operate airplanes to a base for the accomplishment of the modifications required by this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to British Aerospace, Librarian for Service Bulletin, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective August 22, 1988.

Issued in Washington, DC, on July 8, 1988.

M.C. Beard,

Director, Office of Airworthiness.

[FR Doc. 88-15916 Filed 7-14-88; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 88-NM-70-AD; Amdt. 39-5980]

Airworthiness Directives; McDonnell Douglas Model DC-10-10, -10F, -15, -30, -30F, -40, and KC-10A (Military) Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all McDonnell Douglas Model DC-10 and KC-10 series airplanes, which requires inspection and modification or repair, if necessary, of the battery ground cable ground stud installation and the drain valve installations in the Center Accessory Compartment (CAC). This amendment is prompted by a report of a loose and/or corroded battery ground stud connection and possible contamination of insulation blankets, or flammable liquid, within the CAC lower fuselage area. This condition, if not corrected, could result in an in-flight or ground fire in the CAC.

EFFECTIVE DATE: August 3, 1988.

ADDRESSES: The applicable service information may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director of Publications, C1-L00 (54-60). This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at 4344 Donald Douglas Drive, Long Beach, California.

FOR FURTHER INFORMATION CONTACT: Mr. Richard S. Saul, Aerospace Engineer, Systems and Equipment Branch, ANM-130L, FAA, Northwest Mountain Region, Los Angeles Aircraft Certification Office, 4344 Donald Douglas Drive, Long Beach, California 90808; telephone (213) 514-6323.

SUPPLEMENTARY INFORMATION: A McDonnell Douglas Model DC-10 airplane recently experienced a fire in the Center Accessory Compartment (CAC) during taxi after landing. A flight attendant informed the captain of smoke entering the cabin. The airplane continued to the gate and passengers were off-loaded in a normal manner. The fire department accessed the CAC through a hatch in the cabin and extinguished the fire.

Subsequent investigation revealed a loose and/or corroded battery ground stud connection as the ignition source for the fire. Possible contamination of insulation blankets in the CAC, or flammable liquid within the CAC lower fuselage area, may have provided the fuel source for the fire.

The FAA has reviewed and approved McDonnell Douglas Service Bulletin A24-141, Revision 1, dated May 12, 1988, which describes procedures for inspection for arcing and/or corrosion on the CAC battery ground stud installation and for proper operation of the two CAC drain valves. The service bulletin also provides information for proper installation of ground stud parts and advises of an improved drain valve which may be used to replace faulty drain valves.

McDonnell Douglas released Service Bulletin 24-73, Revision 1, dated February 2, 1978, which contains procedures to modify the CAC battery ground stud installation by adding a clamp to the battery ground cable. This service bulletin was released as a result of a McDonnell Douglas investigation which revealed the potential for development of a loose ground stud connection due to wrenching of the ground cable during routine battery maintenance. Installation of this clamp will eliminate the unsafe condition described above.

Since this condition is likely to exist or develop on other airplanes of the same type design, this AD requires inspection and modification or repair, if necessary, in accordance with McDonnell Douglas Service Bulletin A24-141, Revision 1, dated May 12, 1988, and replacement of the main battery ground cable bracket in accordance with McDonnell Douglas Service Bulletin 24-73, Revision 1, dated February 2, 1978.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure herein are impracticable, and good cause exists for making this amendment effective in less than 30 days.

The regulations set forth in this amendment are promulgated pursuant to the authority in the Federal Aviation Act of 1958, as amended (49 U.S.C. 1301, *et seq.*), which statute is construed to preempt state law regulating the same subject. Thus, in accordance with Executive Order 12612, it is determined that such regulations do not have federalism implications warranting the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required).

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

1. The authority citation for Part 39 continues to read as follows:

PART 39—[AMENDED]

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive:

McDonnell Douglas: Applies to McDonnell Douglas Model DC-10-10, -10F, -15, -30, -30F, -40, and KC-10A (Military) series airplanes, as listed in McDonnell Douglas Service Bulletin A24-141, Revision 1, dated May 12, 1988, certificated in any category. Compliance required as indicated, unless previously accomplished.

To prevent a fire in the Center Accessory Compartment (CAC), accomplish the following:

A. For all airplanes: Within 30 days after the effective date of this AD, and thereafter at intervals not to exceed 60 days, inspect the battery ground stud installation for evidence of arcing and/or corrosion, and check the two CAC drain valve installations for proper operation, in accordance with the Accomplishment Instructions of McDonnell Douglas Service Bulletin A24-141, Revision 1, dated May 12, 1988.

1. If the ground stud installation is found to be burnt or corroded, prior to further flight, replace the ground stud installation parts in accordance with the service bulletin.

2. If the drain valve installation is not free of deterioration, is sticking, or is not functioning properly, prior to further flight, repair or replace the drain valve installation in accordance with the service bulletin.

B. For airplanes that have not incorporated McDonnell Douglas Service Bulletin 24-73, Revision 1, dated February 2, 1978, or the production equivalent: Within 90 days after the effective date of this AD, replace the main battery ground cable bracket in accordance with the Accomplishment Instructions of McDonnell Douglas Service Bulletin 24-73, Revision 1, dated February 2, 1978. This constitutes terminating action for the repetitive inspection requirements of paragraph A., above.

C. Alternate means of compliance or adjustment of the compliance time, which provide an acceptable level of safety, may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who may add any comments and then send it to the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service information from the manufacturer may obtain copies upon request to McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director of Publications, C1-L00 (54-60).

This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington or the Los Angeles Aircraft Certification Office, 4344 Donald Douglas Drive, Long Beach, California.

This amendment becomes effective August 3, 1988.

Issued in Washington, DC, on July 8, 1988.

M.C. Beard,

Director, Office of Airworthiness.

[FR Doc. 88-15917 Filed 7-14-88; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 74, 81, and 82

[Docket Nos. 76N-0366 and 83C-0127]

Revocation of Regulations; D&C Red No. 8 and D&C Red No. 9

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing the color additive regulations that provide for the use of color additives D&C Red No. 8 and D&C Red No. 9 for use in ingested drugs and cosmetic lip products and in externally applied drugs and cosmetics. This action is based upon previous findings by FDA that these color additives are carcinogenic in test animals and on the decision of the U.S. Court of Appeals for the District of Columbia on D&C Orange No. 17 and D&C Red No. 19 that carcinogenic color additives cannot be listed as color additives on the basis of a *de minimis* exception to the color additive Delaney clause in the Federal Food, Drug, and Cosmetic Act (the act). Published elsewhere in this issue of the **Federal Register** is a notice denying the color additive petition that requested permanent listing of D&C Red Nos. 8 and 9 as color additives.

DATES: Effective July 15, 1988; objections by August 15, 1988.

ADDRESS: Documents may be seen in, and 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: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202-472-5676.

SUPPLEMENTARY INFORMATION:

I. Regulatory History

In the **Federal Register** of December 5, 1986 (51 FR 43877), FDA published a final rule permanently listing D&C Red No. 8 and D&C Red No. 9 for use in ingested drug and cosmetic lip products and in externally applied drugs and cosmetics. In that final rule FDA concluded that, although available studies establish that D&C Red No. 9 and, by implication, D&C Red No. 8 are carcinogens when ingested by laboratory animals, quantitative risk assessments of the color additives indicate that the risk of human cancer from use of these color additives in ingested drug and cosmetic lip products, and in externally applied drugs and cosmetics, would be extremely low and that there would be no benefit to the public health from prohibiting these uses of the color additives. FDA concluded that the use of D&C Red No. 8 and D&C Red No. 9 were safe under the conditions prescribed in the regulations permanently listing the color additives.

FDA also concluded in the December 5, 1986, final rule that it was appropriate to apply *de minimis* exceptions to the Delaney clause of the Color Additive Amendments of 1960 (the amendments) to the act because any risk of cancer that the color additives may present is of no public health consequence.

II. Comments and Objections

In response to the December 5, 1986, final rule, the Public Citizen Litigation Group (Public Citizen) and others filed objections to the listing of D&C Red Nos. 8 and 9. These objections stayed the effective date of the final regulations. Additionally, the Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), submitted comments to FDA in support of the agency's actions. Neither group requested a hearing.

FDA, in the **Federal Register** of June 5, 1987 (52 FR 21302), responded to the objections. In that document, FDA modified several aspects of the manufacturing process for D&C Red No. 9, and established a new effective date for the permanent listing of D&C Red Nos. 8 and 9. This rule also established a new effective date for the revised new manufacturing process for D&C Red No. 9, incorporated FDA's explanation of its interpretations of the Delaney clause that had been published in the **Federal Register** of February 19, 1987, and reaffirmed the agency's conclusions as to the safety of the two color additives.

On July 31, 1987, FDA confirmed the effective date of the rule revising the manufacturing process for D&C Red No. 9.

III. Legal Action

On August 3, 1987, Public Citizen filed suit in the U.S. Court of Appeals for the Third Circuit of Philadelphia, seeking to overturn FDA's decision to permanently list D&C Red Nos. 8 and 9. However, before a decision was reached by that Court, the U.S. Court of Appeals in Washington, DC issued a decision relating to D&C Red No. 19 and D&C Orange No. 17 and holding that "the Delaney clause of Color Additive Amendments does not contain an implicit *de minimis* exception for carcinogens with trivial risk to humans,"

and that the listing of carcinogenic color additives is contrary to law.

Following this decision, CTFA, an intervenor in the D.C. Circuit case, petitioned the U.S. Supreme Court to grant a writ of certiorari on the decision. On April 28, 1988, the Supreme Court denied certiorari. The agency, on May 26, 1988, asked the Court of Appeals for the Third Circuit to remand the case on D&C Red Nos. 8 and 9 to the agency so that it could revoke the listings of these colors because of the D.C. Circuit's decision, involving the same issues, on D&C Red No. 19 and D&C Orange No. 17. D&C Res Nos. 8 and 9 had been permanently listed based upon legal reasoning identical to that used to permanently list D&C Red No. 19 and D&C Orange No. 17. Subsequently, the Court of Appeals for the Third Circuit granted the agency's request and remanded to FDA the decision in D&C Red Nos. 8 and 9.

IV. FDA Action

In reaching its decision regarding the action to be taken on D&C Red No. 8 and D&C Red No. 9, FDA has considered the D.C. Circuit's decision on D&C Red No. 19 and D&C Orange 17 that the Delaney clause bars the permanent listing of any color additive that has been shown to induce cancer. FDA has found that D&C Red No. 9, and, by implication, D&C Red No. 8, induce cancer in laboratory test animals. There have been no additional data submitted to FDA that would contravene the agency's previous findings. The carcinogenicity of D&C Red No. 9 and other data relevant to the safety of the two additives were discussed in the **Federal Register** in documents published on December 5, 1986 (51 FR 43877), June 5, 1987 (52 FR 21302), and July 31, 1987 (52 FR 28552).

V. Conclusions

FDA has previously concluded that D&C Red No. 9 induces cancer in test animals, that D&C Red No. 8 is toxicologically equivalent to D&C Red No. 9, and that therefore the results of toxicity and carcinogenicity studies of D&C Red No. 9 apply to both additives. No new data or information have been submitted to FDA on this issue. On the basis of the finding of carcinogenicity and the D.C. Circuit Court's decision on D&C Red No. 19 and D&C Orange No. 17 that there is no *de minimis* exception to the Delaney clause for color additives, FDA concludes that the regulations permanently listing D&C Red Nos. 8 and 9 are contrary to law and without legal effect. Moreover, in light of the Court's ruling, the carcinogenicity of the color additives, and the congressional concern as expressed in the Delaney clause about the safety of color additives found to be carcinogens, the agency concludes that not only is there no legal basis upon which to permit the permanent listing of the color additives, but also no basis to put them back on the provisional list (Pub. L. 86–618, section 203(a)). Thus, in the regulations set forth below, the agency is removing those color additive regulations which permanently listed D&C Red No. 8 and D&C Red No. 9, and removing the regulations that provide for the provisional use of the lakes of the color additives.

Consistent with the revocation regulations, all certificates heretofore issued for both D&C Red No. 8 and D&C Red No. 9, their lakes, and all mixtures containing these color additives for ingested drug and cosmetic lip products and for externally applied drug and cosmetic uses are cancelled as of July 15, 1988. After this date, the addition of D&C Red No. 8 or D&C Red No. 9 to drugs or cosmetics will cause such products to be adulterated within the meaning of sections 501 and 601 of the act (21 U.S.C. 351 and 361) and to be subject to regulatory action. This prohibition applies to the use of the straight color additives, their lakes, and mixtures of the color additives and their lakes. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice denying the color additive petition for these two color additives.

FDA also concludes that the health concern regarding the use of these color additives does not represent an acute, imminent hazard. Therefore, the protection of the public health does not require: (1) Recall from the market of drug and cosmetic products for external use that contain either color additive, or (2) the destruction of such drug or cosmetic products to which either color has already been added.

Manufacturers of new drugs and new animal drugs (including certifiable antibiotics for animal use) that contain D&C Red No. 8 or D&C Red No. 9 may either discontinue use of the color additives or substitute different color additives in accordance with the provisions of 21 CFR 314.70(b)(2)(i) and (d)(4) or 21 CFR 514.8(d)(3) and (e), as appropriate. If a substitute color additive is not used, the human drug manufacturer shall describe the change fully in the next annual report as required under § 314.81(b)(2)(iv)(*b*). If a substitute color additive is used, the manufacturer shall file with FDA a supplemental new drug application or a supplemental new animal drug application containing data describing the new composition and showing that the change is composition does not interfere with any assay or other control procedures used in manufacturing the drug, or that the assay and control procedures have been revised to make them adequate.

The applicant shall also submit data available to establish the stability of the revised formulation. If the data are too limited to support a conclusion that the drug will retain its declared potency for a reasonable marketing period, the applicant shall submit a commitment to test the stability of marketed batches at reasonable intervals, to submit to FDA those data as they become available, and to recall from the market any batch found to fall outside the approved specifications for the drug.

Each sponsor of a notice of claimed investigational exemption for a new drug (IND) or a notice of claimed investigational exemption for a new animal drug (INAD) containing D&C Red No.8 or D&C Red No. 9 should promptly amend the IND or INAD to indicate that the color additives have been deleted or a different color additive substituted.

FDA is aware that supplies of alternative color additives and labeling may be difficult to obtain immediately. Consequently, drug and cosmetic labeling that states that the product contains "artificial color" or that specifically identifies D&C Red No. 8 and D&C Red No. 9 may continue to be used with the uncolored product or product containing alternative color additives during the time necessary to obtain supplies of revised labeling or until July 17, 1989, whichever comes first.

VI. Economic and Environmental Impacts

Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354) do not apply to actions of this type.

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. A copy of the FDA environmental assessment is on file with the Dockets Management Branch (address above).

List of Subjects

21 CFR Part 74

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 81

Color additives, Cosmetics, Drugs.

21 CFR Part 82

Color additives, Color additives lakes, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Parts 74, 81, and 82 are 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.

§ 74.1308 [Removed]

2. Section 74.1308 *D&C Red No. 8* is removed.

§ 741.1309 [Removed]

3. Section 74.1309 *D&C Red No. 9* is removed.

§ 74.2308 [Removed]

4. Section 74.2308 *D&C Red No. 8* is removed.

§ 74.2309 [Removed]

5. Section 74.2309 *D&C Red No. 9* is removed.

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

6. 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.

7. Section 81.30 is amended by adding new paragraphs (s) (3) and (4) to read as follows:

§ 81.30 Cancellation of certificates.

* * * * *

(s) * * *

(3) Certificates issued for D&C Red No. 8, and D&C Red No. 9, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drug and cosmetic lip products and in externally applied drugs and cosmetics after July 15, 1988, and use of these color additives in the manufacture of ingested drugs and cosmetic lip products and in externally applied drugs and cosmetics after this date will result in adulteration.

(4) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market ingested drug and cosmetic lip products and externally applied drugs and cosmetics to which the color additives were added on or before July 15, 1988.

* * * * *

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

8. The authority citation for 21 CFR Part 82 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.

§ 82.1308 [Removed]

9. Section 82.1308 *D&C Red No. 8* is removed.

§ 82.1309 [Removed]

10. Section 82.1309 *D&C Red No. 9* is removed.

Dated: July 12, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–16045 Filed 7–14–88; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 74, 81, and 82

[Docket Nos. 76N–0366, 83C–0102, and 83C–0129]

Revocation of Regulations; D&C Red No. 19 and D&C Orange No. 17

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing the color additive regulations that provide for the use of the color additives D&C Red No. 19 and D&C Orange No. 17 for use in externally applied drugs and cosmetics. The FDA action is based upon the fact that the color additives induce cancer and the finding of the U.S. Court of Appeals for the District of Columbia that the two color additives cannot be listed as color additives on the basis of a *de minimis* exception to section 706(b) of the Federal Food, Drug, and Cosmetic Act (the act). (The U.S. Supreme Court subsequently refused a writ of certiorari on the Appeals Court decision.) Published elsewhere in this issue of the **Federal Register** are notices denying the color additive petitions that requested approval of D&C Red No. 19 and D&C Orange No. 17 as color additives.

DATES: Effective July 15, 1988; objections by August 15, 1988.

ADDRESS: Documents may be seen in, and 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: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF–330), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5676.

SUPPLEMENTARY INFORMATION:

I. Regulatory History

In the **Federal Register** of August 7, 1986, FDA published final regulations permanently listing D&C Orange No. 17 and D&C Red No. 19 for use in externally applied drugs and cosmetics (51 FR 28331 and 51 FR 28346, respectively). In these two documents FDA concluded that, although available studies establish that the color additives induced cancer in animals, quantitative risk estimates of the colors indicate that the risk of human cancer from use of these color additives in externally applied drugs and cosmetics would be extremely low and that there would be no benefit to the public health from prohibiting these uses of the color additives. FDA concluded that the use of D&C Red No. 19 and D&C Orange No. 17 in externally applied drugs and cosmetics was safe under the conditions of use prescribed in the regulations permanently listing the colors.

FDA also concluded in the August 7, 1986, documents that it was appropriate to apply *de minimis* exceptions to the Delaney clause of the Color Additives Amendment to the Food, Drug, and Cosmetic Act because any theoretical risk of cancer that the color additives may present is of no public health consequence.

II. Comments and Objections

On August 21, 1986, in response to the final rules permanently listing D&C Orange No. 17 and D&C Red No. 19, the Public Citizen Litigation Group (Public Citizen) filed objections to the final rule. This filing automatically stayed the effective date of the color additive regulations. On September 8, 1986, the Cosmetic Toiletry and Fragrance Association, Inc. (CTFA), filed comments in support of both final rules. Neither the objections nor comments, however, requested a hearing.

FDA, in the **Federal Register** of October 6, 1986 (51 FR 35509), published a final rule which responded to the objections from Public Citizen; removed the stay of the regulations for the permanent listing of D&C Orange No. 17 and D&C Red No. 19; and established the effective date of October 6, 1986, for their use in externally applied drugs and cosmetics.