PART 724—TRUSTEES AND CUSTODIANS OF PENSION PLANS

Sec.
724.1 Federal credit unions acting as trustees and custodians of pension plans.
724.2 Self-directed retirement plans.
724.3 Appointment of successor trustee or custodian.

Authority: 12 U.S.C. 1766 and 1787.

§ 724.1 Federal credit unions acting as trustees and custodians of pension plans.

A federal credit union is authorized to act as trustee or custodian, and may receive reasonable compensation for so acting, under any written trust instrument or custodial agreement created or organized in the United States and forming part of a pension plan which qualifies or qualified for specific tax treatment under section 401(d) or 408 of the Internal Revenue Code, for its members or groups of its members, provided the funds of such plans are invested in share accounts or share certificate accounts of the federal credit union. All funds held in a trustee or custodial capacity must be maintained in accordance with applicable laws and rules and regulations as may be promulgated by the Secretary of Labor, the Secretary of the Treasury, or any other authority exercising jurisdiction over such trust or custodial accounts. The federal credit union shall maintain individual records for each participant which show in detail all transactions relating to the funds of each participant or beneficiary.

§ 724.2 Self-directed retirement plans.

A Federal credit union may act as trustee or custodian of individual retirement plans of its members established pursuant to section 401(d) or 408 of the Internal Revenue Code, and may facilitate transfers of plan funds to assets other than share and share certificates of the credit union, provided the conditions of § 724.1 and the following additional conditions are met:

(a) All contributions of funds are initially made to a share or share certificate account in the Federal credit union;

(b) Any subsequent transfer of funds to other assets is solely at the direction of the member and the Federal credit union exercises no investment discretion and provides no investment advice with respect to plan assets (i.e., the credit union performs only custodial duties); and

(c) The member is clearly notified of the fact that National Credit Union Share Insurance Fund coverage is limited to funds held in share or share certificate accounts of NCUSIF-insured credit unions.

§ 724.3 Appointment of successor trustee or custodian.

Any plan operated pursuant to this part shall provide for the appointment of a successor trustee or custodian by a person, committee, corporation or organization other than the Federal credit union or any person acting in his capacity as a director, employee or agent of the Federal credit union upon notice from the Federal credit union or the Board that the Federal credit union is unwilling or unable to continue to act as trustee or custodian.

[FR Doc. 90-17240 Filed 7-24-90; 8:45 am]
BILLING CODE 7535-01-M

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12 CFR Part 749

Records Preservation Program

AGENCY: National Credit Union Administration ("NCUA").

ACTION: Final rule.

SUMMARY: Part 749 of the NCUA Regulations (12 CFR part 749) sets forth requirements for records preservation for federally insured credit unions. The National Credit Union Administration Board, as part of its periodic review of its regulations, issued a proposed rule soliciting public comments on part 749 in November 1989. (*See* 54 FR 48271, November 22, 1989.) After evaluating the comments and further reviewing the rule, the Board has adopted two minor changes. First, the substitution of "financial officer" for "treasurer" conforms the rule to a change in the Federal Credit Union Act and second, a requirement for storage of locator information for each member clarifies that a credit union must be able to locate its members in the event of a disaster.

EFFECTIVE DATE: August 24, 1990.

ADDRESSES: National Credit Union Administration, 1776 G Street NW., Washington, DC 20456.

FOR FURTHER INFORMATION CONTACT: Hattie M. Ulan, Associate General Counsel, or Margaret R. Suuberg, Staff Attorney, Office of General Counsel, at the above address or telephone: 202/682-9630.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The current control number for part 749 is 3133-0032. No change in the collection requirements is suggested.

Background and Comments

Part 749 establishes minimum requirements for records preservation by federally insured credit unions. The rule requires off-site storage of duplicate vital records in order to provide financial and other necessary data for reconstruction purposes in the event of a catastrophe. The last major revision of part 749 was made in 1981 (*see* 46 FR 17188 (March 18, 1981)), at which time the regulation was substantially deregulated. In 1982, the NCUA Board discontinued its program of NCUA-financed off-site storage of credit union vital records. (*See* 47 FR 8006 (February 24, 1982).) No other changes have occurred. Section 5190 of the Accounting Manual for Federal Credit Unions (NCUA Publication 8022) also addresses records preservation and retention, and provides additional guidance to credit unions.

In November 1989, the NCUA Board issued one proposed modification to part 749 and requested comment on any other needed modifications. (*See* 54 FR 48271, November 22, 1989.) In its earlier form, part 749 assigned the treasurer of the credit union the responsibility for storing duplicative records at a vital records storage center (*see* 12 CFR 749.1). The proposed rule substituted "financial officer" for "treasurer," in order to conform the rule to a change in section 112 of the Federal Credit Union Act (12 U.S.C. 1761a).

Seven comments were received on the proposed rule. Two comments came from national credit union trade associations; three from state credit union leagues; and two from federal credit unions. All of the commenters supported the substitution of "financial officer" for "treasurer," and it has been adopted in the final rule.

Two commenters requested that NCUA address additional issues or make additional changes to the regulation.

One state credit union league expressed concern that a state-chartered, federally insured credit union might interpret the term "financial officer" to mean "treasurer" although the treasurer might not be the officer charged by the credit union with maintaining custody of the credit union's records. This commenter suggested that the words, "or, in the case of a federally insured state credit union, the officer having custody of the records" be added after the words "financial officer." The Board considers the addition of the suggested language unnecessary. It should be understood that the term "financial officer" refers to the officer responsible for the financial records of the credit union.

Another state credit union league suggested that the regulation require credit unions to include, in the vital

records stored, a list of outside vendors that transact business with the credit union. Again, the Board finds the suggested revision unnecessary. The regulation currently sets forth the required minimum for records to be stored; credit unions may store additional records.

One change has been made as a result of further staff review of the proposal. Section 749.2(a)(3) has been added, requiring storage of locator information for each member, such as address and telephone number, unless the board of directors determines that such information is readily available from another source. The Board believes that most credit unions already store locator information, but considers the change advisable in order to clarify that a credit union must be able to locate its members in the event of a disaster.

Regulatory Procedures

Regulatory Flexibility Analysis

The NCUA Board certifies that this rule will not have a significant impact on a substantial number of small credit unions. The rule makes no substantive changes.

Executive Order 12612

This regulation currently applies to all federally insured credit unions. The final rule makes no change in its application. The NCUA Board continues to believe that this regulation should apply to state-chartered, federally insured credit unions. All federally insured credit unions must maintain duplicative vital records in the event that original records are destroyed.

List of Subjects in 12 CFR Part 749

Archives and records, Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on July 17, 1990.

Hattie M. Ulan,

Acting Secretary of the Board.

Accordingly, NCUA amends its regulations as follows:

1. Part 749 is revised to read as follows:

PART 749—RECORDS PRESERVATION PROGRAM

Sec.
749.0 Records preservation.
749.1 Implementation.
749.2 Vital records to be stored.

Authority: 12 U.S.C. 1766, 1783 and 1789.

§ 749.0 Records preservation.

All federally insured credit unions must maintain a records preservation program to identify, store and reconstruct vital records in the event that the credit union's records are destroyed.

§ 749.1 Implementation.

The financial officer of the credit union is responsible for storing duplicate vital records at a vital records center. This responsibility may be delegated.

(a) The Records Preservation Program must be operational within 6 months after the credit union's insurance certificate is issued.

(b) The vital records center is defined as any location far enough from the credit union's offices to avoid the simultaneous loss of both sets of records in the event of disaster.

(c) Records must be stored every 3 months, within 30 days after the end of the 3-month period. Previously stored records may be destroyed when the current records are stored.

(d) A records preservation log will be maintained showing what records were stored, where the records were stored, when the records were stored, and who sent the records for storage.

(e) Stored records may be in any format which can be used to reconstruct the credit union's records. Formats include paper originals, machine copies, micro film or fiche, magnetic tape, etc.

(f) Credit unions which have some or all of their records maintained by an off-site data processor are considered to be in compliance for the storage of those records.

§ 749.2 Vital records to be stored.

At least the following records, as of the most recent month-end, must be stored:

(a) A list of share and/or deposit and loan balances for each member's account.

(1) The list of balances will be individually identified by a name or number.

(2) Multiple loans of one account will be listed separately.

(3) Information sufficient to enable the credit union to locate each member, such as address and telephone number, shall also be included, unless the board of directors determines that such information is readily available from another source.

(b) A financial report which lists all of the credit union's asset and liability accounts.

(c) A list of the credit union's banks, insurance policies, and investments. This information may be marked "permanent" and be updated only when changes are made.

[FR Doc. 90-17241 Filed 7-24-90; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 89C-0203]

Listing of Color Additives for Coloring Contact Lenses; 1,4-Bis[4-(2-Methacryloxyethyl) Phenylamino] Anthraquinone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of 1,4-bis[4-(2-methacryloxyethyl)phenylamino] anthraquinone for coloring contact lenses. This action is in response to a petition filed by Bausch & Lomb, Inc.

DATES: Effective August 27, 1990, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by August 24, 1990.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sandra L. Varner, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of July 20, 1989 (54 FR 30469), FDA announced that a color additive petition (CAP 9C0215) had been filed by Bausch & Lomb, Inc., 1400 North Goodman St., Rochester, NY 14692-0450, proposing that 21 CFR part 73 of the color additive regulations be amended to provide for the safe use of 1,4-bis[4-(2-methacryloxyethyl)phenylamino] anthraquinone to color contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94-295), Congress mandated the listing of color additives for use in medical devices when the color additive comes into direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of 1,4-bis[4-(2-

methacryloxyethyl)phenylamino] anthraquinone as a color additive in contact lenses is subject to this listng requirement. The color additive is added to contact lenses in such a way that at least some of the color additive will come into contact with the eyes when the lenses are worn. In addition, the lenses are intended to be placed on the eyes for several hours a day, each day, for 1 year or more. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive currently before the agency is subject to the statutory listing requirement.

III. The Color Additive

When used to color contact lenses, the color additive 1,4-bis[4-(2-methacryloxyethyl)phenylamino] anthraquinone (CAS Reg. No. 121888-69-5) is copolymerized with hydroxyethyl methacrylate monomer. The color additive covalently bonds to the hydroxyethyl methacrylate monomer through two methacrylate groups. The resulting copolymeric product is formed into a contact lens.

IV. Safety Evaluation

FDA concludes from the data submitted in the petition and from other relevant information that the upper limit of exposure to 1,4-bis[4-(2-methacryloxyethyl)phenylamino] anthraquinone from its use in contact lenses is 280 nanograms per person per day. The agency-calculated upper limit was based on two factors. First, FDA has established a maximum practical use level of 50 micrograms per lens for the color additive in a contact lens (Ref. 1). Second, the agency made two worst-case assumptions: (1) that a user will replace lenses tinted with 1,4-bis[4-(2-methacryloxyethyl)phenylamino] anthraquinone once each year with a new pair of lenses tinted with the color additive at the maximum use level; and (2) that 100 percent of the color additive will migrate from the lenses into the eyes over the 1-year period. Because these assumptions are worst-case estimates, exposure to 1,4-bis[4-(2-methacryloxyethyl)phenylamino] anthraquinone from its use for coloring contact lenses is likely to be far less than 280 nanograms per person per day (Ref. 2).

To establish that 1,4-bis[4-(2-methacryloxyethyl)phenylamino] anthraquinone is safe for use in coloring contact lenses, the petitioner conducted toxicity studies. The studies included three in vitro cytotoxicity studies on the dye, two by the agar overlay method and one by the direct-contact method. The dye was found to be noncytotoxic when tested at a concentration as high as 1,810 micrograms per milliliter by the direct-contact method using mouse fibroblast cells. A 21-day ocular irritation study in rabbits using contact lenses and a guinea pig maximization (Kligman) study using lens extracts were also conducted. These studies demonstrated no evidence of ocular irritation or delayed contact sensitization in the test animals.

To relate the 1,810 micrograms-per-milliliter no-effect level established in the direct-contact cytotoxicity study for the color additive to the 280 nanograms per-person-per-day exposure from wearing the lenses, the agency calculated the maximum concentration level of the color additive in each eye that would result from the use of the contact lens. The agency estimated that the daily exposure to the color additive in each eye would be 140 nanograms and that this would be diluted by the maximum daily tear film of 1.2 milliliters [1] produced in each eye. This contentration is equal to a maximum daily concentration in the tear flow of the eye of 120 nanograms per milliliter. When this concentration is compared with the 1,800 micrograms per milliliter no-effect level, this represents more than a 15,000 fold safety factor.

Based upon the available toxicity data, the small amount of the color additive incorporated into the contact lenses, and the agency's exposure calculation, FDA finds that 1,4-bis[4-(2-methacryloxyethyl)phenylamino] anthraquinone is safe for use as a color additive in contact lenses. FDA further concludes that the safety margin is sufficiently large that a limitation on the amount of the color additive that may be present in the lens is not required beyond the limitation that only the amount necessary to accomplish the intended technical effect may be used. Batch certification is not required to ensure safety.

V. Conclusions

Based on data contained in the petition and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone as a color additive in contact lenses, and that the color additive is safe and suitable for its intended use.

VI. Inspection of Documents

In accordance with 21 CFR 75.15, 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 by appointment with the information contact person listed above. As provided in 21 CFR 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.

VII. Environmental Impact

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

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated February 19, 1985, from the Food Additive Chemistry Evaluation Branch to the Petitions Control Branch, color additives in contact lenses.

2. Memorandum dated May 17, 1989, from the Food and Color Additives Review Section to the Indirect Additives Branch, CAP 9C0215—Bausch & Lomb; 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone as a (color additive) comonomer in poly(hydroxyethyl methacrylate) contact lenses; submission dated December 9, 1988.

3. Moses and Hart, Eds., "Adler's Physiology of the Eye," 8th Ed., p. 22, C. V. Mosby Co., St. Louis, 1987.

4. Mishima, S., et. al., "Determination of Tear Volume and Tear Flow," *Investigative Ophthalmology and Visual Science*, 5:264, 1966.

IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before August 24, 1990, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with

[1] The agency has previously estimated the daily tear film volume to be 1.58 milliliters, calculated by taking 70 microliters of tear production per hour and multiplying this over 24 hours of lens wear. A careful review of the literature (Refs. 3 and 4) indicates that 50 microliters of tear is produced per hour, and thus, 1.2 milliliters is a better approximation of daily tear film volume.

particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish a notice of the objections that the agency has received, or the lack thereof, in the **Federal Register**.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 376).

2. New § 73.3106 is added to subpart D to read as follows:

§ 73.3106 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone.

(a) *Identity.* The color additive is 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone (CAS Reg. No. 121888-69-5). The color additive is copolymerized with hydroxyethyl methacrylate monomer to form the lens material.

(b) *Uses and restrictions.* (1) The color additive listed in paragraph (a) of this section may be used in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used.

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

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

Dated: July 18, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-17312 Filed 7-24-90; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Tylosin, Tylosin/Sulfamethazine, Pyrantel Tartrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing those portions of the animal drug regulations which reflect approval of several new animal drug applications (NADA's), one held by The Eugene Ingmand Co. for the use of a tylosin Type A medicated article; two held by Kay Dee Feed Co., one for the use of a tylosin Type A medicated article, and another for the use of a tylosin-sulfamethazine Type A medicated article; and one held by Good-Life Division of Central Soya Co., Inc., for the use of a pyrantel tartrate Type A medicated article. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: August 6, 1990.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of: The Eugene Ingmand Co.'s NADA 91-465 which provides for the use of a tylosin Type A medicated article to make a Type C medicated swine feed; Kay Dee Feed Co.'s NADA 111-814 which provides for the use of a tylosin Type A medicated article to make a Type C chicken, swine, and beef cattle feed; Kay Dee Feed Co.'s NADA 128-255 which provides for the use of a tylosin-sulfamethazine Type A medicated article to make a Type C swine feed; and Good-Life Division of Central Soya Co., Inc.'s NADA 134-286 which provides for use of a pyrantel tartrate Type A medicated article to make a Type C swine feed. This document amends 21 CFR 558.485(a)(14), 558.625 (b)(49) and (b)(56), and 558.630(b)(8) to reflect the withdrawal of approval of these NADA's.

Also, since The Eugene Ingmand Co. and Kay Dee Feed Co. are no longer sponsors of any approved NADA's, 21 CFR 510.600 (c)(1) and (c)(2) are amended to remove the firms' entries from the list of sponsors of approved applications.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.600 [Amended]

2. Section 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications is amended in the table in paragraph (c)(1) by removing the entries "The Eugene Ingmand Co." and "Kay Dee Feed Co.", and in the table in paragraph (c)(2) by removing the entries "021533" and "026848", respectively.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).