among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Guidance on Repeat-Dose Chronic Toxicity Testing

In the **Federal Register** of October 23, 2003 (68 FR 60703), FDA published the notice of availability of the VICH draft guidance, giving interested persons until November 24, 2003, to submit comments. After consideration of comments received, the draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on May 3, 2004, the VICH Steering Committee endorsed the final guidance for industry, VICH GL–37. This VICH guidance is one of a series of guidances developed to facilitate the mutual acceptance of safety data necessary for the determination of acceptable daily intakes for veterinary drug residues in human food. This guidance was developed after consideration of the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, the United States, Australia, New Zealand, and Canada. It also took account of available data from subchronic and chronic toxicity studies.

Information collection is covered under the Office of Management and Budget (OMB) control number 0910–0032.

III. Significance of Guidance

This document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH document have been substituted with ''should.'' Similarly, words such as ''require'' or ''requirement'' have been replaced by ''recommend'' or ''recommendation'' as appropriate to the context.

The VICH guidance (#160) is consistent with the agency's current thinking on the safety of residues of veterinary drugs in human foods. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

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 with 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.

V. Electronic Access

Copies of the guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing'' (VICH GL–37) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: January 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2266 Filed 2–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

University of Arkansas/Food and Drug Administration Food Labeling; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Small Business Representative Program (SWR SBR), in collaboration with The University of Arkansas (UA), is announcing a public workshop entitled ''UA/FDA 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 April 5, 2005, from 8 a.m. to 5 p.m., and on April 6, 2005, from 8 a.m. to 3 p.m.

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

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 e-mail: *seideman@uark.edu*.

For information on accommodation options, contact Steven C. Seideman (see *Contact*).

Registration: Registration by March 21, 2005, is encouraged. The University of Arkansas has a $75 registration fee to cover the cost of facilities, materials, speakers, 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 $80 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 form below and submit along with a check or money order for $75 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: The FDA Southwest Regional Small Business Representative previously presented this workshop in Kansas City, MO on January 10 and 11, 2002 (66 FR 65976) and in Dallas, TX on April 14 and 15, 2002 (67 FR 15211).

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 Denver District Office. The Southwest Regional Small Business Representative 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), 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 Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, 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 (Public Law 104–121), as outreach activities by Government agencies 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 regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Mandatory label elements, (2) nutrition labeling requirements, (3) health and nutrition claims, (4) FDA's allergen declaration policy, 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: February 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2299 Filed 2–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Publication and Release of the National Response Plan

AGENCY: Department of Homeland Security.

ACTION: Notice.

SUMMARY: This Notice informs the public that the Department of Homeland Security (DHS) has developed and published the National Response Plan, which is now available to the public.

Authority: Homeland Security Act of 2002, Public Law 107–296; Homeland Security Presidential Directive -5, Management of Domestic Incidents.

FOR FURTHER INFORMATION CONTACT: National Response Plan: Bob Shea, Operational Integration Staff, DHS, Washington, DC 20528, 202–282–9651 or *Robert.shea@dhs.gov*.

National Incident Management System: Gil Jamieson, National Incident Management System Integration Center, DHS/FEMA, Washington, DC 20472, 202–646–4090, or *Gil.Jamieson@dhs.gov*.

SUPPLEMENTARY INFORMATION: Homeland Security Presidential Directive -5 required the Secretary of Homeland Security to develop and administer a National Incident Management System and a National Response Plan. The National Incident Management System (NIMS), released in March 2004, established a unified and standardized approach within the United States for protecting citizens and managing homeland security incidents. The National Response Plan standardizes Federal incident management actions by integrating existing and formerly distinct processes. Using the comprehensive framework of the NIMS, the National Response Plan provides the structure and mechanisms for the coordination of Federal support to State, local, and tribal incident managers and for exercising direct Federal authorities and responsibilities. It is applicable to all Federal departments and agencies that may be requested to provide assistance or conduct operations in the context of actual or potential incidents of national significance.

The purpose of the National Response Plan is to establish a comprehensive, national, all-hazards approach to domestic incident management across a spectrum of activities including prevention, preparedness, response, and recovery. The National Response Plan incorporates the best practices and procedures from various incident management disciplines—homeland security, emergency management, law enforcement, firefighting, hazardous materials response, public works, public health, emergency medical services, and responder and recovery worker health and safety—and integrates them into a unified coordinating structure. As such, it is intended to replace the Initial National Response Plan, the Federal Response Plan, the U.S. Government Domestic Terrorism Concept of Operations Plan, and the Federal Radiological Emergency Response Plan, all of which are currently in effect.

The National Response Plan represents a true ''national'' framework in terms of both product and process. The National Response Plan development process included extensive vetting and coordination with Federal, State, local, and tribal agencies, nongovernmental organizations, private-sector entities, and the first-responder and emergency management communities across the country. The activation of the National Response Plan and its coordinating structures and protocols—either partially or fully—for specific incidents of national significance provides mechanisms for the coordination and implementation of