look at the available data and to identify options (pro & con) for food labeling and food packaging, which are relevant to consumers' weight management decisions. Topics to be discussed at the workshop include: ''Current food labels and packaging: Effects on weight management and reduced risk of overweight and obesity'' and ''Data supporting options for change.'' The workshop will include sessions with expert views on food packaging and labeling, and on messaging in the restaurant environment relevant to overall weight management.

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.

Dated: October 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26268 Filed 10–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0470]

Preparation for the International Conference on Harmonisation Meetings and ICH 6 Conference in Osaka, Japan; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH Meetings and ICH 6 Conference in Osaka, Japan, November 9–15, 2003'' to provide information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Osaka, Japan. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Experts Working Groups meetings and ICH 6 Public Conference in Osaka, Japan, November 2003, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on November 3, 2003, from 1 p.m. to 4 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3d floor, Twinbrook Conference Room, Rockville, MD 20857.

Contact Person: Christelle Anquez, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20817, 301–827–0037, FAX: 301–480–0716, *e-mail: canquez@oc.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 October 24, 2003. If you need special accommodations due to a disability, please contact Christelle Anquez at least 7 days in advance.

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.

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. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. 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 (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. 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 at the following Web site: *http://www.ich.org* (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)**.

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 3:15 p.m. and 4 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 October 24, 2003, and submit a brief statement of the general nature of the evidence or arguments they which 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 October 17, 2003, via the Internet at *http://www.fda.gov/cder/calendar/meeting/ich2003/nov3meeting.htm.*

Information on the ICH 6 Public Conference in Osaka, Japan on November 12–15, 2003, can be obtained via the internet at *http://www.ich.org/ich6tris.html* (FDA has verified the Web site address, but is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register).**

Dated: October 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26283 Filed 10–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1997D–0443]

Iron-Containing Supplements and Drugs: Label Warning Statement Requirements; Small Entity Compliance Guide; 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) entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements; Small Entity Compliance Guide'' to revise and update an earlier SECG entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide.'' The revised SECG is being issued in response to the withdrawal, in part, of a final rule. The SECG is intended to set forth in plain language the requirements for label warning statements for iron-containing dietary supplement and drug products in solid oral dosage form and to help small businesses understand these requirements.

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

ADDRESSES: Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECG to *http://www.fda.gov/dockets/ecomments.*

Submit written requests for single copies of the SECG to the Iron Labeling, Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance document.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1441.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 15, 1997 (62 FR 2218), FDA issued a final rule (1997 final rule) requiring: (1) Label warning statements on iron-containing products taken in solid oral dosage form to supplement the dietary intake of iron or to provide iron for therapeutic purposes, and (2) unit-dose packaging for iron-containing dietary supplement and drug products that contain 30 milligrams (mg) or more of iron per dosage unit. This final rule became effective July 15, 1997. In the **Federal Register** of December 12, 1997 (62 FR 65432), FDA announced the availability of a SECG entitled ''Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide'' (1997 SECG). The 1997 SECG was prepared in accordance with section 212 of the Small Business Regulatory Enforcement Act (Public Law 104–121) and was intended to help small businesses understand the requirements of the 1997 final rule.

Elsewhere in this issue of the **Federal Register**, FDA is withdrawing those parts of the 1997 final rule that established regulations in §§111.50 and 310.518(a) and (b) (21 CFR 111.50 and 310.518(a) and (b)) requiring unit-dose packaging for iron-containing dietary supplement and drug products that contain 30 mg or more of iron per dosage unit. FDA is taking this action in response to the Court's ruling in *Nutritional Health Alliance* v. *FDA* (318 F.3d 92 (2d Cir. 2003)), in which the U.S. Court of Appeals for the Second Circuit invalidated the unit-dose packaging regulations based upon its conclusion that the Federal Food, Drug, and Cosmetic Act does not provide FDA with authority to regulate packaging of iron-containing dietary supplement and drug products for poison prevention purposes. The Court's ruling affects only the unit-dose packaging requirements of the 1997 final rule and not the label warning statement requirements. On remand, the U.S. District Court for the Eastern District of New York entered final judgment in accordance with the Court's decision, declaring the provisions of §§ 111.50 and 310.518(a) invalid and without legal force or effect (*Nutritional Health Alliance* v. *FDA*, No. 97–CV–5042 (E.D.N.Y. filed May 29, 2003)). As a result, the 1997 SECG is being revised in accordance with the Court's ruling and FDA's withdrawal of the unit-dose packaging regulations.

Therefore, FDA is making available the revised SECG entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements; Small Entity Compliance Guide,'' which states in plain language the requirements of the final rule on label warning statements for iron-containing dietary supplement and drug products.

FDA is revising 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 this 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. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

II. Comments

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 to *http://www.fda.gov/dockets/ecomments* 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/guidance.html.*

Dated: October 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26189 Filed 10–16–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0231]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until December 16, 2003, the comment period for the draft guidance for industry