

Audit staff informed the Treasurer that the \$20,000 payment was a non-qualified campaign expense subject to repayment pursuant to 26 U.S.C. 9038(b)(2). The Treasurer agreed.

Second, for the same reasons that the \$25,000 in pre-DOI non-qualified campaign expenses could not be included on the NOCO statement, the \$20,000 in post-DOI non-qualified campaign expenses also could not be included.

Thus, the entitlement as calculated by the Treasurer was reduced by \$20,000⁴ and the 26 U.S.C. 9038(b)(2) ratio was applied to the \$20,000 which resulted in a repayment amount of \$6,666.67 for convention expenses. It should be noted that the \$5,000 transfer (dated 5/4/85) was made after all matching funds received had been disposed of and thus, this transfer was considered to have been made using non-federal monies.

The total 26 U.S.C. 9038(b)(2) repayment is \$31,666.67, comprised of the following:

Pre-DOI non-qualified campaign expenses (\$75,000 x 33.3333%)	\$25,000.00
Post-DOI non-qualified expenses (\$20,000 x 33.3333%)	6,666.67
Total 26 U.S.C. 9038(b)(2) Repayment	31,666.67

At the close of follow-up fieldwork, the Treasurer inquired concerning the possible impact of settling a \$500,000 debt for \$50,000 in the near future. The Audit staff advised her of the Commission's debt settlement procedures and informed the Treasurer that all NOCO statements filed carried this debt at \$500,000. Should the debt be settled for less, it was the Commission's policy to recalculate entitlement based on the \$50,000 settlement amount, and seek a 26 U.S.C. 9038(b)(1) repayment, if appropriate.

Statutory Authority

(26 U.S.C. 9007, 9038)

List of Subjects 11 CFR Parts 9007 and 9038

Campaign funds, Administrative practice and procedure, Political candidates.

PART 9007—[AMENDED]

11. CFR Part 9007 is amended by revising §§ 9007.2(b)(2)(i) introductory text, and (b)(2)(ii)(B), (C) and (D); and adding (b)(2)(iii) as follows:

⁴To the extent the candidate's entitlement was inflated by this amount, a repayment determination would also be made under 26 U.S.C. 9038(b)(1).

§ 9007.2 Repayments.

- (b) * * *
- (2) * * *

(i) If the Commission determines that any amount of any payment to an eligible candidate from the Fund was used for purposes other than those described in paragraphs (A) through (C) below, it will notify the candidate of the amount so used, and such candidate shall pay to the United States Treasury an amount equal to such amount.

- (ii) * * *

(B) Determinations that amounts spent by a candidate, a candidate's authorized committee(s), or agent(s) from the Fund were not documented in accordance with 11 CFR 9003.5;

(C) Determinations that any portion of the payments made to a candidate from the Fund was expended in violation of State or Federal law; and

(D) Determinations that any portion of the payments made to a candidate from the Fund was used to defray expenses resulting from a violation of State or Federal Law, such as the payment of fines or penalties.

(iii) In the case of a candidate who has received contributions pursuant to 11 CFR 9003.3 (b) or (c), the amount of any repayment sought under this section shall bear the same ratio to the total amount determined to have been used for non-qualified campaign expenses as the amount of payments certified to the candidate from the Fund bears to the total amount of deposits of contributions and federal funds, as of December 31, of the Presidential election year.

PART 9038—[AMENDED]

11 CFR Part 9038 is amended by revising § 9038.2(b)(2)(i) introductory text, adding (b)(2)(iii) and revising (b)(3) as follows:

§ 9038.2 Repayments.

- (b) * * *
- (2) * * *

(i) The Commission may determine that amounts of any payments made to a candidate from the matching payment account were used for purposes other than those set forth in (A)–(C) below:

(iii) The amount of any repayment sought under this section shall bear the same ratio to the total amount determined to have been used for non-qualified campaign expenses as the amount of matching funds certified to the candidate bears to the total amount of deposits of contributions and

matching funds, as of the candidate's date of ineligibility.

(3) *Failure to Provide Adequate Documentation.* The Commission may determine that amount(s) spent by the candidate, the candidate's authorized committee(s), or agents were not documented in accordance with 11 CFR 9033.11. The amount of any repayment sought under this section shall be determined by using the formula set forth in 11 CFR 9038.2(b)(2)(iii).

Dated: March 5, 1985.

John Warren McGarry,
Chairman.

[FR Doc. 85-5591 Filed 3-7-85; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Director, Center for Devices and Radiological Health

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority on medical devices and electronic products to add new delegations to the Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

EFFECTIVE DATE: March 8, 1985.

FOR FURTHER INFORMATION CONTACT: Robert L. Miller, Office of Management and Operations (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: FDA is amending the delegations of authority to redelegate the authority to CDRH officials to issue notices relating to the approval, denial of approval, or withdrawal of approval of premarket approval applications (PMA's) or supplemental PMA's and to issue notices of the availability of approved variances, and amendments or extensions thereof, for electronic products. This document amends § 5.53 *Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices* (21 CFR 5.53) and § 5.86 *Variances from performance standards for electronic products* (21 CFR 5.86) to delegate

authority to the Director and Deputy Director, CDRH, to issue such notices.

All notices pertaining to highly visible, controversial, or sensitive matters, or which involve granting or denial of a hearing, will be reviewed and issued by the Office of the Commissioner.

All documents will continue to be reviewed and cleared by the Office of General Counsel.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies); Organization and functions (Government agencies).

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), Part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. By adding new § 5.53(c), to read as follows:

§ 5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(c) The Director and Deputy Director, CDRH, for medical devices assigned to their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515 (d), (e), and (g) and 520(h)(1) of the act.

2. By revising § 5.86, to read as follows:

§ 5.86 Variances from performance standards for electronic products.

The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to grant and withdraw variances, and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in Subchapter J of this chapter.

Effective date. This regulation shall

become effective March 8, 1985.

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

Dated: March 4, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-5534 Filed 3-7-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 5

Delegations of Authority and Organization; Associate Commissioner for Health Affairs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority by adding a new delegation to the Associate Commissioner for Health Affairs from the Commissioner of Food and Drugs. The authority being added is under section 156 of Title 35 of the United States Code (35 U.S.C. 156) and pertains to patent term restoration.

EFFECTIVE DATE: March 8, 1985.

FOR FURTHER INFORMATION CONTACT: Robert L. Miller, Office of Management and Operations (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4978.

SUPPLEMENTARY INFORMATION: FDA is amending the regulations under Part 5 to delegate to the Associate Commissioner for Health Affairs the authorities to perform the functions that have been delegated to the Commissioner under 35 U.S.C. 156, except for the holding of informal hearings pursuant to 35 U.S.C. 156(d)(2)(B)(ii).

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies); Organization and functions (Government agencies).

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), Part 5 is amended by adding new § 5.27, to read as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

§ 5.27 Patent term extensions for human drug products, medical devices, and food and color additives.

The Associate Commissioner for Health Affairs is authorized to perform the functions delegated to the Commissioner under section 156 of Title 35 of the United States Code (35 U.S.C. 156), except for the holding of informal hearings pursuant to 35 U.S.C. 156(d)(2)(B)(ii).

Effective date. March 8, 1985.

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

Dated: March 4, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-5544 Filed 3-7-85; 8:45 am]

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21 CFR Part 73

[Docket No. 84C-0135]

Poly (Hydroxyethyl Methacrylate)-Dye Copolymers; Listing of Color Additive for Coloring Contact Lenses

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of coloring contact lenses of the colored polymeric reaction product formed by chemically bonding Reactive Blue No. 19 to poly(hydroxyethyl methacrylate) to produce tinted contact lenses. This action responds to a petition filed by Ciba Vision Care.

DATES: Effective April 9, 1985; objectives by April 8, 1985.

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: Tom C. Brown, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION:

Background

In a notice published in the Federal Register of June 6, 1984 (49 FR 23455), FDA announced that a color additive petition (CAP 4C0183) had been filed by Ciba Vision Care, P.O. Box 105069, Atlanta, GA 30348, proposing that Part 73 (21 CFR Part 73) be amended to provide for the safe use of Reactive Blue

No. 19 [2-anthracenesulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt] (CAS Reg. No. 2580-78-1) chemically bonded to the lens polymer to produce permanently tinted contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 376).

The colored polymeric reaction product that is the subject of this petition is formed when the dye is bonded with poly(hydroxyethyl methacrylate) on the front surface of a contact lens to form a thin layer of colored polymeric material on that surface. This polymeric material colors the contact lens.

Under the Medical Device Amendments of 1976 (Pub. L. 94-295), a color additive for use in a medical device is subject to the listing requirements when the color additive comes in direct contact with the body for a significant period of time (section 706(a) of the act). As explained in the Federal Register of January 4, 1984 (49 FR 372), the polymeric reaction products of bonding reactive dye like Reactive Blue No. 19 to poly(hydroxyethyl methacrylate) are called "poly(hydroxyethylmethacrylate)-dye copolymers" in § 73.3121 (21 CFR 73.3121). These reaction products are color additives within the meaning of section 201(f) of the act (21 U.S.C. 321(f)) because they are substances made by a process of synthesis or similar artifice, and because they are capable of imparting color to food, drugs, cosmetics, or the human body if added or applied thereto. For the color additive considered here, Reactive Blue No. 19 is merely a starting material. In the reaction process that occurs in bonding the reactive dye to the poly(hydroxyethyl methacrylate), the reactive dye ceases to exist as a separate entity.

The use of the poly(hydroxyethyl methacrylate)-dye copolymers as color additives in contact lenses is subject to regulation under section 706(a) of the act. The lenses that have this colored polymeric material on their front surfaces are intended to be placed on the eye for several hours a day, each day, for 1 year or more. These color additives accordingly will come in direct contact with the body for a significant period of time. Consequently, the use of the color additive presented in the petition now before the agency is subject to the statutory listing requirement.

Safety Evaluation

The petitioner submitted various toxicity data to establish that the color additive created by bonding Reactive Blue No. 19 to poly(hydroxyethyl methacrylate) is safe for use in contact lenses. In a primary ocular irritation study with extracts of lens material containing the color additive, and in a 21-day ocular irritation study with contact lenses tinted with the color additive, both of which were done in rabbits, neither the lenses containing the color additive nor the extracts of the colored lens material caused ocular irritation.

The agency has also reviewed data regarding the toxicity of potential impurities, such as unbound reactive dye, remaining in the lens. Because the reactive dye has a lower molecular weight than the polymeric color additive, it would be more readily absorbed into the body than the color additive and would thus be expected to show a greater toxic effect. FDA has concluded that, as a worst case, any material migrating from the color additive in the lens would pose a safety concern no greater than if the reactive dye was placed in the lens unbound, and all migrated into the eye over a 1-year period. The agency concludes, based upon the information submitted in the petition, that a maximum of 34.5 micrograms of reactive dye would be present in each lens. Therefore, the estimated worst case exposure from two lenses would be 180 nanograms per day for both eyes.

The petitioner conducted cytotoxicity studies in which serial dilutions of the reactive dye were applied directly to L-929 mouse fibroblast cells. No toxic effect was seen at a concentration 4,600 times the concentration that would be in the eyes if 180 nanograms migrated into the eyes per day.

Conclusion

Based on the data in the petition and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the proposed use of the reaction product formed by bonding Reactive Blue No. 19 to poly(hydroxyethyl methacrylate) for coloring contact lenses, and that this color additive is suitable for its intended use. The agency, therefore, is amending § 73.3121 by adding Reactive Blue No. 19 to the list of reactive dyes in paragraph (a).

In addition, based on the relevant data, FDA concludes that the safety margin for use of this color additive is large enough to rule out any need for imposing a limitation on the amount of

the additive that may be present on the lens, beyond the limitation that only that amount necessary to accomplish the intended technical effect may be used. Finally, on the basis of factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of the color additive is not necessary for the protection of the public health.

In accordance with § 71.15 (21 CFR 71.15), 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 (address above) by appointment with the information contact person listed above. As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

Environmental Impact

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.

List of Subjects in 21 CFR Part 73

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 73 is amended in § 73.3121 by removing the word "and" before, and the period at the end of, paragraph (a)(4) and by adding new paragraph (a)(5) to read as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

§ 73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers

(a) * * *; and (5) Reactive Blue No. 19 [2-anthracene-sulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt] (CAS Reg. No. 2580-78-1).

* * * * *

Any person who will be adversely affected by the foregoing regulation may, at any time on or before April 8,

1985, file with the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date: April 9, 1985.

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

Dated: March 4, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-5549 Filed 3-5-85; 11:54 am]

BILLING CODE 4160-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 126 and 160

[CGD 84-039]

Radioactive Materials

Correction

In FR Doc. 85-5176 beginning on page 8612 in the issue of Monday, March 4, 1985, make the following corrections: On page 8614, in the first column, in paragraph 4, in the first line, "§ 126.203" should read "§ 160.203"; also, the heading "§ 126.203 Definitions," below paragraph 4, should read "§ 160.203 Definitions."

BILLING CODE 1505-01-M

33 CFR Part 165

[COTP LA/LB-85-03]

Safety Zone, Santa Cruz Island

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: This regulation establishes a safety zone in the vicinity of Santa Cruz Island. Tests of submerged and semi-submerged vessels will be conducted during a four month period. There will also be placement of fixed underwater sound systems making transit, anchoring or fishing hazardous. Limiting access to this area will serve to protect vessels and sensitive underwater gear.

DATES: This regulation becomes effective on February 28, 1985 and expires on June 1, 1985.

ADDRESS: Commanding Officer, U.S. Coast Guard Marine Safety Office, Los Angeles/Long Beach, 165 N. Pico Avenue, Long Beach, CA 90802. The comments will be available for inspection and copying at the Port Operations Department, U.S. Coast Guard Marine Safety Office Los Angeles/Long Beach. Normal Office hours are between 8:00 a.m. and 4:00 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant John A. Turner, U.S. Coast Guard, U.S. Coast Guard Marine Safety Office, Los Angeles/Long Beach (213-590-2215).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking was not published for this regulation and it is being made effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been contrary to the public interest. A safety zone already in effect completely excludes all vessels from the regulated area. This rule amends that zone to allow limited access on an individual basis resulting in more vessels being allowed to use the area when operations do not require exclusion. Although this regulation is published as a final rule without prior notice, an opportunity for public comment is nevertheless desirable to ensure that the regulation is both reasonable and workable. Accordingly, persons wishing to comment may do so by submitting written comments to the office listed under "ADDRESS" in this preamble. Commenters should include their names and addresses, identify the docket number for the regulation, and give reasons for their comments. Receipt of comments will be acknowledged if a stamped, self-addressed postcard or envelope is enclosed. Based upon

comments received, the regulations may be changed.

Drafting Information

The drafters of this regulation are Lieutenant John A. Turner, U.S. Coast Guard, Port Operations Department, U.S. Coast Guard Marine Safety Office, Los Angeles/Long Beach, project officer; Lieutenant Joseph R. McFaul, Eleventh Coast Guard District Legal Office.

Discussion of Regulation

At intermittent times during the months of February, March, April and May, tests of submerged and semi-submerged vessels will take place in the waters off Santa Cruz Island. There will be suspended hydrophone arrays in the water column and test vessels may not be visible making transit of the area hazardous especially at night. Tests will be conducted as meteorological and oceanographic conditions permit. The area will be patrolled as needed by Coast Guard cutters and vessels approaching the safety zone should follow the directions of the Coast Guard cutter. In addition vessels may seek advance clearance from the Coast Guard Marine Safety Office to enter this area. The Marine Safety Office will issue clearances to vessels. The owner can call the Coast Guard, using the clearance, at least twenty-four hours in advance of the anticipated need to enter the safety zone. The Coast Guard will inform the vessel's owner if permission to enter the safety zone can be granted.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Final Regulation:

PART 165—[AMENDED]

In consideration of the foregoing, Part 165 of Title 33, Code of Federal Regulations, is amended by removing § 165.T11-02 and adding § 165.T-11-71 to read as follows:

§ 165.T-11-71 Santa Cruz Island.

(a) A safety zone is established to include all waters enclosed within lines drawn from the following points: beginning from a point on land located approximately at Latitude 33-57.9 N., Longitude 119-42.6 W., then due south to a point on the territorial sea located approximately at Latitude 33-54.9 N., Longitude 119-42.6 W., then following the limit of the territorial sea in an easterly direction to a point approximately located at Latitude 33-56.2 N., Longitude 119-35.5 W., then due