Paperwork Reduction Act

This final rule imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: June 12, 2007.

Michael J. Astrue,

Commissioner of Social Security.

■ For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Appendix 1 to subpart P of part 404 is amended by revising items 1, 4, 6, 8, 10, 12, 13, and 15 of the introductory text before Part A to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

1. Growth Impairment (100.00): July 1, 2008.

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4. Respiratory System (3.00 and 103.00): July 1, 2008.

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6. Digestive System (5.00 and 105.00): July 1, 2008.

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8. Hematological Disorders (7.00 and 107.00): July 1, 2008.

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10. Endocrine System (9.00 and 109.00): July 1, 2008.

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12. Neurological (11.00 and 111.00): July 1, 2008.

13. Mental Disorders (12.00 and 112.00): July 1, 2008.

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15. Immune System (14.00 and 114.00): July 1, 2008.

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[FR Doc. E7–11752 Filed 6–18–07; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 1995C–0286 (formerly Docket No. 95C–0286)]

Listing of Color Additives Subject to Certification; D&C Black No. 3

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. 3 (bone black, subject to FDA batch certification) as a color additive in eyeliner, eye shadow, mascara, and face powder. This action is in response to a petition filed by Ebonex Corp.

DATES: This rule is effective July 20, 2007. Submit written or electronic objections and requests for a hearing by July 19, 2007. See section VIII of the **SUPPLEMENTARY INFORMATION** section of this document for information on the filing of objections.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No 1995C–0286, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written objections in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1071.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of September 1, 1995 (60 FR 45724), FDA announced that a color additive petition (CAP 5C0247) had been filed by the Ebonex Corp., P.O. Box 3247, Melvindale, MI 48122. The petition proposed to amend the color additive regulations to provide for the safe use of bone black as a color additive in cosmetics, including cosmetics intended for use in the eye area. The petitioner subsequently narrowed the proposed uses of bone black to eyeliner, eye shadow, mascara, and face powder.

During its review of the petition, the agency determined that the color additive, bone black, 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. 3. Therefore, this color additive will be identified as D&C Black No. 3.

The requested use of D&C Black No. 3 includes 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.''

Section 70.5(a) (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. 3 is a black pigment made from calcined cattle bones. The bones are heated twice to temperatures in excess of 700°C for at least 6 hours each time. The twice burned char is then washed. The carbon content is approximately 8 percent to 10 percent and most of the remaining composition is tricalcium phosphate (as calcium hydroxyapatite).

As explained under section III.B of this document, D&C Black No. 3 may contain low levels of potentially carcinogenic polycyclic aromatic hydrocarbon (PAH) impurities. To limit the amounts of these impurities in the color additive, FDA is setting a specification for total PAHs and is requiring that D&C Black No. 3 be from a batch of bone black certified by FDA.

To limit the amounts of heavy metals in the color additive, which may be derived from the source of the color and the manufacturing process, the agency also is setting specifications for arsenic and lead. To ensure purity of the color additive, the agency also is setting specifications for carbon, calcium hydroxyapatite, moisture, and silica. To be used lawfully in cosmetics in the United States, all batches of bone black must meet the specifications identified in the regulation.

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 ''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 clause of the color additive amendments (section 721(b)(5)(B) of the act), also known as the Delaney clause) 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

Because D&C Black No. 3 is made from cattle bones, one potential safety concern is the risk from using cattle materials in the preparation of bone black that could be infected with the agent that causes Bovine Spongiform Encephalopathy (BSE). To address the potential risk of BSE, FDA prohibits the use of certain cattle materials in human food and cosmetics. FDA also requires that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle establish and maintain records sufficient to demonstrate that the human food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials (21 CFR 189.5 and 700.27). FDA's regulatory measures to prevent BSE contamination of U.S. food and cosmetics ensure that cattle materials that carry the highest risk of transmitting the agent that causes BSE are excluded from being used as a source to produce D&C Black No. 3 for use in cosmetics. Therefore, FDA concludes that D&C Black No. 3 prepared in compliance with these measures is safe with respect to the potential concern from using cattle materials.

Toxicity studies provided by the petitioner, including a dermal irritation study, an ocular irritation study, a delayed-contact hypersensitivity study, and a bioavailability study, demonstrate the color additive itself is safe for the proposed cosmetic uses. However, the color additive has been shown to contain several impurities in trace amounts, including carcinogenic PAHs. To minimize exposure to PAH impurities, the agency is setting a limit for total PAHs in D&C Black No. 3 of not more than 5 milligrams (mg)/kilogram (kg) (5 parts per million). As discussed in the next three paragraphs, the limit for total PAHs for D&C Black No. 3 will provide a reasonable certainty that no harm will result from the intended use of the color additive.

Current data have shown that benzo(a)pyrene (B[*a*]P) is one of the most potent carcinogens of the PAH family. To assess the risk from exposure to PAHs, FDA used toxic equivalency factors (TEFs) to express the comparative toxicity of individual 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 comprised of one chemical compound. Under this methodology, B[*a*]P was assigned a TEF of 1. In estimating the exposure of B[*a*]P equivalents from the petitioned uses of the color additive, FDA normalized the residue levels of the individual PAHs to yield a total PAH concentration of approximately 5 mg/kg (the limit for total PAHs set by the regulation). Multiplying the normalized residue level for each PAH by the TEF for that PAH and summing the results yields a B[*a*]P-equivalent PAH concentration of approximately 1.2 mg/kg. Data from a bioavailability study presented in the petition show that B[*a*]P is not absorbed in appreciable amounts from cosmetic matrices (4 percent to 6 percent absorption) (Refs. 1 and 2). However, as a conservative assumption based on the chemical composition of the additive, the agency concluded that up to 50 percent of the total PAHs were likely to be extracted from the additive under typical use conditions, and thus available for absorption by the body (i.e., not bound to the cosmetic formulation).

The agency used data from a carcinogenesis bioassay on B[*a*]P (Ref. 3), to estimate the upper-bound limit of lifetime human risk from exposure to B[*a*]P equivalents resulting from the

petitioned uses of the color additive. This bioassay 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 bioassay, FDA estimated the carcinogenic unit risk for B[*a*]P to be 1.75 (mg/kg body weight/day)$^{-1}$. Using this unit risk and an estimated daily exposure of 5 x 10^{-8} mg of B[*a*]P equivalents/kg body weight/day, FDA estimates the upper-bound lifetime human risk from the petitioned uses of the color additive to be 8.8 x 10^{-8} (Ref. 1).

Because conservative assumptions were used to estimate exposure, an individual's actual exposure to PAHs is expected to be substantially less than the estimated exposure. The agency concludes that there is reasonable certainty that no harm from exposure to PAHs would result from the petitioned use of the color additive[1] (Ref. 4).

The agency also considered the potential risk from benzaldehyde, benzonitrile, biphenyl, isoquinoline, pyridine and quinoline, which are additional impurities produced in trace amounts in the color additive from the manufacturing process. The agency concludes that none of these substances is present in the color additive at levels that raise any safety concerns, and that no specifications are necessary to control the amount of these substances as impurities in the color additive (Ref. 4).

IV. Conclusions

Based on data in the petition and other relevant considerations discussed previously, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of D&C Black No. 3 as a color additive in eyeliner, eye shadow, mascara, and face powder. 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. 3 is necessary to protect the public health because of the need to limit the level of PAH impurities, some of which have been shown to be carcinogenic. Therefore, 21 CFR part 74 should be amended as set forth in this document.

[1] FDA also estimated the upper-bound lifetime risk to PAHs using the worst-case assumption that PAHs are present at the maximum allowable limit of 5 mg/kg, and that all PAHs present have carcinogenic potency equivalent to B[*a*]P. Based on this very conservative approach, the upper-bound limit of lifetime human risk from the petitioned uses of the additive is 3.7 x 10^{-7} (Ref. 1).

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 will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (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. Objections

This rule is effective as shown in the ''**DATES**'' section of this document; except as to any provisions that may be stayed by the filing of proper objections. Any person who will be adversely affected by this regulation may 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 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**.

IX. 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 Folmer, Division of Petition Review, Chemistry Review Team, to Kidwell, Division of Petition Review, July 6, 2005.

2. Memorandum from Yourick, Cosmetics Toxicology Branch, Division of Cosmetics and Compliance, to Kidwell, Division of Petition Review, May 13, 2005.

3. Brune, H., R.P. Deutsch-Wenzel, M. Habs, et al., ''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.

4. Memorandum from Carlson, Division of Petition Review, Toxicology Review Group I, to Kidwell, Division of Petition Review, February 15, 2006.

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 74.2053 is added to subpart C to read as follows:

§ 74.2053 D&C Black No. 3.

(a) *Identity.* The color additive D&C Black No. 3 is a washed bone char prepared from calcined cattle bones. The bones are twice heated in excess of 700°C for at least 6 hours.

(b) *Specifications.* D&C Black No. 3 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 current good manufacturing practices:

(1) Calcium hydroxyapatite (CaO and P_2O_5), not less than 75 percent and not more than 84 percent;

(2) Elemental carbon, not less than 7 percent;

(3) Moisture, not more than 7 percent;

(4) Silica (SiO_2), not more than 5 percent;

(5) Arsenic, not more than 3 milligrams (mg)/kilogram (kg) (3 parts per million (ppm));

(6) Lead, not more than 10 mg/kg (10 ppm); and

(7) Total polycyclic aromatic hydrocarbons (PAHs), not more than 5 mg/kg (5 ppm).

(c) *Uses and restrictions*. Cosmetics containing D&C Black No. 3 must comply with § 700.27 of this chapter with respect to prohibited cattle materials in cosmetic products. D&C Black No. 3 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, eye shadow, mascara, and face powder.

(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. 3 shall be certified in accordance with regulations in part 80 of this chapter.

Dated: June 11, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11801 Filed 6–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 1997N–0484T]

Human Cells, Tissues, and Cellular and Tissue-Based Products; Donor Screening and Testing, and Related Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting as a final rule, without change, the provisions of the interim final rule that amended certain regulations regarding the screening and testing of donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps), and related labeling. FDA is taking this action to complete the rulemaking initiated with the interim final rule.

DATES: This rule is effective June 19, 2007.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 25, 2005 (70 FR 29949), FDA issued an interim final rule on Human Cells, Tissues, and Cellular and Tissue-Based Products; Donor Screening and Testing, and Related Labeling (hereinafter referred to as the interim final rule). These regulations became effective upon the date of publication in the **Federal Register**. We issued the interim rule to assure that the changes became effective concurrently with the Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products final rule (69 FR 29786, May 25, 2004) and the Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement final rule (69 FR 68612, November 24, 2004) on May 25, 2005. In this way, establishments were not required to take steps to comply with the provisions in part 1271 (21 CFR part 1271) that were replaced by the changes set out in the interim final rule, and certain HCT/Ps would continue to be available.

II. Comments on the Interim Final Rule and FDA Responses

We received several comments on the interim final rule. To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, will appear before the comment's description, and the word ''Response,'' in parentheses, will appear before our response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was received.

(Comment 1) A comment appreciated and applauded the change to § 1271.370(b)(4) to allow labeling with warning(s) to accompany the HCT/P when the HCT/P container is too small to accommodate the warning(s) on the label. Another comment expressed concern that the accompanying labeling could be ignored or lost.

(Response) We acknowledge and appreciate the supportive comment. This requirement addresses the situation where it is not physically possible to include warnings directly on the HCT/P label, either because the container is too small or the HCT/P is cryopreserved, which may interfere with adherence of label materials. In these situations, the warnings must accompany the HCT/P.

We acknowledge the comment's concern that it is better to provide information on the HCT/P's label. However, we permit other important information, such as the summary of records, to accompany the HCT/P; such important information is not present on the HCT/P label. We believe that consignees are generally careful to make sure information accompanying HCT/Ps is not ignored or lost, and we believe that the accompanying information will be available. Necessity compels this authorization for certain information to accompany an HCT/P when it is not possible to include it on the label, and we conclude that it is adequate to provide such information in accompanying documents when it is necessary to do so.

(Comment 2) A comment noted that § 1271.55(a)(1) requirements (i.e., affixing a distinct identification code to the HCT/P container) were clearly designed to maintain donor anonymity. However, the comment asked if fertility clinics could write in information about the recipient (e.g., name, account number) because by the time a donor's HCT/P is collected, a specific recipient has already been identified. The comment stated that fertility clinics, for example, never collect anonymously donated oocytes without already having a recipient identified and ready to receive the donation.

(Response) The requirements in § 1271.55(a)(1) are focused on protecting the identity of the donor in the interest of confidentiality. We note that this provision prescribes how an establishment must label the HCT/P before releasing it for distribution, but does not prohibit the addition of the recipient's name once the donor eligibility determination is completed and the reproductive HCT/P is released for distribution. For an oocyte donation, the release determination is likely to be completed very soon after collection.

(Comment 3) A few comments suggested changes to the timing of the specimen collection in § 1271.80(b). In particular, a comment noted that § 1271.80(b)(1) permits testing on oocyte donors up to 30 days before recovery, while § 1271.80 seems to maintain a 7-day testing window for semen donors, whose spermatozoa will combine with the oocytes to create an embryo for a