containing restricted or proprietary information shall not be used or disclosed except for evaluation purposes.

Dated: May 14, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12665 Filed 5–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1360]

Guidance for Industry on Preparation of Food Contact Notifications: Administrative; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Preparation of Food Contact Notifications: Administrative.'' This guidance document is intended to provide guidance for industry regarding the preparation of food contact notifications (FCNs). FDA is providing this guidance as part of its implementation of the premarket notification process for food contact substances (FCSs) established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments concerning this guidance document at any time.

ADDRESSES: Submit written comments concerning this guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http//www.fda.gov/dockets/ecomments. Submit written requests for single copies of the guidance document to the Office of Food Additive Safety (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Send one self-addressed adhesive label to assist that office in processing your requests. You also may request a copy of the guidance document by electronic mail at OPAPMN@CFSAN.FDA.GOV, or by telephone to the Office of Food Additive Safety at 202–418–3087 (voice) or FAX 202–418–3131. All requests should be identified with the guidance document by its title. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3083.

SUPPLEMENTARY INFORMATION:

I. Background

FDAMA (Public Law 105–115) amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish an FCN process as the primary method for authorizing new uses of food additives that are FCSs. A ''food contact substance'' is defined in section 409(h)(6) of the act as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' FDA expects most new uses of FCSs that previously would have been regulated by issuance of a listing regulation in response to a food additive petition or would have been exempted from the requirement of a regulation under the ''Threshold of Regulation'' process will be the subject of FCNs. FDA is announcing the availability of the guidance document entitled ''Preparation of Food Contact Notifications: Administrative.'' This guidance document is intended to provide guidance for industry regarding the preparation of FCNs. FDA is providing this guidance document as part of its implementation of the premarket notification process for FCSs established by FDAMA.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the data and information that should be submitted in an FCN and the plan for administration of the FCN program. This guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. This guidance document is a level 1 guidance under the agency's good guidance practices (GGPs) regulations (21 CFR 10.115).

Because it is a level 1 guidance under the agency's GGPs, FDA announced the availability for comment of a draft of the guidance document ''Preparation of Food Contact Notifications: Administrative'' in a notice published in the **Federal Register** of July 13, 2000 (65 FR 43377). The comment period for the guidance document closed on September 26, 2000. FDA received no comments on the guidance document. However, FDA did receive three comments on the proposed rule published simultaneously with the July 13, 2000, notice of availability. Portions of these three comments are relevant to the guidance document and FDA has addressed the relevant portions of the comments in the guidance document announced by this notice. Thus, in accordance with its GGPs, FDA now is reissuing this guidance document in final form.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at http://www.cfsan.fda.gov/~dms/guidance.html.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written and electronic comments regarding the guidance document at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Such comments will be considered when determining whether to amend the guidance.

Dated: May 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12663 Filed 5–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0199]

Advertisements for High-Intensity Mercury Vapor Discharge Lamps; Revocation of Compliance Policy Guide 7133.13

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the Compliance Policy Guide (CPG) entitled ''Sec. 391.100 Advertisement Literature for High-Intensity Mercury Vapor Discharge Lamps (CPG 7133.13)''

because it is obsolete and outdated. This CPG is no longer necessary because it concerns revising advertisements, printed before March 7, 1980, to comply with the Federal performance standard for high-intensity mercury vapor discharge lamps (HIMVDLs).

DATES: June 20, 2002.

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. 391.100 Advertisement Literature for High-Intensity Mercury Vapor Discharge Lamps (CPG 7133.13)'' on October 1, 1980. This CPG addresses a question from manufacturers related to advertisements, printed before March 7, 1980, for HIMVDLs that were manufactured after that date. These advertisements, primarily catalogs, should have been revised by now. Because the requirements for these types of lamps manufactured after March 7, 1980, and their advertisements are included in the Federal performance standard for HIMVDLs (21 CFR 1040.30), this CPG is obsolete and outdated. Therefore, FDA is revoking CPG 7133.13, in its entirety, to eliminate unnecessary compliance policy.

II. Electronic Access

Before June 20, 2002, a copy of the CPG may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs (ORA) homepage includes the referenced document that may be accessed at: http://www.fda.gov/ora/compliance__ref/cpg/cpgdev/cpg391–100.html.

Dated: May 14, 2002.

John Marzilli,

Deputy Associate Commissioner for Regulatory Affairs.

[FR Doc. 02–12623 Filed 5–20–02; 8:45 am]

BILLING CODE 4160–01–S

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 June 20, 2002.

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 June 20, 2002, 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.

[FR Doc. 02–12666 Filed 5–20–02; 8:45 am]

BILLING CODE 4160–01–S