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Dated: April 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8936 Filed 4–13–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–C–0050]

Sun Chemical Corp.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sun Chemical Corp. has filed a petition proposing that the color additive regulations for D&C Red No. 6 and D&C Red No. 7 be amended by replacing the current specification for "Ether-soluble matter" with a maximum limit of 0.015 percent for the recently identified impurity 1-[(4-methylphenyl)azo]-2-naphthalenol.

FOR FURTHER INFORMATION CONTACT: Teresa A. Croce, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1281.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 1C0290) has been filed by Sun Chemical Corp., 5020 Spring Grove Ave., Cincinnati, OH 45232. The petition proposes to amend the color additive regulations for D&C Red No. 6 (21 CFR 74.1306 and 74.2306) and D&C Red No. 7 (21 CFR 74.1307 and 74.2307) by replacing the current specification for "Ether-soluble matter" with a maximum limit of 0.015 percent for the recently identified impurity 1-[(4-methylphenyl)azo]-2-naphthalenol and by removing Appendix A in 21 CFR part 74, which pertains to the "Ether-soluble matter" specification.

The Agency has determined under 21 CFR 25.30(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: April 4, 2011.

Mitchell A. Cheeseman,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2011–8575 Filed 4–13–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0189]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use." This guidance document describes a means by which low level laser systems for aesthetic use may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify low level laser systems for aesthetic use into class II (special controls). This guidance document is being immediately implemented as the special control for low level laser systems for aesthetic use, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: Submit either electronic or written comments on the guidance at any time. General comments on Agency guidances are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use" to the Division of Small Manufacturers, International, and Consumer Assistance, Office of Communication, Education and Radiation Programs, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Richard Felten, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1436, Silver Spring, MD 20993–0002, 301–796–6392.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying low level laser systems for aesthetic use into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for low level laser systems for aesthetic use. Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the FD&C Act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any