Communications, USDA, Washington, DC 20250.

(b) The organization and functions of the Office of the Secretary and the Office of Communications is as follows:

(1) The Office of the Secretary provides the overall policy guidance and direction of the activities of the Department of Agriculture. Department-wide policy statements and announcements are made from this office.

(2) The Office of the Secretary consists of the Secretary, Deputy Secretary, Under Secretaries, Assistant Secretaries, and other staff members.

(3) In the absence of the Secretary and the Deputy Secretary, responsibility for the operation of the Department of Agriculture is as delegated at part 2, subpart A, of this title.

(4) The Office of Communications provides policy direction, review, and coordination of public information programs of the Department of Agriculture. The Office of Communications has responsibility for maintaining the flow of information to the mass communications media, various constituency groups, and the general public.

(5) The Office of Communications is headed by the Director of Communications. In the Director's absence, the Office of Communications is headed by the Deputy Director.

Appendix A to Subpart A—Fee Schedule

* * * * *

Dated: July 18, 2000.

Dan Glickman,

Secretary of Agriculture.

[FR Doc. 00–18767 Filed 7–27–00; 8:45 am]

BILLING CODE 3410–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 99C–1455]

Listing of Color Additives for Coloring Sutures; 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 as a color additive in absorbable sutures prepared from homopolymers of glycolide for general surgery. The agency is also revising the nomenclature ''polyglactin 910 (glycolic-lactic acid polyester)'' to the generic nomenclature ''copolymers of 90 percent glycolide and 10 percent L-lactide.'' This action responds to a petition filed by Genzyme Surgical Products Corp.

DATES: This rule is effective August 29, 2000; except as to any provisions that may be stayed by the filing of proper objections. Submit written objections and requests for a hearing by August 28, 2000.

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 June 3, 1999 (64 FR 29871), FDA announced that a color additive petition (CAP 9C0266) had been filed by Genzyme Surgical Products Corp., 600 Airport Rd., Fall River, MA 02720. 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 as a color additive in absorbable sutures prepared from homopolymers of glycolide for general surgery. The petition also proposed that the nomenclature ''polyglactin 910 (glycolic-lactic acid polyester)'' be revised to the generic nomenclature ''copolymers of 90 percent glycolide and 10 percent L-lactide.'' 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** of June 18, 1999 (64 FR 32803), FDA amended § 74.3602 to list D&C Violet No. 2 as a color additive in absorbable meniscal tacks made from poly(L-lactic acid).

III. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (Public Law 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 sutures prepared from homopolymers of glycolide in such a way that at least some of the color additive will come into contact with the body when the sutures are in place. In addition, the sutures 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) of the act) 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 over a 70-year lifetime of 156 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 average individual lifetime exposure to *p*-toluidine from the petitioned use of D&C Violet No. 2 in absorbable sutures prepared from homopolymers of glycolide to be no more than 0.3 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 0.3 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 2×10^{-11} or 2 in 100 billion (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 has also 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, in meniscal tacks, 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 sutures prepared from homopolymers of glycolide.

VII. Conclusions

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 0.2 percent by weight of the suture material, for coloring absorbable sutures prepared from homopolymers of glycolide for general surgery is safe; and (2) the color additive will achieve its intended coloring effect, and thus, is suitable for this use. Further, FDA has carefully considered the proposal to revise the nomenclature ''polyglactin 910 (glycolic-lactic acid polyester),'' which is currently listed in § 74.3602(b)(2)(i). The agency concludes that the nomenclature, which is a trade name, should be revised to the generic nomenclature ''copolymers of 90 percent glycolide and 10 percent L-lactide.'' Finally, 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 environmental effects of this rule as announced in the notice of filing for CAP 9C0266 (64 FR 29871, June 3, 1999). 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 file with the Dockets Management Branch (address above) written objections by August 28, 2000. 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 are to be submitted and are to 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 notice of the objections that the agency has received or lack thereof in the **Federal Register**.

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 Petition Control (FDA), concerning ''CAP 9C0266 (MATS M2.0 & 2.1): Genzyme Surgical Products Corp. (Submission of March 18, 1999, facsimile dated April 9, 1999, and amendment of April 29, 1999). Request for the Listing of D&C Violet No. 2 in Glycolide Homopolymer Absorbable Sutures for General Surgery,'' dated June 18, 1999.

3. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' *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 ''Estimation of the Upper-Bound Lifetime Risk From *p*-Toluidine in D&C Violet No. 2 When Used as a Color Additive for Sutures Used in General Surgery: CAP 9C0266,'' dated July 21, 1999.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Foods, 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 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 revising paragraph (b)(2)(i) and by adding paragraph (b)(2)(vi) to read as follows:

§ 74.3602 D&C Violet No. 2.

* * * * *

(b) * * *

(2) * * *

(i) At a level not to exceed 0.2 percent by weight of the suture material for coloring copolymers of 90 percent glycolide and 10 percent L-lactide synthetic absorbable sutures for use in general and ophthalmic surgery; and

* * * * *

(vi) At a level not to exceed 0.2 percent by weight of the suture material for coloring absorbable sutures prepared from homopolymers of glycolide for use in general surgery.

* * * * *

Dated: July 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19047 Filed 7–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

23 CFR Part 1313

[Docket No. NHTSA–00–7476]

RIN 2127–AH42

Incentive Grants for Alcohol-Impaired Driving Prevention Programs

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This document announces that the amendments to the regulations that were published in an interim final rule to reflect changes made to the Section 410 program by the Transportation Equity Act for the 21st Century (TEA–21) will remain in effect with minor changes. Under the final rule, States have two alternative means for qualifying for a Section 410 basic grant.

States may qualify for a ''programmatic basic grant'' if they submit materials demonstrating that they meet five out of seven grant criteria. Alternatively, States may qualify for a ''performance basic grant'' by submitting data demonstrating that the State has successively reduced the percentage of alcohol-impaired fatally injured drivers in the State over a three-year period. States that qualify under both sets of requirements may receive both programmatic and performance basic grants. In addition, States that are eligible for one or both of the basic grants may qualify also for a supplemental grant.

This final rule establishes the criteria States must meet and the procedures they must follow to qualify for Section 410 incentive grants, beginning in FY 2000. This final rule also modifies some features of the interim regulations that relate to the graduated driver's licensing system criterion and the young adult drinking and driving program criterion.

DATES: This final rule becomes effective on July 28, 2000.

FOR FURTHER INFORMATION CONTACT: Mr. Glenn Karr, Office of State and Community Services, NSC–10, National Highway Traffic Safety Administration, 400 Seventh Street S.W., Washington, DC 20590 telephone (202) 366–2121; or Mr. Christopher A. Cook, Office of Chief Counsel, NCC–30, National Highway Traffic Safety Administration, 400 Seventh Street, S.W., Washington, DC 20590, telephone (202) 366–1834.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

The Section 410 program was created by the Drunk Driving Prevention Act of 1988 and codified in 23 U.S.C. 410. As originally conceived, States could qualify for basic and supplemental grants under the Section 410 program if they met certain criteria. To qualify for a basic grant, States had to provide for an expedited driver's license suspension or revocation system and a self-sustaining drunk driving prevention program. To qualify for a supplemental grant, States had to be eligible for a basic grant and provide for a mandatory blood alcohol testing program, an underage drinking program, an open