Part 216 is added to 32 CFR to read as set forth below:

Sec.
216.1 Purpose.
216.2 Applicability.
216.3 Policy.
216.4 Responsibilities.
216.5 Guidelines and procedures for identifying institutions of higher learning that bar military recruiters from their premises.
216.6 Reports.
216.7 Effective date and implementation.

AUTHORITY: Sec. 606, Pub. L. 92-436, 86 Stat. 734 (Sept. 26, 1973)

§ 216.1 Purpose.

This part incorporates procedures for the identification of institutions of higher learning which bar recruiting personnel from their premises.

§ 216.2 Applicability.

The provisions of this part apply to the Military Departments.

§ 216.3 Policy.

(a) Subsection (a), section 606 of Pub. L. 92-436[1] provides that no funds appropriated for the Department of Defense may be used at any institution of higher learning if the Secretary of Defense or his designee determines that recruiting personnel of any of the Armed Forces are barred by policy from the institution's premises. Exceptions may be made for: (1) Cases where the Secretary of the Service concerned certifies to the Congress in writing that a specific course of instruction is not available at any other institution of higher learning and furnishes to the Congress the reasons why such course of instruction is of vital importance to the security of the United States (subsection (a), section 606, Pub. L. 92-436; and (2) research and development funds if the Secretary of Defense, or his designee, determines that the expenditure is a continuation or a renewal of a previous program with such institution which is likely to make a significant contribution to the Defense effort (subsection (b), section 606, Pub. L. 92-436.)

(b) Subsection (c), section 606, Pub. L. 92-436, requires the Secretaries of the Military Departments to furnish to the Secretary of Defense, or his designee, the names of any institutions which they have found to be affected by the prohibitions stated in Pub. L. 92-436.

§ 216.4 Responsibilities.

(a) The Assistant Secretary of Defense (Manpower and Reserve Affairs) is hereby designated as the official responsible for determining that recruiting personnel are being barred from the premises of institutions of higher learning as prescribed in Pub. L. 92-436. This determination will be based upon the official evaluation of the reports prepared by the Secretaries of the Military Departments.

(b) The Director of Defense Research and Engineering is hereby designated as the official responsible for determining whether the expenditure of research and development funds for research and development in an institution which has been found to bar recruiters is likely to make a significant contribution to the Defense effort as provided in Pub. L. 92-436, section 606(b).

(c) The Secretaries of the Military Departments will be responsible for the preparation of the reports required by section 606(c) of Pub. L. 92-436 and § 216.5, in accordance with the guidelines set forth in this section of this part; and for making the exceptions to policy where the specific course of instruction is not available elsewhere, as prescribed in § 216.3(a).

§ 216.5 Guidelines and procedures for identifying institutions of higher learning that bar military recruiters from their premises.

(a) *Criteria.* An institution will be reported as "barring recruiting personnel" when it has been determined that military recruiters are not permitted to conduct recruiting activities any place on campus at the time of the report, as a matter of the stated or effective policy of the institution. In making this determination:

(1) The stated policy barring on-campus recruiting should be in writing by an appropriate official. If written confirmation is not obtainable, verbal policy statements will suffice when attributed to an appropriate official.

(2) It will be considered that the institution is in effect barring military recruitment if:

(i) Repeated requests to schedule and accomplish recruiting visits have been unsuccessful, or

(ii) The institution has indefinitely suspended recruiting visits.

(3) A rule of reason will be followed in applying paragraph (a)(2)(ii) of this section. The following are examples of institutions which will not be considered as barring on-campus recruiting:

(i) An institution, unable to schedule recruiting visits in the past academic period because of student disturbances, or whose student body is on vacation at the time of the report, which states its intention to permit recruiting in the coming academic period.

(ii) An institution which follows a policy of permitting visits to its campus by any potential employer, public or private, only in response to an expression of student or faculty interest and which carries out such policy in good faith without discrimination against military recruitment.

(iii) An institution which has a policy of not permitting job recruiting by an employer on its campus, but which does permit recruiting by all employers (including military recruiters) at some other location.

(b) *Coverage.* The report is to be limited to institutions of higher learning normally visited by recruiters. It should be based on:

(1) Experience with these institutions in the past academic semester or period and on any subsequent information received from the institution as to its policies and intentions in the event these are in doubt.

(2) Experience with institutions visited by recruiters since the close of the past academic period in connection with normal recruiting activities.

It is not intended that a survey be made of all institutions of higher learning for purposes of this report, but rather that the report be limited to experience obtained as a result of normal recruiting visits and on any further information furnished by the institution in connection therewith.

(c) *Procedures.* (1) Recruiters will continue to observe the long standing policy of accommodating to the institution's preferences as to times and places for scheduling on-campus recruiting.

(2) Where an appropriate official of the institution has previously informed recruiting officials, verbally or in writing, that the policy of the institution is not to permit military recruiting on campus, or in the event of repeated inability to schedule recruiting visits, or when there is reason to believe that the institution has indefinitely suspended recruiting visits, written clarification as to the present policy will be sought by a letter of inquiry addressed to the head of the institution from the headquarters level of the Recruiting Service. The prototype letter of inquiry, enclosure—1, should be followed to the maximum extent possible.

(3) Based on responses to the letters of inquiry and on such other evidence as is appropriate and consistent with the criteria in paragraph (c)(1) of this section, the Secretary of each Military Department will furnish the Assistant Secretary of Defense (Manpower and Reserve Affairs) the names of any institutions of higher learning which bar military recruiting personnel from their premises or property at the time of the report. Full documentation should be furnished for each institution named, including the institution's formal response to the letter of inquiry.

§ 216.6 Reports.

The Secretaries of the Military Departments will submit a separate report for each of the Military Services to the Assistant Secretary of Defense (Manpower and Reserve Affairs) each January 31st and June 30th listing the names of any institution of higher learning which the Secretaries have determined on such dates are affected by the prohibitions of section 606 of Pub. L. 92-436. The basis for each listing must be included in the report. The reporting requirement has been assigned Report Control Symbol DD-M(SA) 1386.

§ 216.7 Effective date and implementation.

This part is effective immediately. Two copies of implementing regulations shall be forwarded to the Assistant Secretary of Defense (Manpower and Reserve Affairs) within 60 days.

[FR Doc.76-3899 Filed 2-9-76;8:45 am]

[1] Filed as part of the original document.

Title 49—Transportation

CHAPTER X—INTERSTATE COMMERCE COMMISSION

SUBCHAPTER A—GENERAL RULES AND REGULATIONS

[S.O. 1229]

PART 1033—CAR SERVICE

Wolfeboro Rail Road Co. Authorized To Operate Over Certain Tracks Owned by State of New Hampshire

At a session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 4th day of February 1976.

It appearing, that the Boston and Maine Corporation, Robert W. Meserve and Benjamin H. Lacy, Trustees (B&M), in Finance Docket No. 26604 has requested authority to abandon its line between Concord, New Hampshire, and Lincoln, New Hampshire; that the State of New Hampshire in a Declaration of Taking, filed in the Superior Court of Merrimack County on October 30, 1975, has taken title to this line; that the State of New Hampshire has designated the Wolfeboro Rail Road Company (WLFB) as the operator of these lines; that the WLFB has consented to operate these lines pending action of the Commission on the application of the WLFB for approval of the extended contract; that many shippers are solely dependent upon continued operation of the aforementioned lines for essential railroad service; that the operation by the WLFB over the aforementioned tracks owned by the State of New Hampshire is necessary in the interest of the public and the commerce of the people; that notice and public procedure herein are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered, That:

§ 1033.1229 **Service Order No. 1229.**

(a) *Wolfeboro Rail Road Company authorized to operate over certain tracks owned by the State of New Hampshire.* The Wolfeboro Rail Road Company (WLFB) be, and it is hereby authorized to operate over tracks owned by the State of New Hampshire and acquired from the Boston and Maine Corporation, Robert W. Meserve and Benjamin H. Lacy, Trustees (B&M) extending from Concord, New Hampshire, to Lincoln, New Hampshire, a distance of approximately 71.8 miles, and to operate over certain B&M tracks in Concord necessary to the assembling or break-up of trains operated by the WLFB, pending disposition of application of the WLFB for permanent authority.

(b) *Application.* The provisions of this order shall apply to intrastate, interstate, and foreign traffic.

(c) *Rates applicable.* Inasmuch as this operation by the WLFB over tracks presently operated by the B&M and over tracks of the B&M is deemed to be due to carrier's disability, the rates applicable to traffic moved over these lines shall be the rates applicable to traffic routed to, from, or via these lines which were formerly in effect on such traffic when routed via the B&M, until tariffs naming rates and routes specifically applicable via the WLFB become effective.

(d) In transporting traffic over these lines the WLFB and all other common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic. Divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(e) *Effective date.* This order shall become effective at 12:01 a.m., February 6, 1976.

(f) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., August 31, 1976, unless otherwise modified, changed, or suspended by order of this Commission.

(Secs. 1, 12, 15, 17(2), 24 Stat. 379, 383, 384, as amended; 49 U.S.C. 1, 12, 15, and 17(2). Interprets or applies Secs. 1(10–17), 15(4), and 17(2), 40 Stat. 101, as amended 54 Stat. 911; (49 U.S.C. 1(10–17), 15(4), 17(2)))

It is further ordered, That copies of this order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association; and that notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board.

[SEAL] ROBERT L. OSWALD,
Secretary.

[FR Doc.76-3922 Filed 2-9-76;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 75N-0342]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Termination of Provisional Listing and Certification of FD&C Red No. 2

The Food and Drug Administration (FDA) is cancelling all certificates and terminating the provisional listing and certification, and hence the approval, of the color additive FD&C Red No. 2, effective January 28, 1976.

Section 8.501 (21 CFR 8.501) of the color additive regulations designates those color additives that are provisionally listed, pursuant to section 203(b) of the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376 note)), on an interim basis pending completion of scientific investigations needed for determinations as to permanent listing in accordance with section 706 of the Federal Food, Drug, and Cosmetic Act (sec. 706, 74 Stat. 399-403 (21 U.S.C. 376)).

The color additive FD&C Red No. 2 has been in use for over 68 years, having been included under its common name "amaranth" among 7 colors originally approved for use in food, drugs, and cosmetics through issuance on July 13, 1907, of Food Inspection Decision 76 by the Board of Food and Drug Inspection, Department of Agriculture. FD&C Red No. 2 is provisionally listed under § 8.501(a) for food, drug, and cosmetic use and is subject to certification under § 9.61 (21 CFR 9.61).

Under section 706 of the act, revised by the Color Additive Amendments of 1960, a color additive may be approved only if data establish that it is safe under its permitted conditions of use. However, the transitional provisions of those amendments provide for provisional listing of color additives in use in 1960 for a period of time necessary to complete the scientific investigations to establish their safety. Under this procedure FD&C Red No. 2 has been provisionally listed since 1960.

Over many years, numerous studies have been conducted with FD&C Red No. 2 for the purpose of establishing the safety of the color. Acute and chronic studies conducted in laboratory animals during the 1960's revealed no significant adverse effects as a result of oral feeding or dermal application of FD&C Red No. 2. However, no studies capable of demonstrating the effects of the color additive on animal reproduction has been reported prior to 1970.

In that year public concern about the possible potential for harm from FD&C Red No. 2 was triggered by publication in the scientific literature of the results of two studies by Russian investigators, which assertedly implicated amaranth as a test material capable of carcinogenic and adverse reproductive effects in test animals. Although questions remain as to the chemical equivalence to FD&C Red No. 2 of the amaranth used by the Russian investigators, their results pointed up the absence of data related to reproductive physiology. Thus, FDA required industrial sponsors to provide reproductive studies for all provisionally listed colors, including FD&C Red No. 2. In addition, at the request of the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives, FDA initiated a long-term chronic animal feeding study that included in utero exposure to FD&C Red No. 2.

Because of the widspread use of FD&C Red No. 2 and the persistent questions about its safety, at least in the public's mind, FDA decided to refer this study and all of the other studies that have

been presented in support of the color additive's safety to the agency's newly established Toxicology Advisory Committee. The committee, composed of distinguished experts in toxicology and related disciplines, met on November 20 and 21, 1975, to consider the data. Several members expressed an opinion that there appeared to be no immediate cause for concern and that the continued use of FD&C Red No. 2 did not pose a hazard to public health. However, all of the members of the advisory committee expressed reservations about reaching a final conclusion on the safety of the color additive before they had completed examination of the data. The committee specifically called for: (1) confirmatory pathologic diagnosis of animal tissue slides taken from the chronic study recently completed by FDA, as well as those from the earlier studies, if available; (2) a biostatistical analysis of the data derived from FDA's own recent chronic feeding study of FD&C Red No. 2; and (3) a detailed analysis of the chemical composition of the color additive as currently marketed.

Results of the biostatistical analysis have been reported by Dr. David W. Gaylor, principal biological statistician with the Food and Drug Administration's National Center for Toxicological Research in Arkansas, a member of the Toxicology Advisory Committee. In a December 31, 1975 memorandum to the committee, Dr. Gaylor concluded: "Based on the pathological findings of the recent study, it appears that feeding FD&C Red No. 2 at a high dosage results in a statistically significant increase in a variety of malignant neoplasms among aged Osborne-Mendel female rats." A working group of scientists from FDA, the National Cancer Institute, and the committee has evaluated Dr. Gaylor's memorandum and accepted the statistical principles of his analysis. No evaluation of his conclusions by the full committee has yet been made, however, pending confirmation of the pathology findings.

FDA's recent chronic study was flawed because the integrity of the test dose was not maintained, and the degree and extent of autolysis of tissue makes pathological evaluation difficult. Consequently, the working group advised, and the Commissioner agrees, that the study cannot demonstrate the safety of FD&C Red No. 2. Because of the existing uncertainties about the safety of the color additive, the Commissioner concludes that the adverse implications of the FDA study cannot be ignored. In light of continuing public concern and the serious new questions about carcinogenesis raised by Dr. Gaylor's analysis, the Commissioner concludes that a study adequate to dispel all such questions must be performed before the color additive can be demonstrated to be safe as required by the act.

Under the transitional provisions of the Color Additive Amendments of 1960, continued provisional listing of a color additive is appropriate only when studies in progress or under evaluation are capable of demonstrating the safety of the color additive involved. Because no study is available to resolve the uncertainties concerning the safety of FD&C Red No. 2, the Commissioner therefore concludes that, under the statute, continued provisional listing is no longer appropriate.

The current "closing date" for continued use of FD&C Red No. 2 was postponed to September 30, 1976 by a regulation published in the FEDERAL REGISTER of January 5, 1976 (41 FR 754). This postponement was based on the assumption that the studies being evaluated could establish the safety of the color additive. Since it has now become clear that the studies cannot satisfactorily resolve this issue, the Commissioner finds that the basis for the postponement no longer exists and hereby terminates the postponement of the closing date in accordance with section 203(a)(2) of the transitional provisions of the Color Additive Amendments of 1960. Also, under section 203(d)(1)(E) of the amendments, the Commissioner concludes that the provisional listing of FD&C Red No. 2 should be terminated because such action is necessary to protect the public health, in that questions have been raised about the safety of the color additive and the available data do not permit a determination of safety.

All certificates heretofore issued for batches of FD&C Red No. 2 are hereby cancelled, effective January 28, 1976. After January 28, 1976, adding FD&C Red No. 2 to any food, drug, or cosmetic will cause such product to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and subject to regulatory action. This prohibition applies to the use of straight colors, lakes, and mixtures of straight colors with ingredients functioning only as diluents. The Commissioner concludes that the protection of the public health does not require the recall from the market of food, drugs, and cosmetics containing the color additive, or the destruction of products in preparation to which the color additive has already been added.

This action applies to externally applied products as well as to those intended for ingestion, and to pet food and animal feed as well as to human food.

Manufacturers of new drugs and new animal drugs (including certifiable antibiotics for animal use) containing FD&C Red No. 2 may either delete the color additive or substitute a different color in accordance with the provisions of § 314.8(d)(3) and (e) or § 514.8(d)(3) and (e), as appropriate (21 CFR 314.8(d)(3) and (e), 514.8(d)(3) and (e)). The applicant shall submit data providing the new composition and showing that the change in composition does not interfere with any assay or other control procedures used in manufacturing the drug, or that the assay and other control procedures have been revised to make them adequate. Also, the applicant shall submit data available to establish the stability of the revised formulation, or if the data are too limited to support a conclusion that the drug will retain its declared potency for a reasonable marketing period, a commitment to test the stability of marketed batches at reasonable intervals, to submit the data as they become available, and to recall from the market any batch found to fall outside the approved specifications for the drug.

The Commissioner is aware that supplies of alternative color additives may be difficult to obtain immediately. Consequently, food and drug labeling stating that the product contains "artificial color" because of the prior inclusion of FD&C Red No. 2 may continue to be used with uncolored product during the time necessary to obtain supplies of alternative color ingredients or until the current supplies of labeling are used, whichever occurs first.

The Commissioner has carefully considered the environmental effects of this action and, because the action would not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the FDA environmental assessment, together with copies of the other documents mentioned above, are on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852. Because this action is final—not proposed—an inflation impact evaluation under Executive Order 11821 (p. 203 of 3A CFR, 1975 Compilation) is not required.

Published elsewhere in this issue of the FEDERAL REGISTER is a notice terminating the rule making proceeding to establish temporary tolerances for the use of FD&C Red No. 2 in food, ingested drugs, and ingested cosmetics, which was begun on July 4, 1972 (37 FR 13181).

Therefore, under the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 8 and 9 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

1. Part 8 is amended:

§ 8.501 [Amended]

a. In paragraph (a) of § 8.501 *Provisional lists of color additives* the entry for FD&C Red No. 2 is deleted.

b. In § 8.502, new paragraph (f) is added to read as follows:

§ 8.502 Termination of provisional listings of color additives.

* * * * *

(f) *FD&C Red No. 2.* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of FD&C Red No. 2 for use in food, drugs, and cosmetics.

c. In § 8.510, new paragraph (j) is added to read as follows:

§ 8.510 Cancellation of certificates.

* * * * *

(j)(1) Certificates issued for FD&C Red No. 2 and all mixtures containing this color additive are cancelled and have no effect after January 28, 1976, and use

of this color additive in the manufacture of food, drugs, or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market food, drugs, and cosmetics containing the color additive.

§ 9.61 [Revoked]

2. Part 9 is amended by revoking § 9.61 *FD&C Red No. 2.*

Notice and public procedure are not necessary prerequisites to the promulgation of this order because section 203 (d) (2) of Pub. L. 86–618 so provides.

Effective date. These regulations become effective February 10, 1976.

(Title II, Pub. L. 86–618, 74 Stat. 404–407 (21 U.S.C. 376 note).)

Dated: January 23, 1976.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.76–2519 Filed 1–26–76;10:32 am]