authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States.

FDA uses the written authorization from the foreign country or the certification from a responsible company official in the United States to determine whether the foreign country has any objection to the importation of the device into their country.

The respondents to this collection of information are companies that seek to export medical devices.

FDA estimates the reporting burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 801(e)(2) | 20 | 1 | 20 | 2.5 | 50 |
| Total | | | | | 50 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the experience of FDA's medical device program personnel, who estimate that completion of the requirements of this collection of information should take approximately 2.5 hours to complete.

Dated: May 27, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–13755 Filed 6–2–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Arthritis Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Arthritis Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on June 23 and 24, 2003, from 8 a.m. to 5 p.m.

*Location*: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person*: Johanna Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On June 23, 2003, the committee will discuss fibromyalgia, clinical trial design, including important disease endpoints in the study, and development of therapies and treatments. On June 24, 2003, the committee will discuss the safety and efficacy of submission tracking number 103795/5123, ENBREL (etanercept), Immunex, for reducing signs and symptoms of active ankylosing spondylitis.

*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 June 13, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12 noon on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 13, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact LaNise Giles at 301–827–7001, at least 7 days in advance of the meeting.

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

Dated: May 24, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 03–13757 Filed 6–2–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Drug Manufacturing Inspections; Public Workshops

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

**ACTION:** Notice of public workshops.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a series of public workshops to discuss current good manufacturing practice (CGMP) issues, including quality subsystems, areas of change control, and quality management. There will also be a discussion of current compliance issues and trends and the status of the part 11 (21 CFR part 11) draft guidance. The first workshop will be held in June 2003, then repeated in July 2003 and August 2003 at different locations to enable as many people to attend as possible. Held in collaboration with the Consumer Healthcare Products Association (CHPA), the workshops are intended to update participants with respect to issues involving CGMP compliance. Participants will also hear from FDA and industry speakers on

specific topics related to methodologies and implementation of quality systems including areas such as global change control and corrective action preventative action (CAPA) investigations.

**DATES:** For the dates of the workshops, see table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

**ADDRESSES:** For the locations of the workshops, see table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Fred Razzaghi, Consumer Healthcare Products Association, 1150 Connecticut Ave. NW., Washington, DC 20036, FAX 202–223–6835, *fred.razzaghi@chpa-info.org*; *http://www.chpa-info.org*; or Erik N. Henrikson, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9004, FAX 301–827–8907, *henriksone@cder.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

*A. Who Should Attend?*

This document is directed towards professionals involved in the manufacture, control, and regulation of pharmaceutical products. Examples of professionals who may be interested include process/production engineers, quality assurance/quality control and regulatory affairs professionals, auditors, repackers and relabelers, consultants, regulatory investigators, CGMP compliance officials, and FDA center and field personnel. Other entities or individuals may also be interested in attending.

*B. Where and When Will The Workshops Be Held?*

We have scheduled three workshops at different times and locations to enable as many people to participate as possible. Attendees can attend the workshop that is most convenient. The times and locations of the workshops are listed in table 1 of this document.

TABLE 1.—WORKSHOP LOCATIONS AND SCHEDULES

| Workshop Location | Date and Time |
|---|---|
| Sheraton Meadowlands Hotel, Two Meadowlands Plaza, East Rutherford, NJ 07073, 201–896–0500, FAX 201–896–9696. | Monday, June 16, 2003, from 8:30 a.m. to 5 p.m. |
| San Juan Marriott Resort, 1309 Ashford Ave., San Juan, PR 00907, 800–981–8546, FAX 809–722–6800. | Monday, July 14, 2003, from 8:30 a.m. to 5 p.m. |
| Hyatt Regency Chicago, 151 East Wacker Dr., Chicago, IL 60601, 312–565–1234, FAX 312–565–2966. | Tuesday, August 12, 2003, from 8:30 a.m. to 5 p.m. |

*C. How Can I Participate?*

You can participate in person. Anyone interested in attending a workshop can register through the **INFORMATION CONTACT**.

*D. Is There a Registration Fee for This Workshop?*

Yes, a registration fee of $ 320.00 is required. The registration fee includes workshop reference materials and lunch plus a continental breakfast and coffee breaks. Government employees qualify for a discounted rate of $75.

*E. How Can I Get Additional Information?*

The notice of participation form, information about the workshop, and other related documents are available from the **INFORMATION CONTACT** or from the Internet at *http://www.fda.gov.cder/workshop.htm*.

## II. Background Information

*A. Why is FDA Cosponsoring These Workshops?*

FDA is cosponsoring this series of workshops to provide information and training opportunities for industry as well as FDA center and field personnel. The workshops are being scheduled for three different times and locations to enable as many participants to attend as possible.

*B. What Will Be Covered?*

The workshops will provide an update on the progress of the agency's CGMP initiative, the status of the part 11 draft guidance, and the agency's progress in developing ideas about risk management associated with CGMP. In addition, FDA and industry speakers will present information and training on specific topics related to methodologies and implementation of quality systems in categories such as global change control and CAPA investigations. Presentations by both FDA and industry will provide a regulatory and practical perspective on the current relevant critical topics.

Dated: May 27, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–13756 Filed 6–2–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003N–0207]**

### Preparation for ICH Meetings in Brussels, Belgium, and ICH 6 Conference in Osaka, Japan: Public Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration is announcing a public meeting entitled ''Preparation for ICH Meetings in Brussels, Belgium, July 15–18, 2003, and ICH 6 Conference in Osaka, Japan, November 12–15, 2003'' to solicit information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming Meetings in Brussels, Belgium. The topic to be discussed is the Common Technical Document, GMPs Initiative and Update on other 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 Expert Working Group meetings in Brussels, Belgium, July 2003, at which discussion of the topics underway and the future of ICH will continue and also to inform the public about the ICH 6 Public Conference in Osaka, Japan in November 2003.

*Date and Time*: The public meeting will be held on June 24, 2003, from 10 a.m. to 1 p.m.

*Location*: The public meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

*Contact Person*: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX 301–827–6801, email: Topperk@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 June 9, 2003.

If you need special accommodations due to a disability, please contact