



**Food and Drug Administration**

[Docket No. 83C-0408]

**Indian Earth Cosmetics; Withdrawal of Color Additive Petition**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 2C0157) proposing that the color additive regulations be amended to provide for the safe use of hematite as a color additive in cosmetics generally, including those for use in the area of the eye.

**FOR FURTHER INFORMATION CONTACT:** Aydin Örtan, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9515.

**SUPPLEMENTARY INFORMATION:** In a notice published in the *Federal Register* of January 26, 1984 (49 FR 3272), FDA announced that a color additive petition (CAP 2C0157) had been filed by R.F.A. Corp., c/o 1120 G St. NW., Washington, DC 20005. The petition proposed that part 73 *Listing of Color Additives Exempt From Certification* (21 CFR part 73) be amended to provide for the safe use of hematite as a color additive in cosmetics generally, including those for use in the area of the eye. FDA has been notified that R.F.A. Corp. has gone out of business and that Indian Earth Cosmetics, 2967 Randolph Ave., Costa Mesa, CA 92626, owns the petition. Indian Earth Cosmetics has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6).

Dated: April 19, 1994.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 94-10325 Filed 4-29-94; 8:45 am]

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[Docket No. 94N-0151]

**Drug Export; Antibody to Hepatitis B Surface Antigen HBsAg EIA-2.0 and HBsAg Confirmatory Assay-2.0**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Genetic Systems Corp., a Subsidiary

of Sanofi Diagnostics Pasteur, Inc., has filed an application requesting approval for the export of the human biological product Antibody to Hepatitis B Surface Antigen HBsAg EIA-2.0 and HBsAg Confirmatory Assay-2.0 to Australia.

**ADDRESSES:** Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments act of 1986 should also be directed to the contact person.

**FOR FURTHER INFORMATION CONTACT:** Frederick W. Blumenschein, Center for Biologics Evaluation and Research (HFM-660), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-1070.

**SUPPLEMENTARY INFORMATION:** The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of human biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the *Federal Register* within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Genetic Systems Corp., a Subsidiary of Sanofi Diagnostics Pasteur, Inc., 6565 185th Ave. NE., Redmond, WA 98052-5039, has filed an application requesting approval for the export of the human biological product Antibody to Hepatitis B Surface Antigen HBsAg EIA-2.0 and HBsAg Confirmatory Assay-2.0 to Australia. The Genetic Systems Corp.'s Enzyme Immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human serum and plasma. The Genetic Systems HBsAg Confirmatory Assay-2.0 is Genetic Systems Corp.'s assay for the confirmation of HBsAg reactive specimens detected in the Genetic Systems HBsAg EIA-2.0. The application was received and filed in the Center for Biologics Evaluation and Research on February 23, 1994, which

shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 12, 1994, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: April 3, 1994.

P. Michael Dubinsky,

Acting Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 94-10459 Filed 4-29-94; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 94F-0125]

**Foodco Corp.; Filing of Food Additive Petition**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Foodco Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a source of high intensity pulsed light to control microorganisms on the surface of food.

**DATES:** Written comments on the petitioner's environmental assessment by June 1, 1994.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9523.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act

(sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 4M4417) has been filed by Foodco Corp., 8888 Balboa Ave., San Diego, CA 92123. The petition proposes that the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) be amended to provide for the safe use of a source of high intensity pulsed light to control microorganisms on the surface of food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before June 1, 1994, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the *Federal Register*. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the *Federal Register* in accordance with 21 CFR 25.40(c).

Dated: April 19, 1994.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 94-10326 Filed 4-29-94; 8:45 am]

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## Health Care Financing Administration

[MB-088-N]

RIN: 0938-AG

### Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1994

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

**SUMMARY:** This notice announces the final Federal fiscal year (FFY) 1994 national target and individual State allotments for Medicaid payment adjustments made to hospitals that serve a disproportionate number of Medicaid recipients and low-income patients with special needs. We are publishing this notice in accordance with the provisions of section 1923(f)(1)(C) of the Social Security Act (the Act) and implementing regulations at 42 CFR 447.297 through 447.299.

**EFFECTIVE DATE:** The final DSH payment adjustment expenditure limits included in this notice apply to Medicaid DSH payment adjustments that are applicable to FFY 1994.

**FOR FURTHER INFORMATION CONTACT:** Richard Strauss, (410) 966-2019

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 1923(f) of the Social Security Act and implementing Medicaid regulations at 42 CFR 447.297 through 447.299 require us to estimate and publish in the *Federal Register* the national target and each State's allotment for disproportionate hospital share (DSH) payments for each Federal fiscal year (FFY). DSH payments are payment adjustments made to Medicaid-participating hospitals that serve a large number of Medicaid recipients and other low-income individuals with special needs. Our regulations provide for publication of preliminary amounts by October 1 of each FFY and final amounts by April 1 of each FFY.

The implementing regulations provide that the national aggregate DSH limit for a FFY specified in the Act is a target rather than an absolute cap when determining the amount that can be allocated for DSH payments. The national DSH target is 12 percent of the total amount of medical assistance expenditures (excluding total administrative costs) that are projected to be made under approved Medicaid State plans during the FFY.

(Note: Whenever the phrases "total medical assistance expenditures" or "total

administrative costs" are used in this notice, they mean both the State and Federal share of expenditures or costs.)

In addition to the national DSH target, there is a specific State DSH limit for each State for each FFY. The State DSH limit is a specified amount of DSH payment adjustments applicable to a FFY above which Federal financial participation will not be available. This is called the "State DSH allotment".

Each State's DSH allotment for FFY 1994 is calculated by first determining whether the State is a "high-DSH State," or a "low-DSH State." This is determined by using the State's "base allotment." A State's base allotment is the greater of: (1) the total amount of the State's actual and projected DSH payment adjustments made under the State's approved State plan applicable to FFY 1992, as adjusted by HCFA; or (2) \$1,000,000.

A State whose base allotment exceeds 12 percent of the State's total medical assistance expenditures (excluding administrative costs) projected to be made in FFY 1994 is referred to as a "high-DSH State." The FFY 1994 State DSH allotment for a high-DSH State is limited to the State's base allotment.

A State whose base allotment is equal to or less than 12 percent of the State's total medical assistance expenditures (excluding administrative costs) projected to be made in FFY 1994 is referred to as a "low-DSH State." The FFY 1994 State DSH allotment for a low-DSH State is equal to the State's DSH allotment for FFY 1993 increased by growth amounts and supplemental amounts, if any. However, the FFY 1994 DSH allotment for a low-DSH State cannot exceed 12 percent of the State's total medical assistance expenditures for FFY 1994 (excluding administrative costs).

The growth amount for FFY 1994 is equal to the projected percentage increase (the growth factor) in a low-DSH State's total Medicaid program expenditures between FFY 1993 and FFY 1994 multiplied by the State's final DSH allotment for 1993. Because the national DSH limit is considered a target, low-DSH States whose programs grow from one year to the next can receive growth that would not be permitted if the national limit was viewed as an absolute cap.

There is no growth factor and no growth amount for any low-DSH State whose Medicaid program does not grow (that is, stayed the same or declined) between fiscal years FFY 1993 and FFY 1994. This is the case for Oklahoma, Rhode Island, and West Virginia. Furthermore, because a low-DSH State's FFY 1994 DSH allotment cannot exceed