

Dated: August 3, 2005.

John P. Kennedy,

General Counsel.

[FR Doc. 05-15719 Filed 8-4-05; 12:34 p.m.]

BILLING CODE 6725-01-P

FEDERAL TRADE COMMISSION

Public Workshop: Marketing, Self-Regulation & Childhood Obesity

AGENCIES: Federal Trade Commission (FTC or Commission); Department of Health and Human Services (HHS).

ACTION: Notice of Extension of Public Comment Period.

SUMMARY: Due to requests for additional time to prepare more comprehensive comments in response to the issues that were addressed by the public workshop, an amendment is being issued to the Notice Announcing Public Workshop: Marketing, Self-Regulation & Childhood Obesity to extend the time period during which persons may submit written comments on the workshop until August 12, 2005.

DATES: Comments must be received on or before Friday, August 12, 2005.

ADDRESSES: Comments should refer to "Food Marketing to Kids Workshop—Comment, Project No. P034519" to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered, with two complete copies, to the following address: Federal Trade Commission/Office of the Secretary, Room 159-H (Annex H), 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Because paper mail in the Washington area and at the Agency is subject to delay, please consider submitting your comments in electronic form, as prescribed below. Comments containing confidential material, however, must be filed in paper form, must be clearly labeled "Confidential," and must comply with Commission Rule 4.9(c).¹

Comments filed in electronic form should be submitted by clicking on the following Web link: <https://secure.commentworks.com/ftc-foodmarketingtokids> and following the instructions on the Web-based form. To ensure that the Commission considers

an electronic comment, you must file it on the Web-based form at the <https://secure.commentworks.com/ftc-foodmarketingtokids> Web link.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at <http://www.ftc.gov>. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

FOR FURTHER INFORMATION CONTACT:

Richard Kelly, (202) 326-3304, or Michelle Rusk, (202) 326-3148, FTC, Bureau of Consumer Protection. The FTC staff contacts can be reached by mail at: Federal Trade Commission, 601 New Jersey Avenue, N.W., Washington, DC 20580. Jennifer Bishop, (202) 690-8384, HHS, Office of the Assistant Secretary for Planning and Evaluation. The HHS staff contact can be reached by mail at: The U.S. Department of Health and Human Services, 200 Independence Avenue, S.W., Room 447-D, Washington, DC 20201.

A detailed agenda and additional information on the workshop is posted on the FTC's Web site at www.ftc.gov/bcp/workshops/foodmarketingtokids/index.htm.

SUPPLEMENTARY INFORMATION:

Background and Workshop Goals

Obesity in children has recently become one of the top public health issues in the United States. As a result, increased attention has been given to the importance of a balanced and nutritious diet and physical activity in childhood to ensure healthy growth and development and prevent chronic conditions and disease, such as obesity. Within both the government and the private sector, multiple efforts are being taken or proposed to find and implement effective measures to reverse the rise of childhood obesity. These include a wide variety of approaches, including identifying and funding additional research on childhood obesity, considering changes to food and beverage labeling, encouraging physical activity, and educating parents and children about the importance of

physical activity and eating a balanced, nutritious diet.

One frequent area of attention is the role of food and beverage advertising and marketing directed to children. Industry members in the United States have adopted their own set of guidelines to encourage responsible advertising, including food advertising, to children. These guidelines are administered by the Council of Better Business Bureau's Children's Advertising Review Unit (CARU). In recent years, many individual companies in the food, beverage, and restaurant industries, and in the media and entertainment industries, have also taken actions to advance responsible food and beverage marketing to children and promote healthy lifestyles.

In light of the widespread public interest in marketing of food and beverages to children, the FTC and HHS hosted a public workshop, "Marketing, Self-Regulation & Childhood Obesity," in Washington, DC on July 14 and 15, 2005. The workshop provided a forum for discussion of ongoing industry self-regulatory efforts that seek to address the marketing of food and beverages to children.² At the workshop, participants discussed industry members' efforts to address concerns about marketing to children, and CARU's efforts to encourage responsible industry advertising. It also provided a forum to hear from consumer advocacy and public health groups concerning current industry practices. Specific topics and issues addressed at the workshop are set forth in the FTC and HHS Notice Announcing Public Workshop: Marketing, Self-Regulation & Childhood Obesity, published in the **Federal Register** on May 12, 2005.

Extension of Time for Filing Comments

The time period during which public comments may be submitted is extended. Interested parties may submit written comments on the published questions and other related issues addressed by the workshop until August 12, 2005. Especially useful are any studies, surveys, research, and empirical data. All comments should be filed as prescribed in the **ADDRESSES** section

¹ The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

² The workshop focused on food and beverage marketing to children. It did not cover other possible contributors to childhood obesity, including sedentary behaviors like watching television, playing electronic games on a computer, or decreases in exercise, or the marketing of related sedentary entertainment products.

above, and must be received on or before Friday, August 12, 2005.

Donald S. Clark,

Secretary.

[FR Doc. 05-15683 Filed 8-5-05; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0045]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Electronic Records; Electronic Signatures" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 11, 2005 (70 FR 24818), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0303. The approval expires on July 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: July 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-15544 Filed 8-5-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0031]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Premarket Notification for a New Dietary Ingredient" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 3, 2005 (70 FR 22886), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0330. The approval expires on July 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: July 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-15545 Filed 8-5-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0288]

International Conference on Harmonisation; Draft Guidance on Q9 Quality Risk Management; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Q9 Quality Risk Management." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides principles and examples of tools for quality risk management that can be applied to all aspects of pharmaceutical quality throughout the lifecycle of drug substances, drug products, and biological and biotechnological products. The draft guidance is intended to enable regulators and industry to make more effective and consistent risk-based decisions.

DATES: Submit written or electronic comments on the draft guidance by October 7, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: David J.

Horowitz, Center for Drug Evaluation and Research (HFD-300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-8910; Anna M. Flynn, Center for Biologics Evaluation and Research (HFMA-610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6201; Diana J. Kolaitis, Office of Regulatory Affairs (HFR-NE1), Food and Drug Administration,