21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX 301–827–6801, e-mail: Topper@cder.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number) and written material and requests to make oral presentations to the contact person by September 28, 2001.

If you need special accommodations due to a disability, please contact Kimberly Topper (address above) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

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 medical product development among regulatory agencies. The ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with harmonization 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, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and 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. The ICH Steering Committee includes representatives from each of the ICH sponsors and Canadian Therapeutics Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at http://www.ifpma.org/ich1.html.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 12:30 and 2 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by September 28, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on September 28, 2001, under Docket No. 01N–0370, at the Docket Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Transcripts: Transcripts of the meeting 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 meeting at a cost of 10 cents per page.

Dated: August 30, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–22471 Filed 9–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94P–0240]

Small Entity Compliance Guide: ''Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, Pectin;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in the **Federal Register** of March 16, 1999 (64 FR 12887), entitled ''Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, and Pectin.'' The SECG is intended to set forth the requirements of that final rule in plain language and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written comments concerning this SECG 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. Submit written requests for single copies of the SECG to Lori A. LeGault (address below). Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Lori A. LeGault, Center for Food Safety and Applied Nutrition (HFS–840), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5269.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 18, 1997 (62 FR 61476), FDA published a proposed rule to amend the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for the food category ''Baking powder, baking soda, pectin.'' A final rule based on that proposed rule was published in the **Federal Register** of March 16, 1999 (64 FR 12887).

FDA examined the economic implications of that final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–602). The agency determined that the final rule would have a significant economic impact on a substantial number of small entities.

In compliance with section 212 of the Small Business Regulatory Fairness Act (Public Law 104–121), FDA made available (via the Internet) a small entity compliance guide stating in plain language the requirements of this regulation.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on the subject. 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, at any time, submit written or electronic comments on the SECG entitled ''Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, Pectin'' to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the SECG may also be viewed on a personal computer with access to the Internet. The Center for Food Safety and Applied Nutrition's home page includes the SECG and can be found at http://www.cfsan.fda.gov/~dms/sodaguid.html.

Dated: August 28, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–22481 Filed 9–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98N–1230, 96P–0418, and 97P–0197]

Small Entity Compliance Guide: ''Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule that published in the **Federal Register** of December 5, 2000 (65 FR 76092), entitled ''Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution.'' The SECG is intended to set forth the requirements of that final rule in plain language and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on this SECG at any time.

ADDRESSES: Submit written comments concerning this SECG 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. Submit written requests for single copies of the SECG to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St., Washington, DC 20204, 202–205–4561. Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT:

For the labeling provisions: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

For refrigeration provisions: Nancy S. Bufano, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–401–2022.

SUPPLEMENTARY INFORMATION:

I. Background

To reduce the risk of illness and death from consumption of eggs contaminated with *Salmonella enteritidis* (SE), FDA published in the **Federal Register** of July 6, 1999 (64 FR 36492), a proposed rule requiring the labeling of shell eggs with a safe handling statement and the refrigeration of shell eggs at retail. FDA published the final rule in the **Federal Register** of December 5, 2000 (65 FR 76092).

FDA examined the economic implications of that final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–602) and determined that the final rule would have a significant economic impact on a substantial number of small entities.

In compliance with section 212 of the Small Business Regulatory Fairness Act (Public Law 104–121), FDA made available (via the Internet) a SECG stating in plain language the requirements of this regulation.

FDA is issuing this SECG as level 2 guidance consistent with FDAs good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on the subject. 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, at any time, submit written or electronic comments on the SECG entitled ''Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution'' to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the SECG may also be viewed on a personal computer with access to the Internet. Center for Food Safety and Applied Nutrition's home page includes the SECG and can be found at http://www.cfsan.fda.gov/~dms/eggsguid.html.

Dated: August 28, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–22482 Filed 9–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Call for Applications for the Directors Council of Public Representatives (COPR)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH), the Federal government's primary agency for supporting and conducting medical research leading to the improvement in the nation's health, has established a relatively new national advisory council—the Directors Council of Public Representatives (COPR). The Chair of COPR is the Director of the National Institutes of Health. This notice describes the process for the selection of members of the COPR that NIH will use, as the original founding