

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.

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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: