at http://www.fda.gov/ohrms/dockets/ac/00mtbc.htm.

*Procedure:* 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 23, 2000. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 12 noon, and 3:45 p.m. and 4:15 p.m. on March 1, 2000; between approximately 8 a.m. and 8:30 a.m., 11:15 a.m. and 11:45 a.m., 1 p.m. and 1:30 p.m., and 4:15 p.m. and 4:45 p.m. on March 2, 2000; and between approximately 9:15 a.m. and 11:15 a.m., and 2:45 p.m. and 3:15 p.m. on March 3, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 23, 2000, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the March 1, 2, and 3, 2000, General and Plastic Surgery Device Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the General and Plastic Surgery Device Panel of the Medical Devices Advisory Committee meeting were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: February 14, 2000.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 00–4157 Filed 2–16–00; 4:19 pm]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Food and Drug Administration/Industry Exchange Workshop on Scale- Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of workshop.

**SUMMARY:** The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Drug Evaluation and Research, and the Central Region Small Business Office, and the Northeast Region Small Business Office, in cooperation with the International Society for Pharmaceutical Engineering (ISPE) is announcing the following workshops: FDA/Industry Exchange Workshops on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes. The workshops are intended to review the scientific, regulatory, and quality basis of SUPAC; discuss current issues; and provide attendees with information on the impact of the SUPAC guidances that have been finalized, as well as future agency efforts in this area.

*Date and Time:* See Table 1 following the ''Location'' section of this document.

*Location:* See Table 1 below.

TABLE 1

| Workshop Address | Date and Local Time | FDA Contact Person |
|---|---|---|
| Newark Airport Marriot, Newark International Airport, Newark, NJ 07114, 1–800–882–1037, FAX: 973–623–7618 | Monday, March 20, 2000, from 9 a.m. to 5 p.m. | Marie T. Falcone |
| Chicago Marriott Schaumburg, 50 North Martingale Rd., Schaumburg, IL 60173, 847–240–0100, FAX: 847–240–2388 | Monday, April 10, 2000, from 9 a.m. to 5 p.m. | Do. |
| Providence Marriott, One Ohms St., Providence, RI 02904, 1–800–937–7768, FAX: 401–861–3550 | Thursday, May 4, 2000, from 9 a.m. to 5 p.m. | Do. |

Persons needing hotel rooms should mention that they are attending the ISPE, FDA/SUPAC workshop.

*Contact:* Marie T. Falcone, Industry and Small Business Representative, FDA, rm. 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106, 215–597–2120, ext. 4003, e-mail: mfalcone@ora.fda.gov.

*Registration:* Send registration information (including name, title, firm name, address, telephone, and fax number), along with a $295 check (member) or $450 (nonmembers) (which will cover refreshments, lunch, and materials) made payable to ISPE, 3816 W. Linebaugh Ave., suite 412, Tampa, FL 33624, 813–960–2105, or visit the ISPE at the Internet at http://www.ispe.org. Registrations are due 1 week prior to the start of each course. Space is limited, therefore, interested parties are encouraged to register early. Limited on-site registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact ISPE at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** The workshops further implement the FDA Plan for Statutory Compliance (developed under Section 406 of the FDA Modernization Act (21 U.S.C. 393)) by working more closely with stakeholders, maximizing the availability of, and clarifying information about the process for review and submissions, and ensuring access to needed scientific and technical expertise.

The topics to be discussed include the following: (1) The history of SUPAC development; (2) comparison of SUPAC immediate-release solid dosage forms, modified-release oral dosage forms, and semisolid-topical dosage forms; (3) bulk actives postapproval changes; (4) postapproval changes sterile aqueous solutions; (5) FDA field staff's involvement in SUPAC; (6) description

and use of the equipment addenda to SUPAC; and (7) facts, figures, and future directions.

The workshop also complies with the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), which requires outreach activities by government agencies directed to small businesses.

Dated: February 16, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 00–4158 Filed 2–16–00; 4:19 pm]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0436]**

## Food and Drug Administration Draft Study Report; Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing for comment a draft study report on the feasibility of appropriate methods of informing customers of the contents of bottled water, as required by the Safe Drinking Water Act Amendments. This draft feasibility study report evaluates and identifies appropriate methods that may be feasible for conveying information about bottled water to customers.

**DATES:** Written comments must be received by April 24, 2000.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Buckner, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4081.

**SUPPLEMENTARY INFORMATION:** The text of the draft study report on the feasibility of appropriate methods of informing customers of the contents of bottled water follows:

FDA Draft Study Report: Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

### I. Background

On August 6, 1996, the President signed into law the Safe Drinking Water Act (SDWA) Amendments (Public Law 104–182). Under the Public Notification section of the Amendments, the Environmental Protection Agency (EPA) was required to issue regulations mandating that each community water system provide each customer of the system with an annual report, referred to as a consumer confidence report (CCR), on the level of contaminants in the drinking water purveyed by that system. A complete description of the information contained in a CCR can be found in the next section of this document entitled ''FDA's Evaluation of Information about the Contents of Bottled Water.''

In the **Federal Register** of February 13, 1998 (63 FR 7606), EPA published a proposed rule to require local water systems to provide an annual CCR to their customers. Based on this proposal, EPA published a final rule on August 19, 1998 (63 FR 44512). Section 114(b) of the SDWA Amendments also required that, no more than 18 months after the date of its enactment, the Food and Drug Administration (FDA), in consultation with EPA, publish for notice and comment a draft study on the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water.

In a notice published in the **Federal Register** of November 12, 1997 (62 FR 60721) (hereinafter ''the 1997 notice''), FDA requested comment on several matters relevant to the feasibility of appropriate methods of informing customers of the contents of bottled water. We have evaluated the information received and identified appropriate methods that may be feasible for conveying information about bottled water to customers. This draft feasibility study presents the agency's evaluation of those methods. Congress, under the SDWA Amendments, did not expressly address FDA's authority for implementing, by regulation, any appropriate methods deemed feasible. Should FDA, in the future, decide to engage in rulemaking on this subject, FDA would discuss, in such a rulemaking, the agency's statutory authority for requiring any of the types of information or for requiring a specific method for conveying such information on the contents of bottled water to customers. However, such a discussion is outside the scope of this study. Comments received on this draft report will be evaluated and considered in preparation of the final report on the feasibility of appropriate methods, if any, for providing information about the contents of bottled water to customers.

In the 1997 notice, FDA asked for specific information to use in generating the feasibility study. The agency considered this to be the most effective means of obtaining information from all segments of the general public (i.e., industries, trade associations, consumers, consumer advocacy groups, educational institutions) that are interested in the subject of the feasibility of appropriate methods of providing information on bottled water to customers. The following specific information was requested: (1) What methods, if any, may be appropriate for conveying information about the contents of bottled water to customers, and why they are appropriate; (2) for each method identified as being appropriate for conveying information to customers, whether such method is or is not feasible and the supporting reasons why the method is or is not feasible; and (3) the type of information about the contents of bottled water that should be provided to customers within the context of the SDWA Amendments and that would, to the extent possible, be analogous to the information provided in a CCR.

The agency received 51 letters in response to the 1997 notice. Many comments stated that it is not necessary to provide customers with more information than they currently receive on bottled water. Comments that expressed these opinions are beyond the scope of this report and are not discussed.

### II. Information About the Contents of Bottled Water

In the 1997 notice, FDA requested comments on the type of information about the contents of bottled water that should be provided to customers that would, to the extent possible, be analogous to information provided in a CCR. To that end, the agency notes that a CCR, as outlined by EPA, contains: (1) Information about the source of drinking water; (2) definitions of ''maximum contaminant level'' (MCL), ''maximum contaminant level goal'' (MCLG), ''exemption'' and ''variance''; (3) the MCL, MCLG, and contaminant level detected in the water for regulated contaminants and, for any contaminant detected that violates the MCL during the year, information on the health effects that led EPA to regulate that contaminant; (4) information on compliance with EPA's National Primary Drinking Water Regulations and notice if the system operates under a variance or an exemption and the basis on which the variance or exemption was