DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 98C–0158]

Listing of Color Additives For Coloring Meniscal Tacks; D&C Violet No. 2; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of July 20, 1999, for the final rule that appeared in the **Federal Register** of June 18, 1999 (64 FR 32803), and that amended the color additive regulations to provide for the safe use of D&C Violet No. 2 to color absorbable meniscal tacks made from poly(L-lactic acid).

DATES: Effective date confirmed: July 20, 1999.

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 the **Federal Register** of June 18, 1999 (64 FR 32803), FDA amended 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 absorbable meniscal tacks made from poly(L-lactic acid).

FDA gave interested persons until July 19, 1999, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the **Federal Register** of June 18, 1999, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the June 18, 1999, final rule. Accordingly, the amendments issued thereby became effective July 20, 1999.

Dated: October 21, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation

[FR Doc. 99–28108 Filed 10–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 84F–0050]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Polysorbate 60

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polysorbate 60 as an emulsifier in ice cream, frozen custard, fruit sherbet, and nonstandardized frozen desserts. This action is in response to a petition filed by ICI Americas, Inc.

DATES: This regulation is effective October 28, 1999; written objections and requests for a hearing by November 29, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3071.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 20, 1984 (49 FR 10364), FDA announced that a food additive petition (FAP 4A3774) had been filed by ICI Americas, Inc., Wilmington, DE 19897 (now, Wilmington, DE 19850–5391). The petition proposed to amend the food additive regulations to provide for the safe use of polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) as an emulsifier in ice cream, frozen custard, ice milk, fruit sherbet, and nonstandardized frozen desserts when used alone or in combination with polysorbate 65 and/or polysorbate 80. The agency notes that the standard of identity for ice milk was removed from the Code of Federal Regulations in the final rule published in the **Federal Register** of September 14, 1994 (59 FR 47080). Therefore, the amendment to provide for the use of polysorbate 60 in ice milk will be included under the provisions for nonstandardized desserts in the regulation set forth below.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted 1,4-dioxane and ethylene oxide, which are carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants, and manufacturing aids, such as 1,4-dioxane and ethylene oxide are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the general safety standard of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additives anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F. 2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive will result in an estimated mean daily intake of 39 milligrams per person per day (mg/p/d). The cumulative exposure to all ethoxylated direct additives from previously regulated uses is estimated to be 166 mg/p/d (Ref. 1).