each function or activity in such terms as the number of people to be served and the number of activities accomplished. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates.

If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any ''collection of information that is conducted or sponsored by ACF.''

List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

Criterion 4. Budget and Budget Justification (15 points)

Provide line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimated methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. The detailed budget must also include by the funding sources identified in Block 15 of the SF–424.

Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

Required Notification of the State Single Point of Contact

This program is covered under Executive Order 12372, Intergovernmental Review of Federal Programs and 45 CFR part 100, Intergovernmental Review of Department of Health and Human Services Program and Activities. Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

All States and Territories except Alabama, Alaska, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, American Samoa, and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-five jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applicants and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date or contact if no submittal is required) on the Standard Form 424, Item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations.

Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State recommendations which may trigger the ''accommodate or explain'' rule.

When comments are submitted directly to ACF, they should be addressed to: William Wilson, Head Start Bureau, 330 C Street, SW., Washington, DC 20447, Attn: Head Start—Child Development Associate Credentialing Program.

A list of Single Points of Contact for each State and Territory can be found on the web site. http://www.whitehouse.gov/omb/grants/spoc.html.

Dated: December 18, 2001.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 01–31500 Filed 12–20–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA Food Labeling and Allergen Declaration; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Southwest Regional Small Business Program (Small Business Program), Office of Regulatory Affairs, in collaboration with FDA's Center for Food Safety and Applied Nutrition, the State of Missouri Department of Public Health, the Kansas City Department of Health and the Missouri Milk, Food and Environmental Health Association is announcing a public workshop entitled ''FDA Food Labeling and Allergen Declaration.'' This public workshop is intended to provide information about FDA food regulations, food labeling allergen declaration, good manufacturing practices, and other related matters to the regulated industry, particularly small businesses and startups.

Date and Time: The public workshop will be held on January 10 and 11, 2001, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Kansas City Department of Health Auditorium, 2400 Troost Ave., Kansas City, MO.

Contact: Gala Jaramillo, Missouri Milk, Food and Environmental Health Association, P.O. Box 105017, Jefferson City, MO 65110–5017, 573–634–6418, or Sue Thomason, FDA, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247–4982, 214–655–8100, ext. 128, FAX 214–655–8114.

Registration: Preregistration by January 3, 2002, is encouraged. The Missouri Milk, Food and Environmental Health Association has a $20 preregistration fee to cover the cost of breaks. To preregister, please complete the form below and send along with a check or money order for $20 payable to The Missouri Milk, Food and Environmental Health Association (address above). As an alternative, the registration form and directions to the facility can also be obtained on the Internet at http://www.fda.gov/ora/indust_assit/Default.htm. Seats are limited, please submit registration form as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive written confirmation. Registration will close when the course is filled. Registration at the site will be done 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 $25 payable to The Missouri Milk, Food and Environmental Health Association. If you need special accommodations due to a disability, please contact Leslie Foresberg at 816–513–6315 at least 7 days in advance.

Name: _____

Agency: _____

Mailing Address: _____

City: _____

State: _____

Zip Code: _____

Phone: ( ) _____

FAX: ( ) _____

E-mail: _____

Transcripts: Transcripts of the public workshop may be requested in writing from 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 workshop is being held in response to a request by the State of Missouri to present information that would be helpful to regulated industry. The Small Business Program presents this workshop 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 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 the 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 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) FDA food regulations, (2) food labeling, (3) allergen declaration, (4) good manufacturing practices, and (5) the Nutrition Labeling Education Act. FDA expects that participation in this workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food labeling and allergen declaration.

Dated: December 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–31572 Filed 12–19–01; 12:37 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0465]

Guidance for Industry on Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications.'' This guidance is a second revision of the guidance entitled ''Major, Minor, FAX, and Telephone Amendments to Original Abbreviated New Drug Applications.'' FDA's Office of Generic Drugs (OGD) determined that further revision of the policy regarding determination of major, minor, and telephone amendments was necessary to help streamline the review of abbreviated new drug applications (ANDAs).

DATES: Submit written or electronic comments on the guidance by March 21, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rita R. Hassall, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications.'' The guidance is intended to document OGDs policy regarding the determination of major, minor, and telephone amendments to original and supplemental ANDAs. This guidance first published in August 1999 and was originally entitled ''Major, Minor, FAX, and Telephone Amendments to Original Abbreviated New Drug Applications.'' It was revised in May 2000 to explain that the issuance of a major, minor, or FAX amendment would stop the review clock.

The second revision of this guidance (1) deletes the FAX amendment designation, which was found to be unnecessary, (2) now applies to supplemental applications as well, and (3) changes the criteria for determining the type of amendment. The changes in criteria should result in more amendments being categorized as ''minor'' and fewer as ''major.'' A minor amendment request (generally reviewed within 30 to 60 days) has a higher priority than a major amendment. Since the review of a minor amendment takes place sooner than a major amendment after the original review, there is not a long break in the review process for a minor amendment. The response to a major amendment request, however, goes into the 180-day queue. This process causes a greater time lapse from when the original review was done and results in reviewers having to refamiliarize themselves with the application. It is expected that the new policy will help in moving applications through the approval process more quickly than under the previous policy. Thus the total time for approval of ANDAs will be reduced.

Because it lessens the burden on industry, this guidance is being issued as a Level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). As with other Level 1 guidances for immediate