

provide for the safe use of D&C Violet No. 2 to color 2-octyl cyanoacrylate topical tissue adhesives.

**FOR FURTHER INFORMATION CONTACT:** Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of May 1, 1997 (62 FR 23781), FDA announced that a color additive petition (CAP 7C0250) had been filed by Closure Medical Corp., 5265 Capital Blvd., Raleigh, NC 27616 (currently 5250 Greens Dairy Rd., Raleigh, NC 27616). The petition proposed to amend the color additive regulations in § 74.3602 D&C Violet No. 2 (21 CFR 74.3602) to provide for the safe use of D&C Violet No. 2 to color 2-octyl cyanoacrylate topical tissue adhesives.

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94-295), Congress mandated the listing of color additives for use in medical devices when the color additive in the device comes into direct contact with the body for a significant period of time (21 U.S.C. 379e(a)). Since the filing of this petition, the agency has determined that the proposed use of the subject topical tissue adhesives, and therefore, any color additive used in these adhesives, would not contact the body for a significant period of time (Ref. 1). Consequently, the petitioned use of D&C Violet No. 2 is exempt from the statutory listing requirement. Therefore, Closure Medical Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)) (Ref. 2).

The agency received two comments on the safety of D&C Violet No. 2 in response to the notice of filing for this petition. Arts, Crafts & Theater Safety, Inc. (ACTS) commented that D&C Violet No. 2 could possibly be a carcinogen, based on studies of other anthraquinone dyes and structurally related compounds that concluded those substances were reasonably anticipated to be human carcinogens. They stated that the petition should be denied unless D&C Violet No. 2 is studied for cancer effects and found to show no evidence of carcinogenicity. In response to ACTS' comment, Flamm Associates commented that in addition to a consideration of the general chemical class of a substance, other structural features need to be evaluated in determining the carcinogenic potential of a substance. They further stated that D&C Violet No. 2 has been tested for carcinogenicity and found to be noncarcinogenic.

The agency concludes that, although the subject petition is being withdrawn, the safety of the currently approved uses of D&C Violet No. 2 (21 CFR 74.1602, 74.2602 and 74.3602) is supported by an extensive body of toxicity testing data and that the comments provide no basis for a safety concern.

#### References

The following references have been placed on display in the Dockets Management Branch (HFA-305), 5630 Fishers Lane, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from Office of Device Evaluation, Program Operations Staff (Center for Devices and Radiological Health, FDA), to Division of Petition Control (Center for Food Safety and Applied Nutrition, FDA), concerning "CAP 7C0250", dated October 23, 1998.

2. Letter from Hyman, Phelps & McNamara, P.C., to Office of Premarket Approval (FDA), dated August 25, 1998.

Dated: November 3, 1998.

**Laura M. Tarantino,**

*Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-0378]

#### Agency Information Collection Activities; Announcement of OMB Approval; Color Additive Certification Requests and Recordkeeping

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Color Additive Certification Requests and Recordkeeping" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 1, 1998 (63 FR 46461), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the

PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0216. The approval expires on October 31, 2001.

Dated: November 12, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the teleconference meeting of the Advisory Committee for Women's Services of the Substance Abuse and Mental Health Services Administration (SAMHSA) in December 1998.

The meeting of the Advisory Committee for Women's Services will include a discussion of the role and responsibilities of the Advisory Committee in providing advice to SAMHSA, and policy and program issues relating to women's substance abuse and mental health service needs at SAMHSA, including the Fiscal Year 1999 budget and SAMHSA's FY 1999 Knowledge Development and Application Grants.

Public comments are welcome. Please communicate with the individual listed as Contact below to make arrangements to comment or to request special accommodations for persons with disabilities.

A summary of the meeting and/or a roster of committee members may be obtained from: Pamela M. Perry, Executive Secretary, Advisory Committee for Women's Services, Women, Children and Families Team, SAMHSA, Parklawn Building, Room 13-99, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-7625, e-mail: pperry@samhsa.gov.

Substantive information may be obtained from the contact whose name and telephone number is listed below.

*Committee Name:* Advisory Committee for Women's Services.

*Meeting Date(s):* December 18, 1998.