rather than the exhibition of the planetarium being incidental to the presentation of images or lights. This commenter distinguishes planetaria from articles such as the concert organ described in the November 18, 1988, **Federal Register** notice on the basis that, the commenter claims, during planetarium presentations viewers ask questions about the planetarium and the lecturer will often discuss it. Further, many persons visit a planetarium to see it and hear a lecture about it without seeing a planetarium show.

The other commenter opposing the proposal, a Canadian exporter of large format motion picture projection systems, also contends that its system is often of special interest to viewers of presentations utilizing the system because the system is unique. The commenter states that it has no direct competitors in the U.S. Further, the commenter states that many of its systems are purchased by institutions which receive public funding and that it would be consistent for the Government to support these institutions by allowing importation of the systems on a duty-free basis.

Analysis of Comments

The commenter supporting the proposal provides no evidence to support its allegation that the current practice results in unfair competition for it with regard to planetaria projects in the U.S. In the absence of such supporting evidence, we do not consider this comment relevant to the proposed change.

The contentions by the second commenter opposing the proposal that it has no direct competition in the United States and that, since many of the institutions which purchase its systems are supported by public funding, the Government should allow duty-free admission of its systems also are not considered relevant to the proposal. These considerations are not provided for in the tariff provision and cannot be dispositive of the proposal.

We are unconvinced by the arguments of the commenters opposing the proposal that planetaria are imported for the purpose of being exhibited, rather than being used in the presentation of exhibited material. Descriptive material submitted by the commenters describes or illustrates specially built dome-shaped theaters and special screens and special films for use with the planetaria or special projection systems. These theaters and screens are specially constructed for exhibition of the materials *projected* by the planetaria. If the planetaria were only to be exhibited, there would be no necessity for the special construction of uniquely shaped theaters and screens, or for the purchase of special films for projection by them. We conclude that planetaria are imported to be used for the function for which they are designed, i.e., to project astronomical programs for such things as popular-science performances in public observatories, museums, and tourist and recreational centers and to be used as a training and teaching aid in astronomy and navigation.

As stated above, in interpreting subheading 9812.00.20, HTSUSA, Customs has held that the article for which duty-free entry is sought must itself be imported for exhibition; another use of it may only be incidental. The legislative history and stated Congressional intent for the predecessors of subheading 9812.00.20 strongly support this interpretation. (See the Act of September 14, 1959; 73 Stat. 549, consolidating several duty-free provisions into paragraph 1809 of the Tariff Act of 1930, the immediate predecessor of item 862.10, TSUS (paragraph 1809 was not intended to be substantively changed when succeeded by item 862.10; see vol. 2, *Tariff Classification Study, Explanatory Notes* (1960), p. 698). See also, Senate Finance Comm. Rep., *Tourist Literature—Works of Art, Etc.—Importation*, Sen. Rep. No. 695, 86th Cong. 1st Sess. (1959), printed at 1959 U.S.C.C.A.N. 2525.) The published decisions interpreting the predecessors of subheading 9812.00.20 are also consistent with this interpretation (see vol. 1, *Digest of Customs and Related Laws and of Decisions Thereunder*, pp. 1127–1129).

The Customs rulings permitting the duty-free entry of planetaria imported to be used to project or exhibit programs are inconsistent with Customs interpretation of the predecessors of subheading 9812.00.20, HTSUSA. This interpretation by Customs is consistent with the legislative history and Congressional intent described above, as well as published decisions interpreting the predecessors of subheading 9812.00.20. Accordingly, we have reached the following decision.

Decision

After careful analysis of the submitted comments and further review of this matter, the proposed change in the application of the criteria used in determining eligibility for duty-free admission under the tariff provision now in subheading 9812.00.20, HTSUSA, with regard to planetaria is adopted. Planetaria which are to be utilized for the making of presentations or demonstrations will normally be considered as being imported for that purpose. Such planetaria will not be eligible for duty-free admission as articles imported for exhibition by a qualifying institution or State or municipal corporation under subheading 9812.00.20. Only if planetaria are imported primarily for exhibition themselves (e.g., because they are of historical value), could they qualify for duty-free admission under subheading 9812.00.20, provided other requirements for such admission are met.

Approved: May 29, 1990.

Michael H. Lane,

Acting Commissioner of Customs.

Peter K. Nunez,

Assistant Secretary of the Treasury.

[FR Doc. 90-12910 Filed 6-4-90; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 74

[Docket No. 82C-0399]

Listing of Color Additives for Coloring Contact Lenses; D&C Red No. 17

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 Red No. 17 for coloring contact lenses. This action is in response to a petition filed by Polymer Technology Corp.

DATES: Effective July 6, 1990, except as to any provisions that may be stayed by the filing of proper objections; written objections by July 5, 1990.

ADDRESSES: 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: Andrew D. Laumbach, 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 January 28, 1983 (48 FR 4051), FDA announced that a color additive petition (CAP 3C0163) had been filed by Polymer Technology Corp., 33 Industrial

Way, Wilmington, MA 01887, proposing that the color additive regulations be amended to provide for the safe use of D&C Red No. 17 for coloring 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 in contact with the body for a significant period of time (21 U.S.C. 376(a)). In the case of the use of D&C Red No. 17, the color additive is added to contact lenses in such a way that at least some of the additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed in the eye 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. Determination of Safety

A. Legal Standard

Under section 706(b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376(b)(4)), the so-called "general safety clause," a color additive cannot be listed for a particular use unless a fair evaluation of the data establishes that the color additive is safe for that use. Under FDA regulations (21 CFR 70.3(i)), a color additive is safe if there is convincing evidence that establishes with reasonable certainty that no harm will result from the proposed use of an additive.

In addition, the anticancer or Delaney clause of the Color additive Amendments (section 706(b)(5)(B) of the act) provides that a noningested color additive shall be deemed unsafe and shall not 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.

B. Exposure to the Color Additive

From the data submitted and other relevant information, FDA concludes that the upper limit of exposure to D&C Red No. 17 from its use in coloring contact lenses is 280 nanograms per day. The agency calculated this upper limit of exposure based on the following factors. First, based on general worst-case information, FDA estimated that maximum use level of D&C Red No. 17 is 50 micrograms per lens (Ref. 1). Second, the agency made two worst-case assumptions: (1) That a user will replace lenses tinted with D&C Red No. 17 once each year with a new pair of lenses tinted with D&C Red No. 17 at the maximum use level, and (2) that 100 percent of the color additive migrates from these lenses into the eye over the 1-year period. Because these assumptions represent the worst case, exposure to D&C Red No. 17 from its use for coloring contact lenses is likely to be far less than 280 nanograms per day.

C. Toxicology

When presented with a substance whose use will result in the extremely low levels of exposure like those that the agency estimates from the use of D&C Red No. 17 in contact lenses, FDA does not ordinarily consider chronic toxicity testing to be necessary to determine the safety of the color additive's use (Ref. 2). Therefore, FDA did not require additional chronic testing to supplement chronic tests submitted in support of earlier listings of D&C Red No. 17. However, FDA has reviewed the in vitro cytotsxicity studies, ocular and interocular irritation studies in rabbits, and acute toxicity studies in mice submitted by the petitioner. These new studies showed no ocular irritation from the lens extracts and no adverse effects in the in vitro cytotoxicity testing.

Chronic feeding studies and a life-time skin painting study in mice, used to originally list D&C Red No. 17, show no indication of carcinogenicity.

D. Carcinogenic Impurities

1. 4-Aminoazobenzene

Although D&C Red No. 17 itself is not shown to cause cancer, specifications for the color additive in 21 CFR 74.1317 contain a limitation of not more than 0.1 percent for 4-aminoazobenzene, a possible carcinogenic impurity. FDA records show that this impurity has never been detected in any batch of D&C Red No. 17 certified by FDA.

FDA has previously discussed in detail the carcinogenicity of 4-aminoazobenzene in the agency's final rule listing FD&C Yellow No. 6 (51 FR 41765 at 41776; November 19, 1986). As stated in that document, 4-aminoazobenzene is carcinogenic when administered in the diet of Wistar rats, causing liver cell neoplasms and stomach papillomas, and is carcinogenic when applied dermally to rats.

A study implicating 4-aminoazobenzene as a carcinogen by dietary administration to Wistar rats was reported by Kirby et al. (Ref. 3). The study reported that 7 of the 16 animals in the treated group were found to have liver cell neoplasms after a total of 120 weeks of exposure. Six rats in this group displayed papillomas of the stomach. No information is available to determine whether any of the individual rats had neoplasms in both the liver and the stomach. Although the dose was allowed to vary throughout the experiment, the Center for Food Safety and Applied Nutrition's Qualitative Risk Assessment Committee calculated the average dose over 120 weeks to be 0.25 percent in the diet (Ref. 4).

4-Aminoazobenzene was also implicated as a carcinogen in a skin painting study in which 1.0 milliliter of a 0.2-percent acetone solution containing 4-aminoazobenzene (corresponding to a dose of 2.0 milligrams of 4-aminoazobenzene per application) was applied to the skin twice weekly on six male albino rats as part of a larger study utilizing a number of azo compounds (Ref. 5). All six male rats in the treatment group displayed skin neoplasms after 123 weeks compared to none in the control group.

2. Aniline

Specifications for D&C Red No. 17 in 21 CFR 74.1317 also contain a limitation of not more than 0.2 percent for aniline, another carcinogenic impurity. FDA discussed in detail the carcinogenicity of aniline in the agency's November 19, 1986, final rule listing FD&C Yellow No. 6. As stated in that document, aniline is a carcinogen by dietary administration to both rats and mice, causing spleen tumors.

Data reported by the National Cancer Institute demonstrated that aniline was carcinogenic to the spleen of Fischer 344 rats (Ref. 6). This finding was subsequently verified by a dietary study performed by the Chemical Industry Institute of Toxicology (CIIT) using the same strain of rat (Ref. 7). FDA used data from the CIIT study to estimate the lifetime risk of cancer from aniline, if it were present at the limit specified in 21 CFR 74.1317.

3. Prior Action

In the past, FDA refused to list a color additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that scientific developments and experience with risk assessment procedures make it possible for FDA to establish the safety of an additive that contains a

carcinogenic chemical, but that has not itself been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic constituent. Since that decision, FDA has approved the uses of several other color additives that contain carcinogenic impurities, including the use of D&C Green No. 6 for coloring contact lenses (48 FR 13020; March 29, 1983), and the use of D&C Green No. 5 (47 FR 24278; June 4, 1982), and of D&C Red No. 6 and D&C Red No. 7 (47 FR 57661; December 28, 1982) for coloring drugs and cosmetics.

The agency now considers the Delaney clause to be applicable only when the color additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, is properly evaluated under the general safety clause of the statute, using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical, but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

4. Risk Assessment

Using risk assessment procedures to estimate the upper limit lifetime risk presented by the use of D&C No. 17, with its possible impurities, to color contact lenses, the agency has concluded that the additive is safe under the proposed conditions of use (Ref. 8). The risk assessment consists of two parts: (1) Estimation of exposure to 4-aminoazobenzene and aniline from the use of D&C Red No. 17 to color contact lenses, and (2) extrapolation of the risk from 4-aminoazobenzene and aniline observed in the bioassays of those substances to the conditions of exposure in humans.

E. Exposure

As explained above, FDA estimated that the maximum level of exposure to D&C Red No. 17 from its use in coloring contact lenses is 280 nanograms per day. Under the current specifications for D&C Red No. 17, the level of 4-aminoazobenzene and aniline in the color additive is not to exceed 0.1 percent and 0.2 percent, respectively. Thus, the maximum exposure from these impurities that could result from the daily use of contact lenses that are colored with D&C Red No. 17 are 0.015 nanogram per day and 0.03 nanogram per day, respectively.

F. Risk Extrapolation

FDA has estimated the risk from the 4-aminoazobenzene and aniline impurities from the use of D&C Red No. 17 for coloring contact lenses based upon the assumption that the impurities are present at the maximum level permitted by the color additive regulation. The risk for 4-aminoazobenzene was estimated by extrapolating from the risk observed in the Kirby et al., animal study to the very low levels of estimated exposure for humans; the risk for aniline was estimated from the risk observed in the CIIT-sponsored animal studies.

In these extrapolations, the agency used a quantitative risk assessment procedure (linear proportional model) similar to the methods used to examine the risk associated with the presence of minor carcinogenic impurities in D&C Green No. 6 and the other color additives mentioned above. This procedure is not likely to underestimate the actual risk from the very low doses. In fact, the estimate of the risk may be exaggerated because the models used are designed to estimate maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the use of this color additive.

Based on this risk assessment procedure and a worse-case daily exposure estimate of 0.015 nanograms of 4-aminoazobenzene, FDA estimates that the upper-bound limit of individual lifetime risk from potential exposure to 4-aminoazobenzene from the use of D&C Red No. 17 is $2X10^{-7}$ or 2 in 10 million. Also based on this risk assessment procedure and a worse-case daily exposure estimate of 0.03 nanogram, FDA estimates that the upper-bound limit of individual lifetime risk from potential exposure to aniline from the use of D&C Red No. 17 is $2X10^{-10}$ or 2 in 10 billion. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to 4-aminoazobenzene and aniline is expected to be substantially less than the estimated daily exposure and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to 4-aminoazobenzene and aniline that might result from the proposed use of the color additive.

G. Specifications

Based on the low level of exposure to 4-aminoazobenzene and aniline that could result from current specifications for D&C Red No. 17, the agency concludes that these specifications are adequate to assure the safe use of the color additive and to control the amount of 4-aminoazobenzene and aniline that could exist as impurities in the color additive when used in contact lenses. Therefore, the agency concludes that it is not necessary to amend the current specifications for this color additive when it is used to color contact lenses.

IV. Conclusion

Based on the available toxicity data, the small amount of color additive added to the contact lens, the agency's exposure calculation, and the low risk from the possible presence of the impurities, FDA finds that the color additive D&C Red No. 17 is safe and suitable for use in contact lenses. FDA further concludes that no limitation on the amount of the color additive D&C Red No. 17 in the lens is required, except the general requirement that the use level not exceed the amount necessary to accomplish the intended technical effect.

V. 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.

VI. 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.

VII. 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 July 22, 1988, from the Food and Color Additives Review Section, to the Indirect Additives Branch, "CAP 3C0163-Polymer Technology Corp., D&C Red No. 17 for Use in Coloring Contact Lenses."

2. Kokoski, C.J., "Regulatory Food Additive Toxicology" in Chemical Safety Regulation and Compliance, edited by F. Hamburger, J.K. Marquis, and S. Karger, New York, pp. 24–33, 1985.

3. Kirby, A. H. M. et al., "The Induction of Liver Tumor by 4-Aminoazobenzene and *N,N*-Dimethyl Derivative in Rats on a Restricted Diet," Journal of Pathology and Bacteriology, 59:1–18, 1947.

4. Memorandum, Quantitative Risk Assessment Committee, "Report of the Committee on 4-Aminoazobenzene (Dietary and Skin Exposure)," CAP 8C0068, December 20, 1983.

5. Fare, G., "Rat Skin Carcinogenesis by Topical Application of Some Azo Dyes," Cancer Research, 26:2406, 1966.

6. "National Cancer Institute, "Bioassay of Aniline Hydrochloride for Possible Carcinogenicity," NCI Technical Report No. 130, NCI–CG–TR–130, 1978.

7. Chemical Industry Institute of Toxicology, Research Triangle Park, NC, "104 Week Chronic Toxicity Study in Rats: "Aniline Hydrochloride," Final Report, January 4, 1982.

8. Report of the Quantitative Risk Assessment Committee, "Upperbound Risk from Aniline and 4-Aminoazobenzene in CAP 3C0163," June 23, 1989.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 5, 1990 file with the Dockets Management Branch 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. FDA will publish notice of the objections that the agency has received or lack thereof in the Federal Register.

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: 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 § 74.3230 is added to subpart D to read as follows:

§ 74.3230 D&C Red No. 17.

(a) *Identity and specifications.* The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317(a)(1) and (b).

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

(2) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic 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) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

Dated: May 29, 1990.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–12930 Filed 6–4–90; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 178

[Docket No. 89F–0179]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 4,4′-bis(α,α′-dimethylbenzyl)diphenylamine as an antioxidant in polypropylene intended for food-contact use. This action responds to a petition filed by Uniroyal Chemical Co., Inc.

DATES: Effective June 5, 1990; written objections and requests for a hearing by July 5, 1990.

ADDRESSES: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 7, 1989 (54 FR 24425), FDA announced that a petition (FAP 7B4019) had been filed by Uniroyal Chemical Co., Inc., World Headquarters, Middlebury, CT 06749, proposing that § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) be amended to provide for the safe use of 4,4′-bis(α,α′-dimethylbenzyl)diphenylamine as an antioxidant for polypropylene intended for food-contact use.

FDA, in its evaluation of the safety of this additive, reviewed the safety of both the additive and the starting materials used to manufacture the additive. Toxicology data are not available to implicate 4,4′-bis(α,α′-dimethylbenzyl)diphenylamine as a cancer-causing chemical. However, aniline and 4-aminobiphenyl, which could be present as impurities in the additive, have been shown to cause cancer in test animals. Residual amounts to reactants and byproducts, such as these chemicals, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act

(the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d Sess. 4 (1958)). This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additive Amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(C)(3)(A))) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain carcinogenic chemicals as trace impurities. An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the Federal Register of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer even though it contained a carcinogenic impurity. Since that decision, FDA has approved the use of other color additives and food additives on the same basis.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use

FDA estimates that the petitioned use of 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine will result in extremely low levels of exposure of this additive. The agency has calculated an estimated daily intake of 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine based on considerations such as the migration of the additive under the most severe intended use conditions and the probable concentration of the additive in the daily diet from food-contact articles that contain this substance. The estimated daily intake for the additive is 7.2 micrograms per day (2.4 parts per billion in the diet).

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2) and has not required such testing here. However, the agency has reviewed available acute oral rat and Ames mutagenicity data for the additive. These data provided no evidence that the additive is toxic or mutagenic. On the basis of these data and of the low level of migration of the additive, the agency concludes that there is an adequate margin of safety for the proposed use of the additive.

FDA has evaluated the safety of this additive under the general safety clause, using risk assessment procedures to estimate the upper-bound limit of risk presented by the carcinogenic chemicals that may be present as impurities in the additive. Based on this evaluation, the agency has concluded that the additive is safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that it has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see, e.g., 49 FR 13018 and 13019; April 2, 1984). This risk evaluation of the carcinogenic impurities aniline and 4-aminobiphenyl has two aspects: (1) Assessment of the worst-case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

A. Aniline

Based on the fraction of the daily diet that may be in contact with surfaces containing 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine and on the level of aniline that may be present in the additive (Ref. 3), FDA estimated the hypothetical worst-case exposure to aniline from the petitioned use of this additive to be 81 nanograms per day. The agency used data in a carcinogenesis bioassay on aniline (Ref. 4) to estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine. The results of the bioassay on aniline demonstrated that the material was carcinogenic for male rats under the conditions of the study, inducing fibrosarcoma, stromal sarcoma, capsular sarcoma, hemangiosarcoma, and osteogenic sarcoma of the spleen.

FDA reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on aniline. The agency further concluded that the aniline bioassay provided the appropriate basis on which to calculate an estimate of the upper-bound level of lifetime human risk from potential exposure to aniline stemming from the proposed use of 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine. The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of the food additive.

Based on a worst-case exposure of 81 nanograms per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from potential exposure to aniline from the proposed use of 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine is 7×10^{-10}, or less than 1 in 1.4 billion (Ref 5). Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to aniline is expected to be substantially less than the estimated daily intake, and therefore the calculated upper-bound risk would

be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to aniline that might result from the proposed use of 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine.

B. 4-Aminobiphenyl

Based on the fraction of the daily diet that may be in contact with surfaces containing 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine and on the level of 4-aminobiphenyl that may be present in the additive (Ref. 3), FDA estimated the hypothetical worst-case exposure to 4-aminobiphenyl from the petitioned use of this additive to be 41 nanograms per person per day. The agency used data in a carcinogenesis bioassay on 4-aminobiphenyl conducted both by Block et al. and by Rippe et al. (Refs. 6 and 7), to estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine. The results of these bioassay on 4-aminobiphenyl demonstrated that this material was carcinogenic for female dogs under the conditions of the studies, causing papilloma of the bladder.

FDA reviewed the bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 4-aminobiphenyl. The agency further concluded that the 4-aminobiphenyl bioassay provided the appropriate basis on which to calculate an estimate of the upper-bound level of lifetime human cancer risk from potential exposure to 4-aminobiphenyl.

Based on a worst-case exposure of 41 nanograms per person per day, FDA estimates, using a linear proportional model, that the upper-bound limit of individual lifetime risk from potential exposure to 4-aminobiphenyl from the proposed use of 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine is 2×10^{-7} or less than 2 in 10 million (Ref. 5). Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to 4-aminobiphenyl is expected to be substantially less than the estimated daily intake, and therefore, the calculated upper-bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to 4-aminobiphenyl that might result from the proposed use of 4,4'-bis(α,α'-dimethylbenzyl)diphenylamine.

III. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of the aniline and 4-aminobiphenyl in the food additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the levels at which aniline and 4-aminobiphenyl are used in production of the additive, the agency would not expect these impurities to become components of food at other than extremely small levels. (2) The upper-bound limit of lifetime risk from exposure to these impurities, even under worst-case assumptions, is very low, less than 1 in 1.4 billion and 2 in 10 million for aniline and 4-aminobiphenyl, respectively.

IV. Conclusion of Safety

FDA has evaluated the available toxicity and other relevant data and concludes that the proposed use for the additive is safe, and that 21 CFR 178.2010(b) should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), 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 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. 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.

VI. 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. Carr, G. M., "Carcinogenicity Testing Program" in "Food Safety: Where Are We?" Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, July 1979, p. 59.

2. Kokoski, C. J., "Regulatory Food Additive Toxicology," presented at the Second International Conference on Safety Evaluation and Regulation of Chemicals, October 24, 1983, Cambridge, MA.

3. Memorandum dated October 21, 1988, from Food and Color Additives Review Section (HFF-415) to Indirect Additive Branch, FAP 7B4019—Uniroyal Chemical Co. Exposure Estimates for Aniline and 4-Aminodiphenyl.

4. Chemical Industry Institute of Toxicology-Research, Triangle Park, NC., "104-Week Chronic Toxicity Study in Rats: Aniline Hydrochloride," final report, January 4, 1982.

5. Report of the Quantitative Risk Assessment Committee, "Estimation of Upper Bound Risks for Aniline and 4-Aminobiphenyl from Proposed Uses in FAP 7B4019," February 14, 1989.

6. Block, N. L. et. al., "The Initiation, Process and Diagnosis of Dog Bladder Cancer Induced by 4-Aminobiphenyl," Investigative Urology, 16:50–54, 1978.

7. Rippe, D. F. et al., "Urinary Bladder Carcinogenesis in Dogs: Preliminary Studies on Cellular Immunity." Transplantation Proceedings, 7:495–501, 1975.

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 5, 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 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.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.2010 is amended in paragraph (b) by alphabetically adding a new entry to the table to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* *
4,4'-Bis(α,α-dimethylbenzyl)diphenylamine (CAS Reg. No. 10081-67-1).	For use at levels not to exceed 0.3 percent by weight of polypropylene complying with § 177.1520(c) of this chapter. The polypropylene articles are limited to use in contact with non-fatty foods only.
* * *	* *

Dated: May 29, 1990.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-12931 Filed 6-4-90; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

28 CFR Part 0

[Tax Division Directive No. 82]

Redelegation of Authority To Compromise and Close Civil Claims

AGENCY: Tax Division, Department of Justice.

ACTION: Final rule.

SUMMARY: This directive increases the authority of the Attorney-in-Charge of the Dallas Field Office in accepting offers in compromise from $10,000 to $25,000. Under this new directive, the Attorney-in-Charge of the Dallas Field Office can accept offers in compromise in all civil cases in which the amount of the Government concession, exclusive of statutory interest, does not exceed $25,000. This directive supersedes Tax Division Directive No. 54.

DATES: June 5, 1990.

FOR FURTHER INFORMATION CONTACT: Milan Karlan, Tax Division, Department of Justice, Washington, DC 20530 (202) 724-6567.

SUPPLEMENTARY INFORMATION: This directive increase the authority of the Attorney-in-Charge of the Dallas Field Office in accepting offers in compromise from $10,000 to $25,000. Because of an increase in the value of claims arising under the jurisdiction of the Dallas Field Office, it has become necessary in the interest of efficient management of the Department to increase the settlement authority of the Attorney-in-Charge of the Dallas Field Office. Under this new directive, the Attorney-in-Charge can accept offers in compromise in all civil cases in which the amount of the Government concession, exclusive of statutory interest, does not exceed $25,000. This directive supersedes Tax Division Directive No. 54.

This rule relates to internal agency management. Therefore, pursuant to 5 U.S.C. 553, notice of proposed rule making and opportunity for comments are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register**. This regulation is not a major rule within the meaning of Executive Order 12291. Therefore a regulatory impact analysis has not been prepared. Finally, this regulation does not have an impact on small entities and, therefore, is not subject to the Regulatory Flexibility Act.

List of Subjects in 28 CFR Part 0

Authority delegations.

Accordingly, 28 CFR part 0 is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

The authority citation for part 0 continues to read as follows:

Authority: 5 U.S.C. 301, 2303, 3103; 8 U.S.C. 1103, 1324A, 1427(g); 15 U.S.C. 644(k); 18 U.S.C. 2254, 3621, 3622, 4001, 4041, 4042, 4044, 4082, 4201 *et seq.*, 6003(b); 21 U.S.C. 871, 881(d), 904; 22 U.S.C. 263a, 1621-1645o, 1622 note; 28 U.S.C. 509, 510, 515, 516, 519, 524, 543, 552, 552a, 569; 31 U.S.C. 1108, 3801 *et seq.*; 50 U.S.C. App. 1989b, 2001-2017p; Pub. L. No. 91-513, sec. 501; EO 11919; EO 11267; EO 11300.

Directive No. 54 [Removed]

2. Tax Division Directive No. 54 is removed.

3. Tax Division Directive No. 82 is added to read as follows:

[Directive No. 82]

By virtue of the authority vested in me by part 0 of title 28 of the Code of Federal Regulations, particularly sections 0.70, 0.160, 0.162, 0.164, 0.166, and 0.168, it is hereby ordered as follows:

Section 1. The Chiefs of the Civil Trial Sections, the Claims Court Section, the Appellate Section, the Office of Special Litigation, and the Attorney-in-Charge of the Dallas Field Office are authorized to reject offers in compromise, regardless of amount, provided that such action is not opposed by the agency or agencies involved.

Section 2. Subject to the conditions and limitations set forth in Section 8 hereof, the Chiefs of the Civil Trial Sections, the Claims Court Section and the Office of Special Litigation are authorized to.

(A) Accept offers in compromise in all civil cases in which the amount of the Government's concession, exclusive of statutory interest, does not exceed $200,000,

(B) Approve administrative settlements not exceeding $100,000, exclusive of statutory interest,

(C) Approve concessions (other than by compromise) of civil claims asserted by the Government in all cases in which the gross amount of the original claim does not exceed $100,000,

(D) Accept offers in compromise in injunction or declaratory judgment suits against the United States in which the principal amount of the related liability, if any, does not exceed $200,000, and

(E) Accept offers in compromise in all other nonmonetary cases,

provided that such action is not opposed by the agency or agencies involved, and provided further that the case is not subject to reference to the Joint Committee on Taxation.

Section 3. Subject to the conditions and limitations set forth in Section 8 hereof, the Chief of the Appellate Section is authorized to:

(A) Accept offers in compromise with reference to litigating hazards of the issues on appeal in all civil cases in which the amount of the Government's concession, exclusive of statutory interest, does not exceed $200,000,

(B) Accept offers in compromise in declaratory judgment suits against the United States in which the principal amount of the related liability, if any, does not exceed $200,000, and

(C) Accept offers in compromise in all other nonmonetary cases which do not involve issues concerning collectibility,

provided that such action is not opposed by the agency or agencies involved or the chief of the section in which the case originated, and provided further that the case is not subject to reference to the Joint Committee on Taxation.

Section 4. Subject to the conditions and limitations set forth in Section 8 hereof, the Attorney-in-Charge of the Dallas Field Office is authorized to accept offers in compromise in all civil cases in which the amount of the Government's concession, exclusive of statutory interest, does not exceed $25,000, provided that such action is not opposed by the agency or agencies involved, and provided further that the case is not subject to reference to the Joint Committee on Taxation.

Section 5. Subject to the conditions and limitations set forth in Section 8 hereof, the Chief of the Office of Review is authorized to:

(A) Accept offers in compromise in all civil cases in which the amount of the