

patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA approved for marketing the human drug product VEREGEN (kunecatechins). VEREGEN is indicated for the topical treatment of external genital and perianal warts in immunocompetent patients 18 years and older. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for VEREGEN (U.S. Patent Nos. 5,795,911 and 5,968,973) from Mitsui Norin Co., Ltd., and Cancer Institute (Hospital), Chinese Academy of Medical Sciences, and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated July 24, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VEREGEN represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VEREGEN is 3,002 days. Of this time, 2,605 days occurred during the testing phase of the regulatory review period,

while 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* August 14, 1998. The applicant claims August 13, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 14, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* September 30, 2005. The applicant claims September 23, 2005, as the date the new drug application (NDA) for VEREGEN (NDA 21-902) was initially submitted. However, FDA records indicate that NDA 21-902 was submitted on September 30, 2005.

3. *The date the application was approved:* October 31, 2006. FDA has verified the applicant's claim that NDA 21-902 was approved on October 31, 2006.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,300 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 4, 2008. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 1, 2008. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: April 28, 2008.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Food Labeling Workshop; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with The University of Arkansas (UA), is announcing a public workshop entitled "Food Labeling Workshop." This public workshop is intended to provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups.

**Date and Time:** This public workshop will be held on August 12, 2008, from 8 a.m. to 5 p.m., and on August 13, from 8 a.m. to 4 p.m.

**Location:** The public workshop will be held at the Continuing Education Center, 2 East Center St., Fayetteville, AR (located downtown).

**Contact:** David Arvelo, Small Business Representative, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, or email: [david.arvelo@fda.hhs.gov](mailto:david.arvelo@fda.hhs.gov).

For information on accommodation options, contact Steven C. Seideman, 2650 North Young Ave., Institute of Food Science & Engineering, University of Arkansas, Fayetteville, AR 72704, 479-575-4221, FAX: 479-575-2165, or email: [seideman@uark.edu](mailto:seideman@uark.edu).

**Registration:** You are encouraged to register by July 29, 2008. The University of Arkansas requires a \$150 registration fee to cover the cost of facilities, materials, and breaks. Seats are limited;

please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on

the day of the public workshop, beginning at 8 a.m. The cost of registration at the site is \$200, payable to: "The University of Arkansas." If you need special accommodations due to a disability, please contact Steven C. Seideman (see Contact) at least 7 days in advance.

*Registration Form Instructions:* To register, please complete the following form and submit along with a check or money order for \$150, payable to the "The University of Arkansas." Mail to: Institute of Food Science & Engineering, University of Arkansas, 2650 North Young Ave., Fayetteville, AR 72704.

Name:

Affiliation:

Mailing Address:

City/State/Zip Code:

Phone:

Fax:

E-mail:

Special Accommodations Required:

*Transcripts:* Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested at cost through the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

**SUPPLEMENTARY INFORMATION:** This public workshop is being held in response to the large volume of food labeling inquiries from small food manufacturers and startups originating from the area covered by the FDA Dallas District Office. The SWR SBR presents these workshops to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393(f)), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the SBR Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business

Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), as an outreach activity by a government agency to small businesses.

The goal of this public workshop is to present information that will enable manufacturers and regulated industry to better comply with labeling requirements, especially in light of growing concerns about obesity and food allergens. Information presented will be based on agency position as articulated through regulations guidance. Topics to be discussed at the workshop include: (1) Mandatory label elements, (2) nutrition labeling requirements, (3) health and nutrition claims, (4) the Food Allergen Labeling and Consumer Protection Act of 2004, and (5) special labeling issues such as exemptions. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food labeling and increase voluntary compliance.

Dated: May 27, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0306]

#### Preparation for International Cooperation on Cosmetics Regulations Meetings in Washington, DC; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "International Cooperation on Cosmetics Regulations (ICCR)—Preparation for ICCR Meetings in Washington, DC" to provide information and receive comments on the International Cooperation on Cosmetics Regulations (ICCR) as well as the upcoming meetings in Washington, DC. The topics to be discussed are the topics for discussion at the forthcoming ICCR steering committee meeting. The purpose of the meeting is to solicit public input prior to the next steering committee and expert working group meetings in Washington, DC, the week of July 28, 2008, at which the action items from the first ICCR meeting are to be discussed.

**DATES:** The meeting will be held on June 19, 2008, from 3 p.m. to 4:30 p.m. Send