Report to Congress

Labeling Information on the Relationship Between the Use of Indoor Tanning Devices and Development of Skin Cancer or Other Skin Damage

Submitted Pursuant to Section 230 of the Food and Drug Administration Amendments Act of 2007

U.S. Department of Health and Human Services

Food and Drug Administration

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Executive Summary

Section 230 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) requires FDA to make certain determinations regarding the effectiveness of warning labels for indoor tanning devices in conveying information to consumers regarding the risks that such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer. FDA is required to conduct consumer testing in making these determinations, and to submit a report to Congress providing these determinations and identifying measures being implemented to significantly reduce the risks posed by indoor tanning devices. FDA is submitting this report to Congress in response to that mandate.

Based on its analysis of the results of the consumer study required by section 230 of FDAAA, FDA has determined that there are warnings that are capable of adequately communicating the risks of indoor tanning, and that a modified warning statement label may more effectively convey these risks than the current labeling requirements. FDA has also determined that changes to the positioning requirements for the warning statement label may communicate such risks more effectively.

As a result of these determinations, FDA is considering amending the warning label requirements for sunlamp products to include specific formatting requirements to more clearly and effectively convey the risks that these devices pose for the development of irreversible damage to the eyes and skin, including skin cancer. To significantly reduce the risks associated with the use of these devices, FDA is also considering amending the performance requirements in the sunlamp products performance standard, and has begun educational outreach efforts to better inform consumers about the risks of indoor tanning.

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I. Introduction

On September 27, 2007, Congress passed the Food and Drug Administration Amendments Act of 2007, Public Law 110-85 (FDAAA). Section 230 of FDAAA provides:

> **SECTION 230. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.**
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> (a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall determine—
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> (1) whether the labeling requirements for indoor tanning devices, including the positioning requirements, provide sufficient information to consumers regarding the risks that the use of such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; and
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> (2)(A) whether modifying the warning label required on tanning beds to read, ''Ultraviolet radiation can cause skin cancer,'' or any other additional warning, would communicate the risks of indoor tanning more effectively; or
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> (B) whether there is no warning that would be capable of adequately communicating such risks.
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> (b) CONSUMER TESTING.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing to determine consumer understanding of label warnings.
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> (c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

This provision requires the Food and Drug Administration (FDA) to determine whether existing labeling requirements for indoor tanning devices provide sufficient information to consumers regarding the risks these devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; whether modifying the required warning label would better communicate such risks; or whether there is no warning capable of adequately communicating these risks. In making these determinations, FDA must conduct appropriate consumer testing to determine consumer understanding of label warnings. FDA must also submit a report to

Congress by September 27, 2008, providing these determinations and identifying the measures being implemented to significantly reduce the risks associated with such devices. FDA is submitting this report to Congress as required by section 230.

II. Background

A. Current Label Requirements and FDA Policy

FDA promulgated the sunlamp products[1] performance standard, 21 Code of Federal Regulations (C.F.R.) 1040.20, in 1979, 44 Fed. Reg. 65,352 (November 9, 1979), and most recently amended it in 1985, 50 Fed. Reg. 36,548 (September 6, 1985). This regulation requires each sunlamp product to have a label that contains a warning statement with the words:

> DANGER—Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product.

21 C.F.R. 1040.20(d)(1)(i). The regulation does not specify requirements for the format in which these words must appear, or the exact location on the product that the warning label must appear, as long as it is "permanently affixed or inscribed on an exterior surface of the product when fully assembled for use so as to be legible and readily accessible to view by the person being exposed immediately before the use of the product." 21 C.F.R. 1040.20(d)(3)(i).

FDA also issued a letter dated June 25, 1985, regarding the warning label to sunlamp product manufacturers outlining FDA policy.[2] The policy letter states:

> The intended purpose of the warning label required on sunlamp products is to provide that information necessary for the consumer to make an informed decision regarding the risks of using sunlamp products and to provide adequate directions for skin tanning. Therefore, the label must be legible and conspicuously placed on the

[1] "Sunlamp products" and "indoor tanning devices" have the same meaning. This report uses the former term because our performance standard refers to "sunlamp products."
[2] "Policy on Warning Label Required on Sunlamp Products," available at http://www.fda.gov/cdrh/radhlth/pdf/sunpol01.pdf .

product so as to render it likely to be read by the user under normal conditions of purchase and use. The Agency will consider sunlamp products to be noncompliant with the performance standard under Section 358(a)(1) of the RCHSA [Radiation Control for Health and Safety Act] [3] and misbranded under Section 502(c) of the FD&C Act if the required product label is not legible and accessible to view for the following reasons:

1. The label required under 21 C.F.R. 1040.20(d)(1) does not appear on a prominent part or panel which is presented or displayed under normal conditions of purchase and/or use.

2. Adequate space is not provided for the required label or the label is not prominently displayed on the device.

3. The normal individual can not read the label from a distance of one meter because of inadequate lettering size and background contrast. Lettering of ten (10) millimeters (height) for the word "DANGER" and five (5) millimeters for the rest of the label information is recommended to meet the visibility requirements.

B. Reviewing the FDA Performance Standard for Sunlamp Products

Research on the risks and benefits of ultraviolet radiation (UV) exposure has advanced since the mid-1980s. FDA has been active in the development of international standards in this area, particularly the International Electrotechnical Commission (IEC) International Standard 60335-2-27 for sunlamp products. This standard has been periodically updated; the most recent amendments were published on April 27, 2007.

On February 9, 1999, FDA's Center for Devices and Radiological Health (CDRH) published an Advance Notice of Proposed Rulemaking (ANPRM). 64 Fed. Reg. 6,288 (Docket No. 98N-1170). The purpose of the ANPRM was to seek input on several proposed amendments to the performance standard for sunlamp products that FDA was considering at the time. One of the changes considered was to update the warning statement to simplify the wording and highlight the risk of skin cancer. Other changes considered included: (1) updating the recommended exposure schedule and incorporating it into the standard itself (It currently appears in an FDA policy letter dated August 21, 1986.[4]); (2) requiring that the warning statement appear in all catalogs, brochures, and specification sheets pertaining to sunlamp products; and (3) developing a new system for rating the

[3] The Safe Medical Devices Act of 1990 (Pub. L. No. 101-629) transferred the RCHSA's provisions from the Public Health Service Act to the Federal Food, Drug, and Cosmetic Act (FDCA). Section 358(a)(1) of the RCHSA can be found at section 534(a)(1) of the FDCA, 21 U.S.C. 360kk(a)(1).
[4] "Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products," available at http://www.fda.gov/cdrh/radhlth/pdf/sunpol01.pdf.

biological efficacy of UV lamps to facilitate the choice of proper replacement lamps.

Since 1999, CDRH has conducted clinical research on the effects of UV exposure. FDA's Office of Science, Office of Women's Health, Center for Food Safety and Applied Nutrition, and the National Cancer Institute (NCI) supported research on UV risks in the general public and in tanners in particular. The results of these studies have been published in numerous scientific publications (available on request). The data generated in the FDA/NCI studies helped to define typical erythema (sunburn) doses used to calculate exposure schedules and select the maximum timer interval for tanning devices. They also showed that the UV exposures typically provided by sunlamp products are excessive, and that comparable cosmetic effects can be produced with cumulative exposures that are only one-third or one-fourth the levels currently used.

FDA intends to use the results from the FDA/NCI research and the experience we gained from working with international experts on the IEC standard when considering any proposed changes to the FDA performance standard for sunlamp products.

III. FDA Actions in Response to Section 230

A. Consumer Testing of Warning Label

1. Research Objectives

To conduct the consumer testing required by section 230(b) of FDAAA, FDA retained a contractor to evaluate the effectiveness of the warning labels on indoor tanning devices in communicating the risks that use of the devices pose for the development of irreversible damage to the eyes and skin, including skin cancer. The objective of the focus group study was to explore consumers' perceptions and understanding of the warning statement on the labels of sunlamp products (indoor tanning equipment, tanning beds, and tanning booths) currently required by 21 C.F.R. 1040.20(d)(1)(i), as compared to their understanding of an alternative warning statement. The groups explored the labels' content, language, messaging, order, and format. In addition, the testing assessed the participants' reaction to the location of the warning label on the device.

2. Methodology

The contractor used six focus groups, three in Rockville, Maryland, on October 3, 2007, and three in Baltimore, Maryland, on October 18, 2007. A total of 48 respondents participated in the focus groups. In each location, there was one of each of the following groups:

- Group 1: Teenagers in high school, ages 14-17, who either used or considered using indoor tanning equipment.
- Group 2: Adults with a college degree, ages 18 and older (majority 18-30), who either used or considered using indoor tanning equipment.
- Group 3: Adults without a college degree, ages 18 and older (majority 18-30), who either used or considered using indoor tanning equipment.

Each group had a combination of experienced indoor tanners and participants who have never used indoor tanning equipment from both sexes. Prior to being shown the labels, the participants were asked for their general opinions about indoor tanning. In most of the focus groups, and without prompting, participants mentioned some of the dangers associated with indoor tanning – specifically, acute damage to the skin and skin cancer.

Participants were then given each warning statement (the one currently required and an alternative, see below) one at a time and asked a series of questions regarding the information contained in the warning, their understanding of it, and how it might influence their behavior. Finally, participants were shown a life-size picture of an indoor tanning bed and asked to evaluate where they would most likely notice and read the warning statement label.

3. Warning Statements Tested in Consumer Focus Groups

Warning Statement Currently Required[5]

DANGER - Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer.

WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product.

[5] As explained above, the sunlamp products performance standard does not contain formatting requirements for the warning statement. FDA chose the formatting used in the study based on the use of such formatting on certain tanning beds currently on the market.

Alternative Warning Statement Presented to Consumer Focus Groups

DANGER – Ultraviolet Radiation

Avoid overexposure- It may cause severe burns

Read instructions carefully

Ultraviolet Radiation causes:

- Skin Cancer
- Injury to the Eyes and Skin
- Skin Aging

WEAR PROTECTIVE EYEWEAR TO PREVENT EYE INJURY

Certain medicines or cosmetics can increase your sensitivity to ultraviolet radiation – Consult your physician before tanning

In this report, we refer to the two warning statements as "current" and "alternative." This terminology was not used with the participants during the focus group testing. Instead, the labels were referred to as "Label 1" and "Label 2," and the order/numbering was alternated between the Baltimore and Rockville sites to minimize order bias.

4. Key Findings

The majority of participants found the alternative warning statement easier to understand than the current one. Most stated that they found the message to be streamlined, and not as ambiguous as the current label.

The results of the testing indicate that the format of the current label was the characteristic that made it least effective in communicating the dangers associated with indoor tanning. Most participants found that the format of the current label made it difficult to focus on and read due to the paragraph format and length of the label. Responses indicated that seeing a paragraph-style warning statement label in a real-world situation would cause them to disengage and ignore the information.

Almost all participants (45 out of 48, the exceptions were three participants in one of the teen groups) said they would be more likely to read the alternative label. They stated that the shorter length and bulleted format made it easier to focus on the risks and directives. Most participants also found the alternative label easier to understand because of its clarity and simplicity. Comments explained that the

streamlined format and messaging made it more attention-grabbing and easier to process. Participants stated that they were better able to pay attention to the range of messages. Most said the alternative statement sent a stronger message about the dangers associated with indoor tanning equipment.

Focus group participants made a number of recommendations for improving the warning statement labels, including:

- enlarge the font size and use the color red for the danger statement;
- describe the information in order of importance;
- move the need to wear protective eyewear higher up in the statement due to its importance as indicated by its capitalization;
- keep the term “long-term” to describe eye injury because that term is more foreboding;
- keep the descriptor “premature” to describe skin aging because it causes more alarm; and
- refer to the “exposure schedule,” not “instructions,” so that users will understand what is meant by "overexposure."

Some participants expressed confusion with respect to the directive to “consult your physician before tanning.” Participants did not understand that this message communicated that tanning and concurrent use of certain medicines and cosmetics can be dangerous.

5. Location of Warning Statement

There was no single suggested location for the warning statement that a majority picked as optimal. Participants suggested positioning the label in such places as next to the control panel, centered on the canopy, or placed on the head side of the canopy. Participants also recommended that the warning statement label should be placed away from other labels on the tanning bed, so as not to detract from the label’s importance.

B. Measures to Reduce Risks Associated with Sunlamp Products

1. Labeling and Performance Standard

After reviewing findings from the consumer focus group study, FDA has determined that an alternative warning may more effectively communicate the risks of indoor tanning. The consumer focus group study serves as an important step to inform FDA’s deliberations regarding a more effective manner to communicate the risks of using indoor tanning devices. FDA has also determined

that changes to the positioning requirements for the warning statement label may communicate such risks more effectively.

In light of these determinations, FDA is considering amending the warning label requirements for sunlamp products to include specific formatting requirements to more clearly and effectively convey the risks that these devices pose for the development of irreversible damage to the eyes and skin, including skin cancer. FDA is also considering amending the performance requirements for sunlamp products to harmonize them with the IEC International Standard. FDA is continuing to evaluate labeling requirements for sunlamp products and may identify further changes before undertaking any rulemaking to amend 21 C.F.R. 1040.20 with respect to the use of a warning label on sunlamp products.

2. Educational Outreach

FDA also believes that consumer education is an important component in significantly reducing the risks associated with indoor tanning devices. To that end, FDA has begun educational outreach efforts to better inform the target audience before they go to a tanning salon. As part of this educational process, FDA has expanded and revised its "Tanning" Web site, which may be found at http://www.fda.gov/cdrh/tanning/. In a recent issue of *FDA & You: News for Health Educators and Students*, a newsletter targeting teens and health educators, FDA published an article entitled, "The Truth About Tanning: What You Need to Know to Protect Your Skin," that focuses on how to avoid the risks posed by UV radiation.[6] Accompanying this article is a lesson plan for health educators to help students understand the risks associated with tanning and UV exposure. FDA intends to publish reminders in future newsletters. FDA also provides links to tanning information on its Consumer Information Web page at: (http://www.fda.gov/cdrh/consumer/).

IV. Conclusion

As required by section 230 of FDAAA, FDA conducted consumer testing to determine their understanding of label warnings for sunlamp products. As a result of this testing, FDA has determined that certain modifications to the labeling requirements for sunlamp products may communicate the risks of indoor tanning more effectively and is considering rulemaking. FDA is also considering changes to the performance requirements of the sunlamps performance standard, has undertaken educational outreach including an expanded Website, and will continue its efforts in this area as a means of significantly reducing the risks associated with sunlamp products.

[6] *FDA & You*, Issue No. 7 (2005), available at http://www.fda.gov/cdrh/fdaandyou/issue07.html#1.