

C. Grants Policy

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles

- Title 2: Grant and Agreements, Part 225—Cost Principles for State, Local, and Indian Tribal Governments (OMB A–87).

E. Audit Requirements

- OMB Circular A–133, Audits of States, Local Governments, and Non-profit Organizations.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs in their grant application. In accordance with HHS Grants Policy Statement, Rev. 01/07 Part II–27, IHS requires applicants to obtain a current indirect cost rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGO at the time of award, the indirect cost portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGO.

Generally, indirect costs rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <http://rates.psc.gov/> and the Department of Interior (National Business Center) <http://www.aqd.nbc.gov/indirect/indirect.asp>. For questions regarding the indirect cost policy, please call (301) 443–5204 to request assistance.

4. Reporting Requirements

Failure to submit required reports within the time allowed may result in suspension or termination of an active agreement, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the organization or the individual responsible for preparation of the reports.

A. Progress Report

Program progress reports are required semi-annually by the National HIV

Program in order to satisfy quarterly reports due to funding source at Minority AIDS Initiative (MAI). These reports (due mid-November, February, May, August) will include quantitative data as well as a brief comparison of actual accomplishments to the goals established for the period or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of end of the budget/project period.

- An Assessment and Evaluation Report must be submitted within 30 days of the end of each funded year.
- Participation in a minimum of two teleconferences. Teleconferences will be required semi-annually (unless further follow up is needed) for Technical Assistance to be provided and progress to be shared.
- Site visits. Tribal sites using MAI resources should be amenable to the possibility of site visits by IHS staff administering MAI funds.

B. Financial Reports

Annual Financial Status Reports (FSR) must be submitted within 90 days after the budget period ends. Final FSRs are due within 90 days of expiration of the project period. Standard Form 269 (long form for those reporting on program income; short form for all others) will be used for financial reporting.

Federal Cash Transaction Reports are due every calendar quarter to the Division of Payment Management (DPM), Payment Management Branch. Please refer to the DPM Web site at: dpm.psc.gov. Failure to submit timely reports may cause a disruption in timely payments to your organization.

Telecommunication for the hearing impaired is available at: TTY (301) 443–6394.

VII. Agency Contacts

Grants Management Officer

Grants (Business)

Kimberly Pendleton, Grants Management Officer, 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852. (301) 443–5204 or kimberly.pendleton@ihs.gov.

Program (Programmatic/Technical)

CAPT Scott Giberson, IHS National HIV Principal Consultant, 801 Thompson Ave, Reyes Building, Suite 306, Rockville, MD 20852. (301) 443–2449 or scott.giberson@ihs.gov.

The Public Health Service strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of

all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: March 12, 2010.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2010–6206 Filed 3–19–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–N–0050] (Formerly Docket No. 1998N–0046)

Compliance Policy Guide Sec. 540.375 Canned Salmon — Adulteration Involving Decomposition (CPG 7108.10); Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide Sec. 540.375 Canned Salmon — Adulteration Involving Decomposition (CPG 7108.10) (CPG Sec. 540.375). CPG Sec. 540.375 is included in FDA's Compliance Policy Guides Manual, which was listed in the Annual Comprehensive List of Guidance Documents that published on March 28, 2006.

DATES: The withdrawal is effective March 22, 2010.

FOR FURTHER INFORMATION CONTACT:

Robert D. Samuels, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2300.

SUPPLEMENTARY INFORMATION: In a notice containing a cumulative list of guidances available from the agency that published in the **Federal Register** on March 28, 2006 (71 FR 15422 at 15453), FDA included the Compliance Policy Guides Manual, which includes CPG Sec. 540.375. FDA is withdrawing CPG Sec. 540.375 because it is obsolete. Current guidance to FDA staff relating to decomposition in fish and fishery products, including canned salmon, is provided in CPG Sec. 540.370 - Fish and

Fishery Products — Decomposition, which is available on the Internet at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm123201.htm>.

Dated: March 9, 2010.

Michael A. Chappell,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 2010-6209 Filed 3-19-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-C-0077]

Biocompatibles UK Ltd.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Biocompatibles UK Ltd., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of C.I. Reactive Blue No. 4 [2-anthracenesulfonic acid, 1-amino-4-(3-((4,6-dichloro-s-triazin-2-yl)amino)-4-sulfoanilino)-9,10-dihydro-9,10-dioxo, disodium salt] (CAS Reg. No. 4499-01-8) reacted with polyvinyl alcohol as a color additive in vascular embolization devices.

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 20740-3835, 301-436-1071.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 0C0288) has been filed by Biocompatibles UK Ltd., c/o John Greenbaum, Generic Devices Consulting, Inc., 20310 SW. 48th St, Southwest Ranches, FL 33332. The petition proposes to amend the color additive regulations in 21 CFR part 73, subpart D, *Medical Devices*, to provide for the safe use of C.I. Reactive Blue No. 4 [2-anthracenesulfonic acid, 1-amino-4-(3-((4,6-dichloro-s-triazin-2-yl)amino)-4-sulfoanilino)-9,10-dihydro-9,10-dioxo, disodium salt] (CAS Reg. No. 4499-01-8) reacted with polyvinyl alcohol as a color additive in vascular embolization devices.

The agency has determined under 21 CFR 25.32(l) that this action is of a type that does not individually or

cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 5, 2010.

Mitchell A. Cheeseman,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2010-6177 Filed 3-19-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0123]

Impact of Dissolvable Tobacco Use on Public Health; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to provide an opportunity for interested parties to share information, research, and ideas on how use of dissolvable tobacco products may impact public health, including such use among children. This information will be used to support the work of the Tobacco Products Scientific Advisory Committee, which is charged with evaluating this issue.

DATES: Submit written or electronic comments by *[insert date 180 days from date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov/>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathleen K. Quinn, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 240-276-1717, Kathleen.Quinn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Tobacco products are responsible for more than 440,000 deaths each year. The Centers for Disease Control and Prevention report that every day in the United States, approximately 3,900 young people between these ages of 12 and 17 smoke their first cigarette and approximately 1,000 adolescents become daily smokers. Multiple studies

have shown that adolescents who use smokeless tobacco products are more likely to become smokers than those who do not.

Dissolvable tobacco products are a novel class of smokeless tobacco products, which are sold as thin strips, tablets, and sticks resembling toothpicks. Because some of these products look like candy, are highly flavored, and can be easily concealed, public health officials have raised concerns that dissolvable tobacco products may be particularly appealing to children and adolescents. These products also contain up to 4.0 milligrams of nicotine per unit, which could facilitate initiation of tobacco use and the development of nicotine dependence in adolescents, or even serve as a mechanism for inadvertent toxicity in children.

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Among its many provisions, the Tobacco Control Act added section 907(f) to the Federal Food, Drug, and Cosmetic Act (the act). This section requires FDA to refer the issue of “the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children” to a Tobacco Products Scientific Advisory Committee, which will be charged with providing FDA a report and recommendations.

We are requesting comments that will support the work of the Tobacco Products Scientific Advisory Committee in evaluating the public health impact of dissolvable tobacco products. A copy of the Tobacco Control Act is available at <http://www.fda.gov/tobacco>.

II. Request for Comments and Information

Data around the nature, impact, and use of dissolvables tobacco products will be critical to the Tobacco Products Scientific Advisory Committee in studying and reporting on their public health impact. We are therefore requesting comment, research, and data on ways in which these products might be used by individuals, including children and adolescents, how the risks of using these products are perceived by smokers and non-smokers, and how use of these products affects health. Such research may address: