By direction of the Commission.
Donald S. Clark,
Secretary.
[FR Doc. 90-12956 Filed 6-4-90; 8:45 am]
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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 152

[T.D. 90-44]

Application of Criteria Utilized in Determining the Eligibility of Planetaria for Duty-Free Admission Under Subheading 9812.00.20, HTSUSA

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final interpretative rule.

SUMMARY: This document gives notice of a change in Customs application to planetaria of the criteria for duty-free admission as articles imported for exhibition by a qualifying institution or State or municipal corporation under subheading 9812.00.20, Harmonized Tariff Schedule of the U.S. Annotated (HTSUSA). Customs has permitted the duty-free admission of planetaria under item 862.10, Tariff Schedules of the U.S. (TSUS), the predecessor in the TSUS of subheading 9812.00.20, even though planetaria are usually imported for the purpose of making presentations rather than serving as the exhibit to be viewed. Planetaria now will not ordinarily qualify for duty-free admission, under subheading 9812.00.20, if they are to be utilized for the making of presentations or demonstrations.

EFFECTIVE DATE: This decision will be effective as to merchandise entered, or withdrawn from warehouse for consumption, on or after July 5, 1990.

FOR FURTHER INFORMATION CONTACT: Paul G. Hegland, Commercial Rulings Division, Office of Regulations and Rulings, (202) 566-5856.

SUPPLEMENTARY INFORMATION:

Background

In connection with a request for a ruling on the duty-free entry of a planetarium projector for a university, Customs has reviewed its application of the criteria for determining the applicability of item 862.10, TSUS, to planetaria. Customs published notice in the **Federal Register** on November 18, 1988 (53 FR 46625), proposing a change in its application of these criteria with regard to planetaria and inviting public comments on the proposed change. Three (3) comments were received in response to the notice.

Until replacement of the TSUS by the HTSUSA on January 1, 1989, item 862.10, TSUS, provided for the duty-free entry of articles for permanent exhibition under bond when they are imported by certain types of organizations or for any State or municipal corporation for exhibition. Headnote 1 of part 5B, Schedule 8, TSUS, which covered articles for permanent exhibition under bond, including item 862.10, stated that the provisions therein "do not apply to articles intended for sale or for any purpose other than exhibition or erecting a public monument * * *." Item 862.10 was similar to predecessor provisions dating back at least as far as 1897 (paragraph 702, Tariff Act of 1897) in providing duty-free entry for exhibition of works of art and similar articles.

Over the years Customs has used certain criteria to determine the eligibility of an article for duty-free entry under item 862.10, TSUS. These criteria, as set forth in Treasury Decision (T.D.) 78-420, published in 12 Cust. Bull. 929, are:

(1) The article must be imported for exhibition itself, another use of it can only be incidental;

(2) The article must be imported by the institution itself or its agent; and

(3) Admission to view the article can be charged only to defray expenses and the article cannot be used in connection with a commercial venture.

In our review of this matter, we found that the application of these criteria to planetaria has not been consistent with that to other articles. The regular use of the planetaria has been considered to be part of the exhibition of the planetaria, apparently because it has been felt that use of the planetaria was necessary for a full and effective demonstration of them. This concept has not been applied to other similar articles. For example, a concert organ to be installed in a music hall was considered as a musical instrument and primarily utilitarian rather than an exhibition object.

We noted, in our review, that planetaria are usually purchased for the purpose of making presentations rather than serving as an exhibit to be viewed. We noted that the institutions importing planetaria and seeking duty-free entry appear to be using the planetaria primarily for research, teaching, testing or classroom study. The primary reason persons attend a "star show" or other planetarium presentation appears to be to view the pictures, images, lights, sounds, etc., produced by the planetarium rather than viewing the planetarium itself. This is so even though the planetarium may be on view during such presentations.

Based on the above-described review of this matter, we concluded that the criteria described in T.D. 78-420 should be applied in the same manner to all articles, including planetaria, for which duty free entry is sought under item 862.10, TSUS. Customs gave notice of its intention to change the treatment of planetaria under item 862.10 in the November 18, 1988, **Federal Register** notice. In that proposal, we stated that planetaria which are to be utilized for the making of presentations or demonstrations would normally be considered as being imported for that purpose. The observation of the planetaria, in connection with these presentations or demonstrations, would be considered as incidental to the purpose for which they were imported.

Since publication of the November 18, 1988, **Federal Register** notice, the TSUS has been replaced by the HTSUSA.The subheading of the HTSUSA corresponding to item 862.10, TSUS (subheading 9812.00.20, HTSUSA) and the note of the HTSUSA corresponding to headnote 1 of Part 5B, Schedule 8, TSUS (U.S. Note 1 to Subchapter XII, HTSUSA) are substantively unchanged. When nomenclature in the TSUS remains unchanged in the HTSUSA, administrative decisions under the TSUS are to be considered instructive in interpreting the HTSUSA on a case-by-case basis (House Conference Report on H.R. 3, Omnibus Trade and Competitiveness Act of 1988, 100th Cong., 2d Sess., H. Conference Report No. 100-576; see 134 Cong. Rec. H2021 (daily ed. April 20, 1988)). On this basis, we proceeded with our review of the applicability of subheading 9812.00.20, HTSUSA, to planetaria on the same basis as our review of the applicability of item 862.10, TSUS, to planetaria, discussed above and in the November 18, 1988, **Federal Register** notice.

Summary of Comments

Of the three (3) comments received, one (1) favored the proposed change and two (2) opposed the change. The commenter favoring the proposal, a domestic manufacturer of planetaria, asserts that the duty-free importation of planetaria as "exhibits" puts it in an unfair position in competition for planetaria projects in the U.S.

Of the commenters opposing the change, one contends that planetaria are of special interest to persons viewing a planetarium presentation, that "the projection of images or lights by a planetarium is coincident with the exhibition of the projector *per se*",

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]

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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