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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]

**BILLING CODE 4160–01–P**

## 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]

**BILLING CODE 4160–01–P**

## 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

comments that are received in response to this notice to determine whether to amend the guidance document.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on low level laser systems for aesthetic use. It 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.

**III. Electronic Access**

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1735 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR 801 have been

approved under OMB control number 0910-0485.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 7, 2011.  
**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2011-8945 Filed 4-13-11; 8:45 am]  
**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Sickle Cell Disease Program Evaluations and Quality Improvement Activities—[NEW]**

The Sickle Cell Disease and Newborn Screening Program (SCDNBSP) and the

Sickle Cell Disease Treatment Demonstration Program (SCDTDP) are both administered by the Genetic Services Branch (GSB) of the Division of Services for Children with Special Health Needs in the Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau (MCHB). The SCDTDP is comprised of geographically distributed regional networks that provide coordinated, comprehensive, culturally competent, and family-centered care to families with sickle cell disease and a national coordinating center to support grantee activities. The SCDTDP is designed to improve access to services for individuals with sickle cell disease, improve/expand patient and provider education, and improve/expand the continuity and coordination of service delivery for individuals with sickle cell disease and carriers of the sickle cell gene mutation. The SCDNBSP is comprised of several national funded community-based sickle cell disease networks located in the U.S. and the National Coordinating and Evaluation Center. The community-based sickle cell disease networks partner with State newborn screening programs, comprehensive sickle cell treatment centers, and health care professionals to provide support to infants screened positive for sickle cell disease, carriers of the sickle cell gene mutation and their families.

HRSA seeks to conduct two evaluations (SCDTDP evaluation previously approved by OMB) and a quality improvement project, the purpose of which are to assess the service delivery processes and outcomes resulting from the systems of care delivered by the SCDNBSP and SCDTDP networks to individuals affected by sickle cell disease who present at their sites for care. The clients of the three programs will be the respondents for this data collection activity.

The annual estimate of burden for both the SCDNBSP and the SCDTDP evaluations and quality improvement effort is as follows:

ESTIMATED HOUR AND COST BURDEN OF THE DATA COLLECTION

Questionnaires	Number of respondents	Responses per respondent	Total responses	Average hours per response	Total hour burden	Wage rate	Total hour cost
MDP SCD Questionnaire .....	140	2	280	.45	126	\$20.90	\$2633.4
MDP SCT Questionnaire .....	1400	1	1400	.30	420	20.90	8778
Utilization Questionnaire (pre-demonstration) .....	900	1	900	.75	675	20.90	14,107.5