the contact lens, the agency's exposure calculation, and the extremely low risk for *p*-toluidine, FDA finds that the color additive D&C Green No. 6 is safe for use in contact lenses at the levels requested in the petitions.

In accordance with § 71.15(a) (21 CFR 71.15(a)), the petitions and the documents that FDA considered and relied upon in reaching its decision to approve the petitions are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 71.15(b), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

This document adds a new Subpart D to 21 CFR Part 74 that provides for listing certified color additives for use in or on medical devices. In a future issue of the **Federal Register**, FDA will add to Subpart D medical devices currently listed in Subpart B—Drugs (e.g., sutures which are now medical devices, but which were regulated as drugs before the passage of the Medical Device Amendments).

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

Reference

The following information has been put on file at the Dockets Management Branch (address above) and is available for review in that office between 9 a.m. and 4 p.m., Monday through Friday.

1. Weisburger, E. K., et al., "Testing of Twenty-one Environmental Aromatic Amines or Derivatives for Long-Term Toxicity or Carcinogenicity," *Journal of Environmental Pathology and Toxicology*, 2:325:356, 1978.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371(e), 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 74 is amended by adding a new Subpart D, to read as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart D—Medical Devices

§ 74.3206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 shall conform to the identity requirements of § 74.1206(a).

(b) *Specifications.* The color additive D&C Green No. 6 for use in contact lenses shall conform to the specifications of § 74.1206(b)(2).

(c) *Uses and restrictions.* (1) The color additive D&C Green No. 6 may be safely used to color contact lenses at levels not to exceed .03 percent by weight of the contact lens material.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k) and 515 of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which D&C Green No. 6 is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time on or before April 28, 1983 submit to the Dockets Management Branch (address above) written objection thereto. Objections shall show how the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issue for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Three copies of all documents shall be filed 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.

Effective date. This regulation shall become effective April 29, 1983, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the **Federal Register**.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371(e), 376))

Dated: March 21, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-7704 Filed 3-22-83; 10:47 am]

BILLING CODE 4160-01-M

---

21 CFR Parts 74, 81, and 82

[Docket No. 82N-0378]

Provisional Listing of D&C Red No. 6 and D&C Red No. 7; Postponement of Closing Date and Stay of Effectiveness

AGENCY: Food and Drug Administration.

ACTION: Final rule; stay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Red No. 6 and D&C Red No. 7 for general use as a color additive in drugs and cosmetics, except for use in the area of the eye. FDA is establishing a new closing date for D&C Red No. 6 and D&C Red No. 7 to give the agency time to complete evaluation of an objection received in response to the final regulation approving the petition for the permanent listing of D&C Red No. 6 and D&C Red No. 7. The regulation that permanently lists D&C Red No. 6 and D&C Red No. 7 and that removes them from the provisional list is stayed until the agency takes final action on the objection.

DATES: Effective March 29, 1983; the new closing date for D&C Red No. 6 and D&C Red No. 7 will be May 31, 1983.

FOR FURTHER INFORMATION CONTACT: John L. Herrman, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: FDA established the current closing date of March 29, 1983, for the provisional listing of D&C Red No. 6 and D&C Red No. 7 in a regulation published in the **Federal Register** of December 28, 1982 (47 FR 57681). The agency established the March 29, 1983 closing date for D&C Red No. 6 and D&C Red No. 7 to provide time for receipt and evaluation of any objections to the final regulation approving the petition for permanent listing of these color additives.

After the review and evaluation of the data relevant to the color additive petition to list D&C Red No. 6 and D&C Red No. 7 for use in drugs and cosmetics, the agency concluded that D&C Red No. 6 and D&C Red No. 7 were safe for general use in drugs and

cosmetics, except for use in the area of the eye. Therefore, FDA issued a regulation in the **Federal Register** of December 28, 1982 (47 FR 57681) that would permanently list D&C Red No. 6 and D&C Red No. 7. FDA stated that the regulation would become effective on January 28, 1983, unless stayed by the filing of proper objections.

FDA has received an objection to the listing regulation. Because of the objection, under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(e)(2), the regulation (47 FR 57681) that permanently lists D&C Red No. 6 and D&C Red No. 7 and that removes these color additives from the provisional list is stayed until the agency can rule upon the objection. FDA expects that the agency will need only a brief time to complete the evaluation of the objection and publish a final decision concerning it in the **Federal Register**. Therefore, FDA concludes that a brief postponement is necessary. The regulation set forth below will postpone the March 29, 1983 closing date for provisional listing of D&C Red No. 6 and D&C Red No. 7 until May 31, 1983.

Because the current closing date expires on March 29, 1983, FDA has concluded that the use of a notice and public procedure on this regulation is impracticable. Thus, good cause exists for issuing the postponement as a final rule. Moreover, this action is consistent with the protection of the public health because the agency has previously concluded that D&C Red No. 6 and D&C Red No. 7 are safe for their intended use under the Color Additive Amendments of 1960. This regulation will permit the uninterrupted use of these color additives until May 31, 1983. To prevent any interruption in the provisional listing of D&C Red No. 6 and D&C Red No. 7, and in accordance with 5 U.S.C. 553(d) (1) and (3), this regulation is being made effective on March 29, 1983.

List of Subjects

21 CFR Part 74

Color additives, Color additives subject to certification, Cosmetics, Drugs.

21 CFR Part 81

Color additives, Color additives provisional list, Cosmetics, Drugs.

21 CFR Part 82

Color additives, Color additive lakes, Color additives provisional list, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act [secs. 701(e) 706 (b), (c), and (d), 70 Stat. 919 as amended, 74 Stat. 399–403 (21 U.S.C. 371(e), 376 (b), (c), and (d))) and the Transitional Provisions of the Color Additive Amendments (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), Chapter I of Title 21 of the Code of Federal Regulations (as amended in the **Federal Register** of December 28, 1982 (47 FR 57681)) is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. Part 74 is amended:

§ 74.1306 [Stayed]

a. By staying § 74.1306 D&C Red No. 6.

§ 74.1307 [Stayed]

b. By staying § 74.1307 D&C Red No. 7.

§ 74.2306 [Stayed]

c. By staying § 74.2306 D&C Red No. 6.

§ 74.2307 [Stayed]

d. By staying § 74.2307 D&C Red No. 7.

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

2. Part 81 is amended as follows:

§ 81.1 [Amended]

a. In § 81.1 Provisional lists of color additives, the amendment in paragraph (b) to remove the entries "D&C Red No. 6" and "D&C Red No. 7" is stayed, and their closing date is revised to read "May 31, 1983."

§ 81.27 [Amended]

b. In § 81.27 Conditions of provisional listing, the amendment in paragraph (d) to remove the entries for "D&C Red No. 6" and "D&C Red No. 7" is stayed, and the closing date for the entries is revised to read "May 31, 1983."

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

3. Part 82 is amended:

§ 82.1306 [Stayed]

a. By staying § 82.1306 D&C Red No. 6.

§ 82.1307 [Stayed]

b. By staying § 82.1307 D&C Red No. 7.

Effective date. This regulation is effective March 29, 1983.

(Secs. 701(e), 706 (b), (c), and (d), 70 Stat. 919 as amended, 74 Stat. 399–403 (21 U.S.C. 371(e), 376 (b), (c), and (d))); (sec. 203, Pub. L. 86–618, 74 Stat. 404–407 (21 U.S.C. 376, note))

Dated: March 16, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-7742 Filed 3-28-83; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Parts 131, 135, and 166

Food for Human Consumption; Editorial Amendments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: Food and Drug Administration (FDA) is amending various regulations to correct editorial errors.

EFFECTIVE DATE: March 29, 1983.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–245–1155.

SUPPLEMENTARY INFORMATION: FDA believes that two of the editorial corrections should be explained because they appear to be substantive changes when, in reality, they are not. The first error first appeared in FR Doc. 74–24082 at page 42353 in the **Federal Register** of December 5, 1974, in which carriers for vitamins A and D were permitted, under paragraph (c)(1) of § 131.115, as safe and suitable optional ingredients. FDA never intended to permit carriers for vitamin A as safe and suitable optional ingredients. The reference to carriers for vitamin A is obviously in error and is meaningless because vitamin A is not even referred to in paragraph (b), *vitamin addition (optional)*, or paragraph (e), *nomenclature* and therefore is not part of the standard. This notice corrects the error and potential confusion by deleting the reference to vitamin A in paragraph (c)(1) of § 131.115.

The second error first appeared in FR Doc. 78–2967 at page 4596 in the **Federal Register** of February 3, 1978, in which there appeared a contradiction between the text and the table in paragraph (a)(4) of § 135.120. In the text, it is stated that nonfat milk solids content cannot be less than 7 percent, while in the table immediately following the minimum is set at 4 percent, which is the correct amount. This notice corrects the text to provide for a minimum of 4 percent nonfat milk solids content.

List of Subjects

21 CFR Part 131

Cream, Food standards, Milk, Yogurt.

21 CFR Part 135

Frozen desserts, Food standards, Ice cream.

21 CFR Part 166

Food standards, Margarine.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), 21 CFR, Subchapter B, is amended as follows:

PART 131—MILK AND CREAM

1. In Part 131:

a. In § 131.115 Concentrated milk, paragraph (c)(1), by changing "Carriers for vitamins A and D" to "Carrier for vitamin D." (The error first appeared in FR Doc. 77–7048 at page 14361 in the **Federal Register** of Tuesday, March 15, 1977.)

b. In § 131.123 Lowfat dry milk, paragraph (e)(1), by changing "percent" to "%".

c. In § 131.149 Dry cream, paragraph (d)(1), by changing "percent" to "%".

PART 135—FROZEN DESSERTS

2. In Part 135, in § 135.120 Ice milk, first sentence in paragraph (a)(4), by changing "7 percent" to "4 percent". (The error first appeared in FR Doc. 78–2967 at page 4596 in the **Federal Register** of Friday, February 3, 1978.)

PART 166—MARGARINE

3. In Part 166, in § 166.110 Margarine, paragraph (a), by changing ". . . prescribed under section 16.163, 'Indirect Method,' of the 'Official Methods of Analysis of the Association of Official Analytical Chemists,' 11th Ed. (1970)" to read ". . . prescribed under section 16.206 of the 'Indirect Method,' in 'Official Methods of Analysis of the Association of Official Analytical Chemists,' 13th Ed. (1980)."

Effective date: March 29, 1983.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: March 18, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-7941 Filed 3-28-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 211

[Docket No. 80N-0291]

Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding; Reduction of Reserve Sample Requirements for Radioactive Drugs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the current good manufacturing practice (CGMP) regulations for human and veterinary drugs by reducing the time that reserve samples of radioactive drugs containing radionuclides are required to be retained by manufacturers and by exempting reserve samples of these drug products from the annual visual examination requirement. This action is being taken because the current requirements concerning reserve samples are unnecessary to ensure the quality of certain radioactive drugs that typically have short expiration dating periods because of the rapid rate of radioactive decay.

DATE: Effective April 28, 1983.

FOR FURTHER INFORMATION CONTACT: Clifford G. Broker (HFN–323), 301–443–5307, or Robert J. Meyer (HFN–7), 301–443–5220, National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: Section 211.170 of the CGMP regulations (21 CFR 211.170) requires that a reserve sample representative of each lot in each shipment of each active ingredient be retained for at least 1 year after the expiration date of the last lot of the drug product containing the active ingredient and, further, that a reserve sample representative of each lot or batch of the drug product be retained for at least 1 year after the expiration date of the drug product. In addition, reserve samples of drug products are to be at least visually examined annually for evidence of deterioration unless such examination would affect the integrity of the samples.

In the **Federal Register** of November 28, 1980 (45 FR 79089), FDA proposed to amend the CGMP regulations by specifying that the retention period be 3 months for reserve samples of radioactive drugs with an expiration dating period of 30 days or less and 6 months for radioactive drugs with an expiration dating period of more than 30 days. The agency specifically requested comments on its proposed retention period of 6 months. FDA also proposed to exempt radioactive drug products from the requirement for evidence of deterioration. Under the proposal, nonradioactive reagent kits, which do not contain radionuclides, but are defined as "radioactive drugs" under § 310.3(n) (21 CFR 310.3(n)) for other purposes of regulating radiopharmaceuticals, were not included in the proposed exemption.

The agency received comments from a drug manufacturer and an educational organization. Both commentors supported the proposal and found the proposed 6-month retention period satisfactory. In addition, the drug manufacturer recommended the retention time period be expressed as some multiple of the half-life of the specific radionuclide (e.g., 2.5 times the half-life).

The agency has not incorporated the manufacturer's suggestion into the final rule. The agency notes that the range of half-lives of radionuclides presently used in nuclear medicine extends from 6 hours to 271 days. The application of the manufacturer's suggested multiple (2.5) results in a range of sample retention time periods extending from 15 hours to 677 days. Retention periods at the low end of this range, i.e., those measured in hours, would provide little practical time for surveillance of reserve samples; those at the high end require unnecessarily long surveillance periods given the time in which they must be used. Therefore, the agency has decided that the manufacturer's recommendation does not provide a useful criterion for calculating reserve sample retention time periods for radioactive drugs.

The agency has considered the economic consequences of this rulemaking and has determined that it does not require a regulatory impact analysis, as specified in Executive Order 12291. Specifically, the final rule amends the current good manufacturing practice regulations for human and veterinary drugs by reducing the time that reserve samples of radioactive drugs containing radionuclides are required to be retained by the manufacturer, and by exempting reserve samples from the annual visual examination requirement. The agency believes that the final rule will relieve a regulatory burden on the industry and eliminate the cost associated with the requirement for manufacturers of these drugs. Therefore, the agency concludes that the final rule is not a "major" rule as defined in Executive Order 12291. The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because

the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

List of Subjects in 21 CFR Part 211

Drugs, Manufacturing, Labeling, Laboratories, Packaging and containers, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 502, 505, 512, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 82 Stat. 343–351 (21 U.S.C. 351, 352, 355, 360b, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 211 is amended by revising § 211.170 to read as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

§ 211.170 Reserve samples.

(a) An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows:

(1) For an active ingredient in a drug product other than those described in paragraphs (a) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the last lot of the drug product containing the active ingredient.

(2) For an active ingredient in a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:

(i) Three months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is 30 days or less; or

(ii) Six months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is more than 30 days.

(3) For an active ingredient in an OTC drug product that is exempt from bearing an expiration date under § 211.137, the reserve sample shall be retained for 3 years after distribution of the last lot of the drug product containing the active ingredient.

(b) An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Reserve samples, except those drug products described in paragraph (b)(2), shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve samples. Any evidence of reserve sample deterioration shall be investigated in accordance with § 211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows:

(1) For a drug product other than those described in paragraphs (b) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the drug product.

(2) For a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:

(i) Three months after the expiration date of the drug product if the expiration dating period of the drug product is 30 days or less; or

(ii) Six months after the expiration date of the drug product if the expiration dating period of the drug product is more than 30 days.

(3) For an OTC drug product that is exempt from bearing an expiration date under § 211.137, the reserve sample must be retained for 3 years after the lot or batch of drug product is distributed.

Effective date: This regulation is effective April 28, 1983.

(Secs. 501, 502, 505, 512, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 82 Stat. 343–351 (21 U.S.C. 351, 352, 355, 360b, 371))

Dated: February 23, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-7935 Filed 3-28-83; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Parts 610, 620, 630, 640, 660, and 680

Biological Products; Editorial Amendments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending various biologics regulations to correct editorial errors.

EFFECTIVE DATE: March 29, 1983.

FOR FURTHER INFORMATION CONTACT: Albert Rothschild, National Center for Drugs and Biologics (HFN–813), Food and Drug Administration, 8800 Rockville Pike, Rockville, MD 20205, 301–443–1306.

SUPPLEMENTARY INFORMATION: This document corrects several editorial errors in the biologics regulations.

List of Subjects

21 CFR Part 610

Biologics, Labeling.

21 CFR Part 620 and 630

Biologics.

21 CFR Part 640

Blood.

21 CFR Part 660

Biologics, Labeling.

21 CFR Part 680

Biologics, Blood.

Therefore, under the Federal Food, Drugs, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))), and under authority delegated to the Commissioner (21 CFR 5.10), 21 CFR Subchapter F, is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

§ 610.15 [Amended]

1. In § 610.15 *Constituent materials*, in the introductory text of paragraph (a), by changing the words "Polio Virus" to read "Poliovirus".

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

§ 620.6 [Amended]

2. In § 620.6 *General requirements*, paragraph (h), by changing the name "Bureau of Biologics" to "Office of Biologics".

§ 620.24 [Amended]

3. In § 620.24 *General requirements*, paragraph (c), by changing the name "Bureau of Biologics" to "Office of Biologics".

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

§ 630.17 [Amended]

4. In § 630.17 *General requirements*, paragraph (e), by changing the name "Bureau of Biologics" to "Office of Biologics".