By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 88-29579 Filed 12-23-88; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 74 and 81

[Docket Nos. 76N-0366 and 87N-0182]

Listing of Color Additives Subject To Certification; D&C Red No. 36; Termination of Stay and Further Amendment

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is terminating the stay of the provision for ingested drug use of D&C Red No. 36. Under the formal rulemaking provisions of the Federal Food, Drug, and Cosmetic Act (the act), the filing of an objection to this provision of the final rule stayed its effect while FDA evaluated and acted on the objection. The agency has now completed its evaluation of the objection and, in response, is revising 21 CFR 74.1336(c). This document also removes D&C Red No. 36 from the provisional list.

DATES: Effective (January 27, 1989; written objections and requests for a hearing by January 26, 1989).

ADDRESS: Written objections to the Docket Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia J. McLaughlin, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 2, 1988 (53 FR 29024), FDA published a final rule permanently listing D&C Red No. 36 for general use in drugs and cosmetics, except for use in the area of the eye. The action was in response to a petition filed by the Cosmetic, Toiletry and Fragrance Association (CTFA). The rule amended 21 CFR Part 74 by adding new §§ 74.1336 and 74.2336. The rule also amended 21 CFR 81.1, 81.25, and 81.27 by removing the entries for D&C Red No. 36 from those regulations. The rule revised 21 CFR 82.1336 to require that D&C Red No. 36 conform in identity and specifications to the requirements of § 74.1336 and to require that all lakes of the color additive be manufactured from previously certified batches of the straight color additive. FDA stated that the final rule would become effective on September 2, 1988, except for any provision stayed by the filing by September 1, 1988, of a proper objection. Under section 701(e) of the act, (21 U.S.C. 371(e)(2)), the filing of an objection to a particular provision of the final rule stays the effectiveness of that provision until FDA can rule on the objection.

FDA received a single objection to the final rule from a drug manufacturer. That objection, which is on file with the Dockets Management Branch (address above) under Docket No. 87N-0182, concerned only the provision in the final rule limiting the amount of D&C Red No. 36 in ingested drug products. Accordingly, the agency stayed the provision in the final rule concerning the use of D&C Red No. 36 in ingested drug products (that is, the first sentence in § 74.1336(c)), as well as those parts of the final rule that removed entries for D&C Red No. 36 from the provisional list (21 CFR 81.1(b)) and from the temporary tolerances (21 CFR 81.25(c)(1)). FDA published this stay in the **Federal Register** of October 28, 1988 (53 FR 43682). In the same document, FDA confirmed the effective date of September 2, 1988, for the remainder of the final rule. In addition, the October 28, 1988, document postponed the closing date of the provisional listing for D&C Red No. 36 to December 27, 1988.

In its petition, CTFA requested that a limit of 1.7 milligrams (mgs) of the color additive per daily dose be established for the use of D&C Red No. 36 in ingested drug products. In the August 2, 1988, final rule permanently listing D&C Red No. 36, FDA stated that the petitioner had not provided information on levels of use of the color additive in drugs. The agency had searched its files of new drug applications for data on current use levels and found that only three ingested drug products contain D&C Red No. 36, all at very low levels of use. Because this information indicated to the agency that only low levels were necessary to accomplish the intended technical effect, consistent with section 706(b)(7)(B) of the act (21 U.S.C. 376(b)(7)(B)), FDA limited the use of D&C Red No. 36 in ingested drugs to 1.0 mg per daily dose.

One drug manufacturer objected to this limitation of 1.0 mg because it manufactures an approved ingested drug that is usually prescribed at dosages that provide 0.8 mg or less of the color additive in a day. However, in extreme cases, double doses of this drug may be prescribed, resulting in a daily intake of 1.6 mgs of the color additive. This manufacturer requested that the regulation be amended to permit the 1.7 mgs per daily dose originally sought by the petitioner and provided by the temporary tolerances in § 81.25. The objection requested a hearing if the agency did not concur.

The agency finds that the usage described in the objection is supported by the data in the petition and, for the reasons discussed in the August 2, 1988, final rule, concludes that ingestion of D&C Red No. 36 in drugs in amounts up to 1.7 mgs per day is safe for less than lifetime use. FDA finds that the objection is consistent with the agency's primary conclusion that 1.0 mg of the color additive is ordinarily sufficient to color the amount of drug ingested in 1 day. However, the agency also recognizes that higher than usual doses of a drug may be necessary in extreme cases and that the color additive regulations should be able to accommodate such situations. Accordingly, FDA is revising § 74.1336(c) to establish a limit of 1.7 mgs of D&C Red No. 36 per daily dose of an ingested drug for drugs that are not taken continuously for more than 1 year. Drugs that may be taken continuously for longer than 1 year are limited to 1.0 mg of color additive per daily dose.

Because the objection has been resolved, this document terminates the stay of 21 CFR 74.1336(c). Because the agency is providing for the usage described in the objection, a hearing is unnecessary, and therefore is denied.

When this revision of § 74.1336(c) becomes effective, continued provisional listing for ingested drug use of this color additive will no longer be appropriate or necessary. Thus, this document will also terminate the stay of those parts of the August 2, 1988, final rule that removed those parts of the regulations that pertain to the provisional listing of this color additive; i.e., §§ 81.1(b) and 81.25(c)(1).

FDA is providing an objection period of 30 days and a 31-day delayed effective date for this revision of 21 CFR 74.1336(c). Any person who will be adversely affected by this revision may at any time on or before January 26, 1989 submit to the Dockets Management Branch (address above) written objections. Such objections shall be limited to the revision of § 74.1336(c) discussed in this document. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of § 74.1336(c) to which objection is

made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Notice of the filing of objections or lack thereof will be published in the **Federal Register.**

Elsewhere in this issue of the **Federal Register**, FDA is postponing the closing date of D&C Red No. 36 for 60 days to provide time for interested persons to submit objections to this document.

The agency has determined under 21 CFR 25.24(b)(3) 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.

List of Subjects

21 CFR Part 74

Color additives, Cosmetics, Drugs.

21 CFR Part 81

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376)) and the Transitional Provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), the stay of effectiveness of the first sentence in 21 CFR 74.1336(c) is terminated, the stays on the removal of D&C Red No. 36 from 21 CFR 81.1(b) and 81.25(c)(1) are terminated, and Part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 74 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

2. Section 74.1336 is amended by revising the first sentence in paragraph (c) to read as follows:

§ 74.1336 D&C Red No. 36.

* * * * *

(c) *Uses and restrictions.* The color additive D&C Red No. 36 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 1.7 milligrams per daily dose of the drug for drugs that are taken continuously only for less than 1 year. For drugs taken continuously for longer than 1 year, the color additive shall not be used in amounts to exceed 1.0 milligram per daily dose of the drug. * * *

* * * * *

Dated: December 22, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–29703 Filed 12–22–88; 11:54 am]

BILLING CODE 4160–01–M

---

21 CFR Part 81

[Docket Nos. 76N–0366 and 87N–0182]

Provisional Listing of D&C Red No. 36; Postponement of Closing Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Red No. 36 for use as a color additive in drugs and cosmetics. The new closing date for the provisional listing of this color additive will be February 27, 1989. FDA has decided that this postponement is necessary to provide time for the receipt and evaluation of any objections and comments submitted in response to the final rule published in the **Federal Register.**

DATE: Effective December 27, 1988, the new closing date for D&C Red No. 36 will be February 27, 1989.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food and Safety and Applied Nutrition (HFF–330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5676.

SUPPLEMENTARY INFORMATION: FDA established the current closing date of December 27, 1988, for the provisional listing of D&C Red No. 36 by a regulation published in the **Federal Register** of October 28, 1988 (53 FR 43682).

In the **Federal Register** of August 2, 1988 (53 FR 29024), FDA permanently listed the drug and cosmetic uses of D&C Red No. 36. FDA received one objection in response to that final rule. Published elsewhere in this issue of the **Federal Register** is a final rule responding to the objection and revising the listing regulation for D&C Red No. 36. The postponement of the closing dates for the provisional listing of this color additive for 60 days by this order will provide time for receipt and evaluation of, and appropriate agency action to, objections or requests for a hearing submitted in response to the final rule. The regulation set forth below will postpone the December 27, 1988, closing date for the provisional listing of this color additive until February 27, 1989.

FDA believes that it is reasonable to postpone the closing date for this color additive until February 27, 1989, to provide a short period of time for its receipt and evaluation of any comments or objections and subsequent agency action. FDA concludes that this extension is consistent with the public health and the standards set forth for continuation of the provisional listing in *McIlwain* v. *Hayes*, 690 F.2d 1041 (D.C. Cir. 1982).

Because of the shortness of time until the December 27, 1988, closing date, FDA concludes that notice and public procedure on this regulation are impracticable and that good cause exists for issuing the postponement as a final rule and for an effective date of December 27, 1988. This regulation will permit the uninterrupted use of this color additive until further action is taken. In accordance with 5 U.S.C. 553 (b), (d)(1), and (d)(3), this postponement is issued as a final regulation, effective December 27, 1988.

List of Subjects in 21 CFR Part 81

Color additives, Cosmetics, Drugs.

Therefore, under the Transitional Provisions of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 81 is amended as follows:

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

1. The authority citation for 21 CFR Part 81 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); Title II, Pub. L. 86–618; sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note); 21 CFR 5.10.

§ 81.1 [Amended]

2. Section 81.1 *Provisional lists of color additives* is amended in the table of paragraph (b) for the entry "D&C Red No. 36" by revising the closing date to read "February 27, 1989."

§ 81.27 [Amended]

3. Section 81.27 *Conditions of provisional listing* is amended in the table, appearing in the introductory text in paragraph (d), by revising the closing date for the entry "D&C Red No. 36" to read "February 27, 1989."

Dated: December 22, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–29704 Filed 12–22–88; 11:54 am]

BILLING CODE 4160–01–M

---

21 CFR Part 175

[Docket No. 88F–0053]

Indirect Food Additives; Adhesives and Components of Coatings

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethylene-octene-1 copolymers containing not less than 70 weight percent ethylene, as adhesives in the manufacture of multilayer structures intended to contact food. This action is in response to a petition filed by The Dow Chemical Co.

DATES: Effective December 27, 1988; written objections and requests for a hearing by January 26, 1989.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard H. White, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 17, 1988 (53 FR 8805), FDA announced that a food additive petition (FAP 8B4066) had been filed by The Dow Chemical Co., 1803 Bldg., Door 7, Midland, MI 48674, proposing that § 175.105 *Adhesives* (21 CFR 175.105) of the food additive regulations be amended to provide for the safe use of ethylene-octene-1 copolymers as adhesives in multilayer structures intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency finds that the additive is more specifically identified as "ethylene-octene-1 copolymers containing not less than 70 weight percent ethylene." The agency further concludes that the proposed use of this food additive is safe, and that the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Any person who will be adversely affected by this regulation may at any time on or before January 26, 1989 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, Part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR Part 175 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 175.105 is amended in paragraph (c)(5) by alphabetically adding a new entry in the table to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
Ethylene-octene-1 copolymers containing not less than 70 weight percent ethylene (CAS Reg. No. 26221–73–8)	
* * * * *	

Dated: December 15, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–29573 Filed 12–23–88; 8:45 am]

BILLING CODE 4160–01–M