Personal Care Products Council
Committed to Safety, Quality & Innovation

Dr. Ruth Lunn
Director, Office of the RoC
DNTP, NIEHS
P.O. Box 12233, MD K2-14
Research Triangle Park, NC 27709
lunn@niehs.nih.gov

February 27, 2012

RE: Comments on the nomination of carbon black for listing in the Report on Carcinogens

The Personal Care Products Council (the Council)[1] appreciates this opportunity to comment on the nomination of carbon black to the Report on Carcinogens (RoC) (77 Federal Register 2728).

Specifically, the Council is requesting that D&C Black 2 as defined by 21 CFR 74.2052 be excluded from the general class of carbon blacks being evaluated by NTP for addition to the RoC. As the NTP website notes, there are many commercial grades of carbon black. Many of these commercial grades are made through a manufacturing process different from that used for the preparation of D&C Black 2. Further, the raw materials used in the manufacture of many of these commercial grades of carbon black are not the same as that defined for D&C Black 2. The US FDA thoroughly evaluated the manufacturing process and raw material used for the manufacture of D&C Black 2 and concluded that it does not present a hazard to human health when used as specified in the regulation 21 CFR 74.2052.

D&C Black 2 is an FDA certified color permitted for use in "eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel". D&C Black 2 is defined by 21 CFR 74.2052 as "a high-purity carbon black prepared by the oil furnace process. It is manufactured by the combustion of aromatic petroleum oil feedstock and consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 200 to 260 meters (m)2/gram."

---

[1]Based in Washington, D.C., the Council (formerly the Cosmetic, Toiletry and Fragrance Association) is the leading national trade association for the cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As makers of a diverse range of products that millions of consumers rely on every day, personal care product companies are global leaders committed to product safety, quality and innovation.

In addition to specifying the manufacturing method of D&C Black 2, 21 CFR 74.2052 also provides the following specifications for this material:

1. "Surface area by nitrogen BET (Brunauer, Emmett, Teller) method, 200 to 260 m^2/gram.
2. Weight loss on heating at 950 deg. C for 7 minutes (predried for 1 hour at 125 deg. C), not more than 2 percent.
3. Ash content, not more than 0.15 percent.
4. Arsenic (total), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million).
5. Lead (total), not more than 10 mg/kg (10 parts per million).
6. Mercury (total), not more than 1 mg/kg (1 part per million).
7. Total sulfur, not more than 0.65 percent.
8. Total PAHs, not more than 0.5 mg/kg (500 parts per billion).
9. Benzo[a]pyrene, not more than 0.005 mg/kg (5 parts per billion).
10. Dibenz[a,h]anthracene, not more than 0.005 mg/kg (5 parts per billion).
11. Total color (as carbon), not less than 95 percent."

All D&C Black 2 used in cosmetics is certified by FDA as meeting these specifications. Since its approval in 2004, a range of 2,205 to 109,384.5 pounds of D&C Black 2 have been certified by the FDA each fiscal year[2].

During the process of listing D&C Black 2 as a certified color permitted for use in specified cosmetic products, FDA completed a thorough safety review. The attached Federal Register Notice (69(144): 44927-44930, July 28, 2004), reviews FDA's risk assessment process for this color. The information reviewed by FDA is contained in Docket No. 1987 C-0023 for color additive petition No. 7C0208. The Office of Cosmetics and Colors, FDA, may be contacted for more information concerning D&C Black 2.

D&C Black 2, as defined by 21 CFR 74.2052, should be excluded from the general class of carbon blacks being evaluated for addition to the RoC.

Thank you for your attention to this issue.

Sincerely,

[Redacted]

Carol Eisenmann, Ph.D. DABT
Senior Toxicologist
Personal Care Products Council

---

[2]Information from FDA color certification reports at http://www.fda.gov/ForIndustry/ColorAdditives/ColorCertification/ColorCertificationReports/default.htm

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2004–15–02 Rolls-Royce plc: Amendment 39–13736. Docket No. 2003–NE–38–AD.

Effective Date

(a) This AD becomes effective September 1, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Rolls-Royce plc (RR) models RB211 Trent 875–17, Trent 877–17, Trent 884–17, Trent 884B–17, Trent 892–17, Trent 892B–17, and Trent 895–17 turbofan engines, with low pressure (LP) compressor fan blades, part number (P/N) FW18548, installed. These engines are installed on, but not limited to, Boeing 777 series airplanes.

Unsafe Condition

(d) This AD was prompted by a number of new production LP compressor blades found with surfaces formed outside of design intent. Findings included sharp edges, burrs, and damage present in the area at the top of the shear key slots. We are issuing this AD to prevent possible multiple uncontained LP compressor fan blade failure, due to cracking in the blade root caused by increased stresses in the shear key slots.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done.

Actions Required for LP Compressor Fan Blades

(f) Replace LP compressor fan blades with new or previously reworked LP compressor blades at or before accumulating the specified cycles-since-new (CSN) in the following Table 1, or rework the existing blades as specified in paragraph (g) of this AD.

(g) Rework LP compressor fan blades at or before accumulating the specified CSN in the following Table 1. Follow paragraphs 3.B.(1) through 3.B.(22) of Accomplishment Instructions of RR service bulletin (SB) No. RB.211–72–E044, Revision 1, dated May 2, 2003, to do the blade rework.

TABLE 1.—LP COMPRESSOR FAN BLADE REPLACEMENT OR REWORK SCHEDULE

For engines installed on:	Engine model:	Replace or rework LP compressor fan blades at or before accumulating
Boeing 777–300 Series	Trent 884–17	2,400 CSN.
Boeing 777–300 Series	Trent 884B–17	2,400 CSN.
Boeing 777–300 Series	Trent 892–17	2,400 CSN.
Boeing 777–200 Series	Trent 895–17	3,200 CSN.
Boeing 777–200 Series	Trent 892–17	4,100 CSN.
Boeing 777–200 Series	Trent 892B–17	4,100 CSN.
Boeing 777–200 Series	Trent 884–17	4,100 CSN.
Boeing 777–200 Series	Trent 875–17	4,100 CSN.
Boeing 777–200 Series	Trent 877–17	4,100 CSN.

(h) For engines moved between configurations, the cycles remaining may be calculated using either of the following:

(1) Subtract the total CSN from the most limiting configuration's limit from Table 1; or

(2) Calculate the cycles remaining using the following equation:

Where:

Xr = Cycles remaining in current configuration.

Lc = Cyclic limit of current configuration from Table 1 of this AD.

Xn = Cycles accumulated in configuration n.

Ln = Cyclic limit in configuration n from Table 1.

(i) Information on the source life of the cycle limits in Table 1 of this AD can be found in RR Alert SB No. RB.211–72–AE055, Revision 3, dated May 28, 2003.

Alternative Methods of Compliance

(j) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(k) You must use RR SB No. RB.211–72–E044, Revision 1, dated May 2, 2003, to perform the blade rework required by this AD. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You can get a copy from Rolls-Royce plc, PO Box 31, Derby, England, DE248BJ; telephone: 011–44–1332–242424; fax: 011–44–1332–245418. You can review copies at FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Related Information

(l) CAA airworthiness directive 001–05–2003, dated June 20, 2003, and RR Alert SB No. RB.211–72–AE055, Revision 3, dated May 28, 2004, pertain to the subject of this AD.

Issued in Burlington, Massachusetts, on July 14, 2004.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 04–16548 Filed 7–27–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 1987C–0023]

Listing of Color Additives Subject to Certification; D&C Black 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 Black No. 2 (a high-purity furnace black, subject to FDA batch certification) as a color additive in the following cosmetics: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel. This action is in response to a petition filed by the Cosmetic, Toiletry, and Fragrance Association.

DATES: This rule is effective August 30, 2004. Submit objections and requests for a hearing by August 27, 2004. See

section VIII of this document for information on the filing of objections.

ADDRESSES: Submit written objections and requests for a hearing to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3423.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of March 13, 1987 (52 FR 7933), FDA announced that a color additive petition (CAP 7C0208) had been filed by the Cosmetic, Toiletry, and Fragrance Association, Inc., 1110 Vermont Ave. NW., Washington, DC 20005 (current address, 1101 17th St. NW., suite 300, Washington, DC 20036–4702). The petition proposed to amend the color additive regulations in part 74 (21 CFR part 74, subpart C) to provide for the safe use of carbon black as a color additive for coloring cosmetics generally, including cosmetics for use in the area of the eye. The petitioner has now limited its proposed use of carbon black to the following cosmetics: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel. During its review of the petition, the agency determined that the subject carbon black is a fine-particle high-purity furnace black that will require batch certification by FDA. The agency intends to give each certified batch of the subject color additive the name D&C Black No. 2. Therefore, this color additive will be identified as D&C Black No. 2.

The petitioner has requested the use of D&C Black No. 2 in cosmetics, including cosmetics for use in the area of the eye. The term "area of the eye" is defined in § 70.3(s) (21 CFR 70.3(s)) as "the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge."

The regulation in 21 CFR 70.5(a) states that "No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in the area of the eye unless such listing or certification of such color additive specifically provides for such use."

II. Identity and Specifications

D&C Black No. 2 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by injecting a heated aromatic petroleum oil feedstock into the combustion zone of a natural gas fired furnace. The reaction is quenched with water and the carbon particles are further cooled and collected on a fabric filter. The high-purity furnace black that is the subject color additive of this rule consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 200 to 260 meters^2/gram.

As explained under III.B of this document, the color additive D&C Black No. 2 may contain low levels of potentially carcinogenic polynuclear aromatic hydrocarbon (PAH) contaminants. To limit the amounts of these contaminants in the color additive, FDA is requiring that D&C Black No. 2 for use in cosmetics be from a batch of the color additive certified by FDA, and is setting specifications for total PAHs, benzo[*a*]pyrene (B[*a*]P), and dibenz[*a*,*h*]anthracene. Because any PAH contaminants in the color additive can tightly bind to the carbon particles, the bioavailability of PAHs will be inversely related to the surface area of the carbon particles. Therefore, the agency is setting a specification for surface area, determined by the nitrogen Brunauer, Emmett, Teller (BET) method.

In general, the surface area of the carbon particles is also inversely related to their particle size. Because eye irritation may be caused by larger carbon particles, a specification for surface area by nitrogen BET will also limit the size of the carbon particles to those fine enough to ensure eye area safety.

To limit the amounts of heavy metals in the color additive, which substances may be derived from the manufacturing process water and the feedstock, the agency is also setting specifications for arsenic, lead, and mercury.

For a certifiable color additive, the sum of total color plus the levels of appropriate impurities should approximate 100 percent, allowing mass accountability. The total color from D&C Black No. 2 comes from the elemental carbon itself. The levels of appropriate impurities can be obtained from data for ash, volatile matter, and total sulfur. Therefore, the agency is setting specifications for total color (as carbon), ash content, weight loss on heating, and total sulfur.

III. Safety Evaluation

A. Determination of Safety

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(b)(4)), the so-called "general safety standard" for color additives, a color additive cannot be listed for a particular use unless a fair evaluation of the data and information available to FDA establishes that the color additive is safe for that use. FDA's color additive regulations (§ 70.3(i)) define safe as "convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive."

The anticancer or Delaney clause of the color additive amendments (section 721(b)(5)(B) of the act) provides that for any use of a color additive which will or may result in ingestion of all or part of such additive, the color additive shall be deemed to be unsafe and shall not be listed if the additive is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal (section 721(b)(5)(B)(i) of the act). Further, under section 721(b)(5)(B)(ii) of the act, for any use of a color additive which will not result in ingestion of any part of such additive, the color additive shall be deemed to be unsafe and shall not be listed if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, 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 a reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

B. Safety of Petitioned Use of the Additive

D&C Black No. 2 is inert. Its insolubility and lack of toxicity, coupled with a history of safe use of activated carbon in medicine, contribute to the agency's conclusion that the color additive itself is safe for its proposed uses. However, the color additive has been shown to contain low levels of PAH impurities, some of which are carcinogenic. To minimize exposure to contaminants, the agency is setting

limits for the following PAHs as a proportion of D&C Black No. 2: total PAHs (0.5 milligram (mg)/kilogram (kg)); B[*a*]P (0.005 mg/kg); and dibenz[*a*,*h*]anthracene (0.005 mg/kg).

Current data have shown B[*a*]P to be one of the most potent carcinogens of the PAH family. To assess the risk from exposure to PAHs, FDA has used toxic equivalency factors to express the comparative toxicity of PAHs as fractions of the toxicity of B[*a*]P. This approach expresses the amount of PAHs present in terms of B[*a*]P equivalents and estimates the risk for a mixture of PAHs as if it were one chemical compound. Under this system, B[*a*]P has been assigned a B[*a*]P toxic equivalency of 1. FDA has estimated the exposure to B[*a*]P equivalents from the use of high-purity furnace black in cosmetics to be no greater than 7.2×10^{-10} mg/kg body weight/day (Ref. 1). In estimating the exposure to B[*a*]P equivalents from the petitioned use of the color additive, FDA assumed that both B[*a*]P and dibenz[*a*,*h*]anthracene were present at their proposed limits of 0.005 mg/kg and that each of the other possible PAH contaminants would be present in equal amounts, with a total PAH concentration of 0.5 mg/kg (Ref. 1). Based on the evidence presented in the petition, the agency also concluded that no more than 10 percent of the total PAHs present were likely to be extractable from the additive under typical use conditions, and thus available for absorption by the body (Refs. 2 and 3).

The agency used data from a carcinogenesis bioassay on B[*a*]P, conducted by H. Brune, et al., to estimate the upper-bound limit of lifetime human risk from exposure to B[*a*]P equivalents resulting from the petitioned use of the color additive (Ref. 4). The authors reported treatment-related benign forestomach tumors or esophageal tumors in male rats exposed to B[*a*]P. Using a linear-at-low-dose extrapolation method and tumor incidence data from the H. Brune, et al. study, the FDA estimated the carcinogenic unit risk for B[*a*]P to be 1.75 (mg/kg body weight/day)$^{-1}$. Using this carcinogenic risk for B[*a*]P and an estimated daily exposure of 7.2×10^{-10} mg of B[*a*]P equivalents/kg body weight/day, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the additive is 1.3×10^{-9}, or less than 1 in 1 billion (Refs. 1 and 5 through 7).

Because conservative assumptions were used to estimate exposure, and PAHs bind tightly to carbon black and are not expected to be bioavailable, the average individual exposure to B[*a*]P toxic equivalents is expected to be substantially less than the estimated exposure (Refs. 5 and 6). The actual risk will likely be less than the calculated upper-bound limit of risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to PAHs would result from the petitioned use of the additive.[1]

In addition, no toxicity was noted in studies provided by the petitioner to support the safety of D&C Black No. 2 to color cosmetics intended for use in the area of the eye (Ref. 8).

IV. Conclusions

Based on the data in the petition and other relevant considerations discussed in section III of this document, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of D&C Black No. 2 as a color additive in the following cosmetics: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel. The agency also concludes that the color additive will achieve its intended technical effect, and thus, is suitable for this use. The agency further concludes that in accordance with 21 CFR 71.20(b), batch certification of D&C Black No. 2 is necessary to protect the public health because of the need to limit the levels of PAHs, some of which have been shown to be carcinogenic. Therefore, part 74 should be amended as set forth in this document.

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 by appointment with the information contact person listed (see **FOR FURTHER INFORMATION CONTACT**). 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 Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Paperwork Reduction Act of 1995

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

VIII. References

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

1. Memorandum from Jensen, Division of Product Manufacture and Use, to White, Division of Petition Control, March 23, 1998.

2. Memorandum from Cramer, Food and Color Additives Review Section, to Kashtok, Direct Additive Branch, July 25, 1990.

3. Memorandum from Folmer, Division of Petition Review Chemistry Review Group, to Johnston, Division of Petition Review, September 30, 2003.

4. Brune, H., R. P. Deutsch-Wenzel, M. Habs, S. Ivankovis, and D. Schmahl, "Investigation of the Tumorigenic Response to Benzo[*a*]pyrene in Aqueous Caffeine Solution Applied Orally to Sprague-Dawley Rats," *Journal of Cancer Research and Clinical Oncology*, 102:153–157, 1981.

5. Memorandum from Carlson, Division of Petition Review, to Peiperl, Division of Petition Review, July 2, 2003.

6. Memorandum from Kraeling, Cosmetic Toxicology Branch, to Peiperl, Division of Petition Control, April 22, 2003.

7. Memorandum from Folmer, Division of Petition Review Chemistry Review Group, to Peiperl, Division of Petition Review, July 1, 2003.

8. Memorandum from Kraeling, Office of Cosmetics and Colors, to Peiperl, Division of Petition Review, July 15, 1999.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. 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

[1] FDA has also estimated the upper-bound limit of lifetime human risk to PAHs using the worst-case assumption that all PAHs in the additive have the same carcinogenic potency as B[*a*]P. Based on this highly conservative approach, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the additive is 1.5×10^{-8}, or about 1 in 100 million (Ref. 6).

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

■ 2. Section 74.2052 is added to subpart C to read as follows:

§ 74.2052 D&C Black No. 2.

(a) *Identity.* The color additive D&C Black No. 2 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by the combustion of aromatic petroleum oil feedstock and consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 200 to 260 meters (m)^2/gram.

(b) *Specifications.* D&C Black No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Surface area by nitrogen BET (Brunauer, Emmett, Teller) method, 200 to 260 m^2/gram.

(2) Weight loss on heating at 950 °C for 7 minutes (predried for 1 hour at 125 °C), not more than 2 percent.

(3) Ash content, not more than 0.15 percent.

(4) Arsenic (total), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million).

(5) Lead (total), not more than 10 mg/kg (10 parts per million).

(6) Mercury (total), not more than 1 mg/kg (1 part per million).

(7) Total sulfur, not more than 0.65 percent.

(8) Total PAHs, not more than 0.5 mg/kg (500 parts per billion).

(9) Benzo[e]pyrene, not more than 0.005 mg/kg (5 parts per billion).

(10) Dibenz[*a,h*]anthracene, not more than 0.005 mg/kg (5 parts per billion).

(11) Total color (as carbon), not less than 95 percent.

(c) *Uses and restrictions.* D&C Black No. 2 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.

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

(e) *Certification.* All batches of D&C Black No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

Dated: July 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–17153 Filed 7–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9143]

RIN 1545–AP30

Allocation and Apportionment of Deductions for Charitable Contributions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary and final regulations.

SUMMARY: This document contains temporary regulations relating to the allocation and apportionment of the deduction for charitable contributions allowed by sections 170, 873(b)(2), and 882(c)(1)(B). These regulations change the method of allocating and apportioning these deductions from ratable apportionment on the basis of gross income to apportionment on the basis of income from sources within the United States. The temporary regulations will affect individuals and corporations that make contributions to charitable organizations and that have foreign source income and calculate their foreign tax credit limitations under section 904. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the Proposed Rules section in this issue of the Federal Register. This document also contains final regulations that remove the existing regulations concerning allocation and apportionment of charitable contribution deductions.

DATES: *Effective Date:* These regulations are effective July 28, 2004.

Applicability Dates: For dates of applicability, see §§ 1.861–8(a)(5), 1.861–8T(e)(12)(iv), and 1.861–14T(e)(6)(ii). The regulations are applicable to charitable contributions made on or after July 28, 2004. Taxpayers may elect to apply these regulations to contributions made before July 28, 2004, but during a taxable year ending after July 28, 2004.

FOR FURTHER INFORMATION CONTACT: Teresa Burridge Hughes (202) 622–3850 (not a toll free call).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the regulations under section 861 relating to the allocation and apportionment of the deduction for charitable contributions allowed under sections 170, 873(b)(2), and 882(c). Currently, regulations under § 1.861–8(e)(9)(iv) provide that such deductions generally are not definitely related to any gross income and therefore are ratably apportioned to the statutory and residual groupings on the basis of gross income.

In 1991, the Treasury Department and the IRS issued proposed regulations (the 1991 proposed regulations) that would have changed the ratable apportionment rule of the final regulations to a rule that, assuming certain requirements are met, generally would apportion the deduction for a charitable contribution based on where the contribution would be used. Prop. Treas. Reg. § 1.861–8(e)(12), 56 Fed. Reg. 10,395 (1991). More specifically, the 1991 proposed regulations provided that the deduction for a charitable contribution would have been apportioned solely to foreign source gross income if the taxpayer, at the time of the contribution, knows or has reason to know that the contribution will be used solely outside the United States or that the contribution may necessarily be used only outside the United States. The 1991 proposed regulations also provided that the deduction for a charitable contribution would have been apportioned solely to U.S. source gross income if the taxpayer,