

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0200]

Sunlamp Product Performance Standard and UVA Tanning Products; Revocation of Compliance Policy Guide 7133.16

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the compliance policy guide (CPG) entitled “Sec. 396.100 Applicability of the Sunlamp Performance Standard to UVA Tanning Products (CPG 7133.16).” This CPG is no longer necessary because the agency has amended the sunlamp product performance standard (21 CFR 1040.20) to include sunlamp products and ultraviolet lamps that emit only ultraviolet A (UVA) radiation.

DATES: The revocation is effective [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411 or FAX your request to 301-827-0482.

A copy of the CPG may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA issued the CPG entitled “Sec. 396.100 Applicability of the Sunlamp Performance Standard to UVA Tanning Products (CPG 7133.16)” on October 1, 1980. This CPG describes how the sunlamp product performance standard (§ 1040.20 (21 CFR 1040.20)), that became effective on May 7, 1980, applied to: (1) Any sunlamp product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body by ultraviolet radiation with wavelengths, in air, between 180 and 320 nanometers (nm) to induce skin tanning and (2) any ultraviolet lamp that produces radiation in the wavelength interval of 180 to 320 nm, in air, and is intended for use in any sunlamp product. Sunlamp products, that emit only UVA radiation (320 to 400 nm), were not subject to the 1980 performance standard.

In the **Federal Register** of September 6, 1985 (50 FR 36548 at 36550), FDA amended the sunlamp product performance standard to accommodate new products and designs that were significantly different from those for which the original standard was developed. This revised performance standard, which became effective on September 8, 1986, applies to sunlamp products and ultraviolet lamps that emit ultraviolet radiation with wavelengths, in air, between 200 and 400 nm and are intended for skin tanning (§ 1040.20(b)(9) and (b)(11)). Accordingly, sunlamp products and ultraviolet lamps which emit only UVA radiation are now subject to the performance standard.

Given the current sunlamp product performance standard, FDA is revoking CPG 7133.16, in its entirety.

II. Electronic Access

Prior to [*insert date 30 days after date of publication in the **Federal Register***], a copy of the CPG may also be downloaded to a personal computer with access to the Internet. The Office

of Regulatory Affairs home page includes the referenced document that may be accessed at http://www.fda.gov/ora/compliance__ref/cpg/cpgdev/cpg396-100.html.

Dated: May 14, 2002.

John Marzilli,

Deputy Associate Commissioner for Regulatory Affairs.

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