
Dated: March 9, 2010.

Michael A. Chappell,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 2010–6209 Filed 3–19–10; 8:45 am]
BILLING CODE 4160–01–S

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-sulfooanilino)-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.


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 Greembrook, 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-sulfooanilino)-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]
BILLING CODE 4160–01–S

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 Quinn, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd, Rockville, MD 20852.

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 dissolvable 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:
• Perceptions of dissolvable tobacco products from current tobacco users and tobacco-naïve individuals, by age;
• Marketing of dissolvable tobacco products to current tobacco users and tobacco-naïve individuals, by age;
• Impact of dissolvable tobacco products on initiation of tobacco use in tobacco-naïve individuals, by age;
• Dual use of dissolvable tobacco products by current tobacco users;
• Impact of dissolvable tobacco products on cessation of tobacco use;
• Risk of accidental ingestion of dissolvable tobacco products;
• Risk of accidental nicotine toxicity through use of dissolvable tobacco products; and
• Consumer understanding of the potential toxicity of dissolvable tobacco products to children.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified by the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 17, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6216 Filed 3–19–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Molecular and Cellular Neuroscience.
Date: April 1, 2010.
Time: 1 p.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
(Telephone Conference Call.)
Contact Person: Laurent Taupenot, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4811, MSC 7850, Bethesda, MD 20892. 301–435–1203, taupenot@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Virology and Viral Immunity.
Date: April 6–7, 2010.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
(Virtual Meeting)
Contact Person: Richard G. Kostriken, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892. 301–402–4454, kostrikr@csr.nih.gov.

Dated: March 12, 2010.

Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–6107 Filed 3–19–10; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Date: May 7, 2010.
Time: 2 p.m. to 4 p.m.
Agenda: To review and evaluate grant applications.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel, Eureka Meeting.
Date: April 15–16, 2010.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3AN12B, Bethesda, MD 20892.
(Virtual Meeting).
Contact Person: Lisa A. Dunbar, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301–504–2849, dunbarl@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)
Dated: March 12, 2010.

Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–6112 Filed 3–19–10; 8:45 am]