO
Euro Bronze Magnifier 7.0 Plus F73T12/BL/HO	Bellarium Plus	-50%	NO
	Bellarium S	-49%	NO
	Crystal Sun S	-49%	NO
	Diamond Sun S	-49%	NO
	EuroSun S3	-47%	NO
	EverGlo	-47%	NO
	Dominion	-29%	NO

<u>Int'l Tan Makers Model</u>	<u>Competitive Lamp</u>	<u>Difference</u>	<u>Compatible?</u>
Euro Bronze Magnifier 7.0 Plus F73T12/BL/HO (continued)	CosmoLux ESP	-22%	NO
	Accelerator	-50%	NO
	Goldarium S	-44%	NO
	Velocity	-44%	NO
	Goldarium SP	-44%	NO
Euro Bronze Magnifier 7.0 Plus F72T12/BL/HO	Bellarium VHO	-31%	NO
	CosmoLux VHO	-32%	NO
Euro Bronze Magnifier 7.0 Plus F73T12/BL/VHO	Bellarium VHO	-31%	NO

A spreadsheet of the production specification data is attached at Tab 3.

This data shows that at least 31 of the individual compatibility claims stated by International Tan Makers in the current User Instructions sheet are blatantly false. International Tan Makers is presently promoting incompatible replacement lamps, in violation of the "Policy on Lamp Compatibility." According to that policy, such activity is considered to be marketing a falsely certified product.

A cursory examination of the two User Instructions sheets distributed by International Tan Makers suggests that no re-determination of compatibility was made when it changed suppliers for its Euro Bronze Magnifier products. Rather, it appears that International Tan Makers simply took the very same sheet and merely replaced the old manufacturer's name with the new manufacturer's logo. Unfortunately, this adulteration of a certification under Federal law has caused very real risks to tanning bed users, due to the egregiously false claims of product compatibility.

International Tan Makers' unlawful conduct represents a serious health threat to the users of suntanning beds and booths, as well as a significant economic risk to the owners and operators of commercial tanning salons. The compatibility requirements exist to help ensure that suntanning equipment, in actual use, remains within the safety and performance specifications for which it was initially certified. Replacement of

tanning lamps with incompatible models causes a performance change in the tanning equipment unintended by the equipment manufacturer (and operator) and undisclosed to the user, resulting in likely overexposure (when the replacement lamps are more powerful than the original lamps) or poor tanning results (when the replacement lamps are less powerful than the original lamps).

**C. Environmental Impact**

The requested relief will have no foreseeable environmental impact.

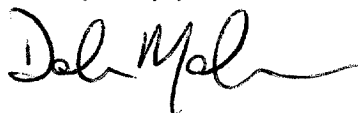
**D. Economic Impact**

[to be submitted upon request following the Commissioner's review of the petition]

**E. Certification**

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Very truly yours,



Dale A. Malone

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