group to develop guidance for pharmaceutical development throughout the life cycle of a product.

In November 2004, the ICH Steering Committee agreed that a draft guidance entitled ''Q8 Pharmaceutical Development'' should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

This document is a significant element in FDA's initiative, ''Pharmaceutical Current Good Manufacturing Practices for the 21 Century,'' which encourages review of current manufacturing science practices. Scientific information obtained during the design of a product and from the pharmaceutical development studies is important for the development and selection of a product formulation that meets the purpose specified in the product application.

The draft guidance describes the suggested contents for the pharmaceutical development section (section 3.2.P.2 of module 3: Quality) of a regulatory submission in the CTD format. The draft guidance is intended to assist in the development of pharmaceutical studies that provide scientific understanding to support the establishment of specifications and manufacturing controls and serve as the basis for evaluating risk management over the life cycle of the product.

This draft guidance applies to pharmaceutical studies as defined in section 3.2.P.2 of module 3 of the CTD. The draft guidance does not apply to submissions for drug products during the clinical research stages. However, the principles described in the draft guidance are important to consider during product development.

This draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this draft guidance. 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. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: February 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2449 Filed 2–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

New Mexico State University/Food and Drug Administration Food Labeling; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Small Business Representative Program (SWR SBR), in collaboration with New Mexico State University (NMSU), Department of Extension Home Economics is announcing a public workshop entitled ''NMSU/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: The public workshop will be held on March 21, 2005, from 8 a.m. to 5 p.m. and on March 22, 2005, from 8 a.m. to 3 p.m.

Location: The public workshop will be held at NMSU, Las Cruces, NM 88003, Gerald Thomas Hall, rm. 337. Directions to the facility are available at *http://www.nmsu.edu/General/Maps/*.[1]

Contact: Gloria Hernandez, New Mexico State University, P.O. Box 30003, MSC 3AE, Las Cruces, NM 88003, 505–646–2198, FAX 505–646–1889, or e-mail: *glorhern@nmsu.edu*.

Registration: Registration by March 11, 2005, is encouraged. NMSU has an $89 registration fee to cover the cost of facilities, materials, speakers, and breaks. Seats are limited to 80 people, 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 $99 payable to New Mexico State University. If you need special accommodations due to a disability, please contact Gloria Hernandez (see *Contact*) at least 7 days in advance.

Registration Form Instructions: To register, please complete the form below and send along with a check or money order for $89 payable to the New Mexico State University. Mail to: New Mexico State University, P.O. Box 30003, MSC 3AE, Las Cruces, NM 88003–8003. After March 11, 2005, the registration cost is $99. Credit card payment is not available.

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 December 21, 2001 (66 FR 65976), and in Dallas, TX on March 29, 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

[1]FDA has verified the Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

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 increased voluntary compliance.

Dated: February 2, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2450 Filed 2–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 17, 2005, from 8 a.m. to 5:30 p.m., and on March 18, 2005, from 8:30 a.m. to 2:30 p.m.

Location: Holiday Inn Gaithersburg, 2 Montgomery Village Ave., Gaithersburg, MD.

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 17, 2005, the committee will hear updates on the following topics: Summary of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability meeting, summary of the Transmissible Spongiform Encephalopathies Advisory Committee meeting, update on West Nile Virus guidance, and summaries of the Critical Path Initiative workshop. In the morning, the committee will also discuss and provide recommendations on the safety of albumin. In the afternoon, the committee will hear additional updates on the following topics: International agreements, and a presentation on sharing information with the public. Additionally, the committee will hear presentations, and discuss and provide recommendations on rapid freezing of plasma for transfusion. On the morning of March 18, 2005, the committee will hear presentations, and discuss and provide recommendations on the study design for the abbreviated uniform donor history questionnaire. The committee also will hear presentations related to the review of the site visit report for the Laboratory of Molecular Virology, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review.

Procedure: On March 17, 2005, from 8 a.m. to 5:30 p.m., and on March 18, 2005, from 8:30 a.m. to 12:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 25, 2005. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon, and 3:30 p.m. and 4:45 p.m. on March 17, 2005, and between approximately 9:30 a.m. and 10 a.m. on March 18, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 9, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On March 18, 2005, between 1:30 p.m. and 2:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the site visit report for the Laboratory of Molecular Virology, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Evaluation and Research.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Pearline K. Muckelvene at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 1, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–2452 Filed 2–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Chiropractor Loan Repayment Demonstration Project

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: General notice.

SUMMARY: The authority for the Demonstration Project has been extended with respect to chiropractors (see legislative authority below). The Health Resources and Services Administration (HRSA) announces that applications from qualified chiropractors who agree to serve