Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Aerospace Building, Washington, DC 20447, Phone: 800–281–9519, E-mail: *ocsgrants@acf.hhs.gov.*

VIII. Other Information

Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *http://www.Grants.gov*. Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html*.

Please visit the OCS Asset Building Web page at *http://www.acf.hhs.gov/assetbuilding* for additional information about this program. The Web site includes a wealth of ideas and suggestions for developing and managing an AFI Project. In particular, it includes downloadable text of the AFI Act and a synopsis of grantee responsibilities imposed by the Act. It also includes a downloadable guidebook, The AFI Project Builder, which includes many tips, suggestions and best practices for planning, starting and implementing an AFI Project. Applicants can visit the site for in-depth information regarding the requirements for applying for and implementing an AFI Project.

Applicants will be sent acknowledgements of received applications.

Dated: February 4, 2005.

Clarence H. Carter,

Director, Office of Community Services.

[FR Doc. 05–2512 Filed 2–8–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0021]

International Conference on Harmonisation; Draft Guidance on Q8 Pharmaceutical Development; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Q8 Pharmaceutical Development.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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). This draft guidance describes the suggested contents for the pharmaceutical development section in the quality module of a regulatory submission in the ICH M4 Common Technical Document (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 The draft guidance is intended to assist in the development of pharmaceutical studies that provide scientific understanding to support the establishment of specifications and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.

DATES: Submit written or electronic comments on the draft guidance by April 11, 2005.

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 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 (HFM–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. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Ajaz Hussain, Center for Drug Evaluation and Research (HFD–3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2847; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

During the July 2003 ICH meeting in Brussels, agreement was reached on a common vision and approach for developing an international plan for a harmonized pharmaceutical quality system that would be applicable across the life cycle of a product. This plan emphasizes an integrated approach to review (assessment) and inspection based on scientific risk management. One aspect of the plan was the establishment of an expert working

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**.