environmental impact statement is required.

J. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. As explained in the NPR, the rule requiring CR packaging for household products containing more than 5 percent MAA would preempt non-identical state or local special packaging standards for such MAA-containing products.

In accordance with Executive Order 12612 (October 26, 1987), the Commission certifies that the rule does not have sufficient implications for federalism to warrant a Federalism Assessment.

List of Subjects in 16 CFR Part 1700

Consumer protection, Cosmetics, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission amends 16 CFR part 1700 as follows:

PART 1700—[AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91–601, secs. 1–9, 84 Stat. 1670–74, 15 U.S.C. 1471–76. Secs 1700.1 and 1700.14 also issued under Pub. L. 92–573, sec. 30(a), 88 Stat. 1231. 15 U.S.C. 2079(a).

2. In § 1700.14 the introductory text of paragraph (a) is republished and paragraph (a)(29) is added to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) Substances. The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(29) *Methacrylic acid*. Except as provided in the following sentence, liquid household products containing more than 5 percent methacrylic acid (weight-to-volume) in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a),(b) and (c). Methacrylic acid products applied by an absorbent material contained inside a dispenser (such as a pen-like marker) are exempt from this requirement provided that: (i) the methacrylic acid is contained by the absorbent material so that no free liquid is within the device, and (ii) under any reasonably foreseeable conditions of use the methacrylic acid will emerge only through the tip of the device.

Dated: June 15, 1999.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

Note: The following list will not appear in the Code of Federal Regulations.

List of Relevant Documents

1. Briefing memorandum from Susan Aitken, Ph.D., EH, to the Commission, ''Proposed Special Packaging Standard for Household Products Containing Methacrylic Acid,'' November 23, 1998.
2. Memorandum from Susan Aitken, Ph.D., EH, to Mary Ann Danello, Ph.D., Associate Executive Director, EH, ''Toxicity of Methacrylic Acid'' August 12, 1998.
3. Memorandum from Susan C. Aitken, Ph.D., EH, to Mary Ann Danello, Ph.D., EH, ''Human Injuries from Nail Products Containing Methacrylic Acid,'' August 12, 1998.
4. Memorandum from Marcia P. Robins, EC, to Susan Aitken, Ph.D., EH, ''Economic Considerations: Proposal to Require Child-Resistant Packaging for Household Products Containing Methacrylic Acid,'' August 17, 1998.
5. Memorandum from Tewabe A. Asebe, EH, to Susan Aitken, Ph.D., EH, ''Technical Feasibility, Practicability, and Appropriateness Determination for Proposed Rule to Require Special Packaging for Methacrylic Acid-Containing Products,'' August 17, 1998.
6. Memorandum from Bhooshan Bharat, Ph.D., LS, and Bhavi K. Jain, MS, LS, ''Report on the Testing of Nail Products for Titratable Acid Reserve (''TAR''), Quantification of Methacrylic Acid, and pH,'' August 20, 1998.
7. Briefing memorandum from Susan Aitken, Ph.D., EH, to the Commission, ''Final Rule to Require Child-Resistant Packaging for Household Products Containing More Than 5 Percent Methacrylic Acid in a Single Package,'' May 21, 1999.
8. Memorandum from Marcia P. Robins, EC, to Susan Aitken, Ph.D., EH, ''Final Rule for Child-Resistant Packaging for Household Products Containing Methacrylic Acid: Regulatory Flexibility Issues,'' April 8, 1999.
9. Memorandum from Tewabe A. Asebe, EH, to Susan Aitken, Ph.D., EH, ''Assessment of Technical Feasibility, Practicability, and Appropriateness for the Final Rule to Require Child-Resistant Packaging for Methacrylic Acid Products,'' April 23, 1999.

[FR Doc. 99–15580 Filed 6–17–99; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 98C–0158]

Listing of Color Additives For Coloring Meniscal Tacks; D&C Violet No. 2

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 D&C Violet No. 2 to color absorbable meniscal tacks made from poly(L-lactic acid). This action responds to a petition filed by Linvatec Corp.

DATES: This regulation is effective July 20, 1999; except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by July 19, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of March 13, 1998 (63 FR 12473), FDA announced that a color additive petition (CAP 8C0255) had been filed by Linvatec Corp., P.O. Box 2917, Largo, FL 33779–2917. The petition proposed to amend the color additive regulations in § 74.3602 *D&C Violet No. 2* (21 CFR 74.3602) to provide for the safe use of D&C Violet No. 2 to color absorbable meniscal tacks made from poly(L-lactic acid). The petition was filed under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(d)(1)).

II. Regulatory History

The regulatory history of D&C Violet No. 2 was summarized in a final rule published in the **Federal Register** of May 7, 1990 (55 FR 18865). Since the publication of the May 7, 1990, final rule, other uses of D&C Violet No. 2 have been approved by the agency. For example, in a final rule published in the **Federal Register** on April 23, 1998 (63 FR 20096), FDA amended § 74.3602 to list D&C Violet No. 2 as a color additive in glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures for use in general surgery.

III. 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 in the device comes into direct contact with the body for a significant period of time (section 721(a) of the act). D&C Violet No. 2 is added to absorbable meniscal tacks made from poly(L-lactic acid) in such a way that at least some of the color additive will come into contact with the body when the tacks are in place. In addition, the meniscal tacks are intended to be absorbed by the body, and during the absorption, the color additive will be deposited in body tissue. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the petitioned use of the color additive is subject to the statutory listing requirement.

IV. The Color Additive

D&C Violet No. 2 is principally 1-hydroxy-4-[(4-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 81–48–1). It is manufactured by either condensation of quinizarin with *p*-toluidine or by condensation of 1-hydroxy-halogenoanthroquinone with *p*-toluidine. Because no chemical reaction consumes all the starting materials and yields only the desired product, both the resulting reaction mixture and commercial product will contain residual amounts of the starting materials, including *p*-toluidine. This fact is significant because Weisburger et al., have demonstrated that *p*-toluidine is a carcinogen in the mouse (Ref. 1).

Residual amounts of reactants, such as *p*-toluidine, and manufacturing aids are commonly found as impurities in chemical products, including color additives.

V. Determination of Safety

Under the general safety standard of the act (section 721(b)(4)) for color additives, a color additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the color additive is safe for that use. FDA's color additive regulations (21 CFR 70.3(i)) define ''safe'' as ''reasonable certainty that no harm will result from the intended use of the color additive.''

The color additives anticancer, or Delaney, clause of the color additive amendments (section 721(b)(5)(B)) provides that no noningested color additive shall be deemed safe and shall be listed if, after tests that are appropriate for evaluating the safety of the additive for such use, it is found to induce cancer in man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

VI. Safety of The Petitioned Use of The Additive

FDA estimates that the petitioned use of the additive, D&C Violet No. 2, will result in exposure to no greater than 105 microgram (μg) per person over a 70-year lifetime or an estimated daily intake (EDI) of 4 nanograms per person per day (ng/p/d) (Ref. 2).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 3), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that the estimated small daily exposure resulting from the proposed use of this additive is safe.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by *p*-toluidine, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of *p*-toluidine has two aspects: (1) Assessment of exposure to the impurity from the proposed use of the additive, and (2) extrapolation of the risk observed in the animal bioassay to the conditions of exposure to humans.

A. p-Toluidine

FDA has estimated the lifetime exposure to *p*-toluidine from the petitioned use of D&C Violet No. 2 in absorbable meniscal tacks made from poly(L-lactic acid) to be no more than 0.008 ng/p/d (Ref. 4). The agency used data from a long-term rodent bioassay on *p*-toluidine conducted by Weisburger et al. (Ref. 1), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the proposed use of the additive. The authors reported that the rodent bioassay showed that the test material caused an increased incidence of hepatomas (liver tumors).

Based on the agency's estimate that exposure to *p*-toluidine will not exceed 0.008 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 5.3×10^{-13} or 5.3 in 10 trillion (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to *p*-toluidine is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to *p*-toluidine would result from the proposed use of the additive.

B. Specifications

The agency also has considered whether specifications are necessary to control the amount of *p*-toluidine present as an impurity in D&C Violet No. 2. The additive is currently produced as a certified color additive for use in externally applied drugs and cosmetics, in sutures, and in contact lenses in accordance with 21 CFR part 80. Based upon the low level of exposure to *p*-toluidine that results under the current specifications for D&C Violet No. 2 in § 74.1602 (21 CFR 74.1602), the agency concludes that the specifications listed in § 74.1602 are adequate to ensure the safe use of this color additive and to control the amount of *p*-toluidine that may exist as an impurity in the color additive when used in absorbable meniscal tacks made from poly(L-lactic acid).

VII. Conclusions on Safety

FDA has evaluated the data and information in the petition and other relevant material. Based on this information the agency concludes that: (1) The proposed use of D&C Violet No. 2, at a level not to exceed 0.15 percent

by weight of the tack material, for coloring absorbable meniscal tacks made from poly(L-lactic acid) is safe; and (2) the color additive will achieve its intended coloring effect, and thus, is suitable for this use. Further, the agency concludes that the color additive regulations in § 74.3602 should be amended as set forth below.

VIII. Inspection of Documents

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.

IX. Environmental Impact

The agency has previously considered the potential environmental effects of this rule as announced in the notice of filing for the petition (63 FR 12473, March 13, 1998). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

X. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XI. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 19, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with 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.

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

2. Memorandum from the Division of Product Manufacture and Use, Chemistry Review Team (FDA), to the Division of Product Policy (FDA), concerning ''CAP 8C0255 (MATS M2.0 & 2.1): Linvatec, Inc. (Submission of 28 January, 1998). Petition for the Safe Use of of [sic] D&C Violet #2 to Tint Poly(L-lactic acid) Meniscal Taks.'' dated April 13, 1998.

3. Kokoski, C. J., ''Regulatory Food Additive Toxicology'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger and J. K. Marquis, published by S. Karger, New York, NY, pp. 24–33, 1985.

4. Memorandum from Division of Petition Control (FDA), to Executive Secretary, Quantitative Risk Assessment Committee (FDA), concerning ''Estimate of the Upper Bound Lifetime Risk From *p*-toluidine in D&C Violet No. 2 Used as a Color Additive for Meniscal Tacks Made from Poly(L-lactic acid): CAP 8C0255,'' dated September 28, 1998.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 74 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

2. Section 74.3602 is amended by redesignating paragraph (b)(4) as paragraph (b)(5) and by adding new paragraph (b)(4) to read as follows:

§ 74.3602 D&C Violet No. 2.

* * * * *

(b) * * *

(4) The color additive, D&C Violet No. 2, may be safely used for coloring absorbable meniscal tacks made from poly (L-lactic acid) at a level not to exceed 0.15 percent by weight of the tack material.

* * * * *

Dated: June 3, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–15512 Filed 6–17–99; 8:45 am]

BILLING CODE 4160–01–F

OVERSEAS PRIVATE INVESTMENT CORPORATION

22 CFR Chapter VII

Abolishment of the U.S. International Development Cooperation Agency and Revision of Code of Federal Regulations Chapter Heading

AGENCY: Overseas Private Investment Corporation.

ACTION: Final rule.

SUMMARY: The Overseas Private Investment Corporation (''OPIC'') is amending its chapter in the Code of Federal Regulations (''CFR'') to delete the reference to the U.S. International Development Cooperation Agency (''IDCA''). Under the provisions of the Foreign Affairs Reform and Restructuring Act of 1998, IDCA was abolished, effective April 1, 1999.

DATES: Effective June 18, 1999.

FOR FURTHER INFORMATION CONTACT: Eli Landy, Legal Affairs Department, 202–336–8418, eland@opic.gov.

SUPPLEMENTARY INFORMATION: Under the provisions of the Foreign Affairs Reform and Restructuring Act of 1998, as contained in Public Law 105–277, IDCA was abolished, effective April 1, 1999.

The abolition of IDCA does not affect the status and validity of OPIC regulations, directives, rulings, policies; they continue in effect.

This is a procedural rule exempt from notice and comment under 5 U.S.C. 533(b)(3)(a). This rule is not a significant rule for purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget. This rule does not have a significant impact on small business entities under the Regulatory Flexibility Act.

For the reasons set forth in the preamble and under the authority of 22 U.S.C. 2191, revise the heading of