measuring patient experiences within the health care system of the United States. As the research partner of the Centers for Medicare & Medicaid Services (CMS), AHRQ is charged with the development of a hospital patient experience of care instrument as well as the development of reporting strategies to maximize the utility of the survey results.

The mutual goal of AHRQ and CMS is to develop a standardized instrument for use in the public reporting of patients' hospital experiences that is reliable and valid, freely accessible, and that will make comparative non-identifiable information on hospital patients' perspectives on care widely available. While there are many good survey tools available to hospitals, there is currently no nationally used or universally accepted survey instrument that allows comparisons across all hospitals. In response, and at the request of CMS, AHRQ and the CAHPS® II Grantees developed an initial instrument with input from the various stakeholders in the industry. The initial draft of the HCAHPS® instrument was tested as part of a CMS three-State pilot by hospitals in Arizona, Maryland, and New York. Based on an analysis of these data, the instrument was revised and shortened. The revised 32-item HCAHPS® instrument is currently undergoing additional testing as specified in a **Federal Register** Notice published on July 31, 2003 (FR Vol. 68, No. 147, 44951–44953) which can be accessed at *http://www.access.gpo.gov/su_docs/fedreg/a030731c.html.* Based on the results of this additional testing by selected sites and public comments on the current instrument, further revisions to the HCAHPS® instrument may be made.

Once the HCAHPS® instrument is finalized, it will be on the AHRQ and CMS websites for use by interested individuals and organizations. Plans have been made to make the HCAHPS instrument available to ''The Quality Initiative: A Public Resource on Hospital Performance,'' which is a public/private partnership that includes the major hospital associations, governments, consumer groups, measurement and accrediting bodies, and other stakeholders interested in reporting on hospital quality. In the first phase of the partnership (which has already begun), hospitals are voluntarily reporting the results of their performance on ten clinical quality measures for three medical conditions: acute myocardial infarction, heart failure, and pneumonia. HCAHPS® reporting will comprise an additional and differently focused phase of quality of care measurement. For more information or to participate in the Quality Initiative, please visit *http://www.aha.org* under ''Quality and Patient Safety, Quality Initiative,'' or at *http://www.fah.org,* under ''Issue/Advisories,'' or at *http://www.aamc.org* by going to ''Government Affairs,'' ''Teaching Hospitals'' and then ''Quality.''

Dated: February 9, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04–3332 Filed 2–13–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices 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: Ophthalmic Devices Panel of the Medical Devices 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 March 5, 2004, from 9 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, ext. 127, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512396. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss general issues surrounding the use of intraocular lenses for correction of presbyopia after clear lens extraction. The committee will address clinical study design elements including the risk/benefit ratio for patients with various refractive errors, study sample size, the need for control groups, inclusion/exclusion criteria, and the incidence of retinal detachment and other complications. Background information, including the attendee list, agenda, and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at *http://www.fda.gov/cdrh/panelmtg.html.*

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 24, 2004. On March 5, 2004, formal oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. Near the end of the committee discussion a second 30-minute open public session will be conducted for interested persons to comment further on the discussion topic. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 24, 2004, 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 AnnMarie Williams at 301–594–1283, ext. 113 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: February 9, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–3334 Filed 2–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0016]

Medical Devices; Revised MedWatch Forms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised MedWatch Voluntary Reporting Form (FDA Form 3500), the revised Mandatory Reporting Form (3500A), and the respective instructions for each form.

DATES: The revised MedWatch forms are effective immediately. The forms were approved by the Office of Management and Budget (OMB) on September 12, 2003 (see 68 FR 58691, October 10, 2003); however, reporters may continue to use the prior version of Forms 3500 and 3500A until August 17, 2004.

FOR FURTHER INFORMATION CONTACT: Howard A. Press, Center for Devices and Radiological Health (HFZ–531), 1350 Piccard Dr., Rockville, MD 20850, 301–827–2983.

SUPPLEMENTARY INFORMATION:

I. Background

Section 303 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) amended the Federal Food, Drug, and Cosmetic Act (the act) to require FDA to modify Forms 3500 and 3500A, the MedWatch voluntary and mandatory reporting forms respectively, to facilitate the reporting, by user facilities or distributors, of adverse events involving single-use devices (SUDs) that have been reprocessed for reuse in humans. The following two questions were added to the revised MedWatch forms: (1) Is this a single-use device that was reprocessed and reused on a patient? and (2) If yes, enter the name and address of the reprocessor.

II. Comments

In the **Federal Register** of April 29, 2003 (68 FR 22716), FDA published a notice requesting public comment on the information collection provisions. FDA received several comments.

One comment stated that there are no affirmative mechanisms that would allow original equipment manufacturers (OEMs) to detect when a single-use device had been reprocessed.

FDA disagrees with this comment. We believe that there are several ways an OEM can ascertain whether a single-use device has been used and reprocessed.

Under § 803.50(b) (21 CFR 803.50(b)), the medical device reporting regulation (MDR), manufacturers are obligated to report information that is reasonably known to them. The information that is reasonably known to a manufacturer includes information that: (1) Can be obtained by contacting the user facility, importer, or other initial reporter; (2) is in the manufacturer's possession, or (3) can be obtained by analysis, testing, or evaluation of the device (see § 803.50(b)).

If an OEM has reason to believe that the SUD has been reprocessed, there are a number of steps the OEM can take to follow up. The OEM can contact either the user facility or the reporter to determine if the SUD was reprocessed and reused on a patient (question D8 of both Forms 3500 and 3500A). This information should be readily available to a user facility since the practice of reusing reprocessed SUDs generally requires the user facility to have in place a written policy, procedure, or contract that supports this practice. In all cases, FDA recommends that requests for information to user facilities or individual reporters be in writing so that the OEM has documentation about its reasonable efforts to determine if the SUD was reprocessed and reused on a patient. In addition, OEMs may already be in possession of information, such as reports from their sales representatives, which will help them determine if an SUD was reprocessed. An OEM can conduct testing and analysis of any SUD that has been returned to them to try to get additional information about whether the device was reprocessed.

FDA believes that there may be occasional situations where an OEM has exhausted all reasonable mechanisms to determine whether the SUD has been reprocessed and is still unable to determine its status. In that event, the OEM should enter ''UNK'' (unknown) in block D8 and report in block H10 of the 3500A form that it is unable to determine if the suspect device was reprocessed and reused on a patient. The OEM also should describe in block H10, the steps the OEM took to try to obtain the information, including any responses from user facilities or other reporters. The OEM's MDR files should include supporting documentation for what has been reported in block H10.

FDA wishes to emphasize that it considers any entity that reprocesses an SUD for reuse in humans to be the manufacturer of the reprocessed SUD and, accordingly, subject to all the regulatory requirements currently applicable to OEMs, including the responsibility for MDR reporting. Therefore, if an OEM determines that an SUD has been reprocessed for reuse in humans, the OEM has no further MDR obligation for the device involved in this event. The OEM should forward all of the information concerning the event to FDA and state in the cover letter that the SUD was reprocessed. In that case, the SUD is not the OEM's device, but rather is now the reprocessor's device (see § 803.22(b)(2) (21 CFR 803.22(b)(2)).

One comment referred to an apparent conflict between the amended section 303 of MDUFMA and MDR (§ 803.52(f)(11)(i) and (f)(11)(iii)), which requires manufacturers to provide corrected and/or missing data on the MedWatch form. If the data are not provided, the manufacturer is required to explain why the information was not provided and the steps that were taken to obtain the information.

FDA disagrees with this comment. We do not believe that there is a conflict between section 303 of MDUFMA and the MDR regulation. The purpose of section 303 of MDUFMA was to facilitate the reporting of information relating to reprocessed SUDs. We believe that this information will come primarily from user facilities, which generally have in place policies, procedures, or agreements supporting the reuse of reprocessed SUDs. As stated previously, once an OEM determines that the SUD has been reprocessed by either contacting the user facility, reviewing information in the firm's possession, or by testing or evaluating the device itself, the OEM is no longer responsible for reporting the event or any information related to the event.

A comment addressed the redesign of both forms FDA 3500 and FDA 3500A. The comment suggested revising sections F and H of the mandatory MedWatch form (FDA Form 3500A) and section D of the voluntary MedWatch Form (FDA Form 3500).

FDA disagrees with this comment. The MedWatch forms are used by all entities that report to the agency. However, the two new questions pertain only to medical devices. Consequently, we redesigned the forms to limit the changes to those required under MDUFMA. The instructions for completing the revised Forms 3500 and 3500A have been modified accordingly and are available on FDA's MedWatch Web site (see **III. Availability of Forms**).

Some comments requested to extend the deadline to comply with the revised forms. Initially, one comment asked that manufacturers be given until September 30, 2005, to comply with the revised form. A later comment suggested providing a 1-year interim period for industry to modify their reporting systems.

FDA partially agrees with the comments. Congress required FDA to modify the MedWatch forms by April 26, 2003. We agree that a reasonable period of time is needed for medical device reporters to incorporate the two new questions into their reporting systems. In the October 10, 2003, notice, FDA announced that OMB approved the information collection for the MedWatch program. At FDA's request, OMB approved the continued use of the previous forms for 6 months to allow

time for the reporters to make the necessary changes to their computerized systems.

During this transitional period FDA will accept both the newly effective Forms 3500 and 3500A and the prior versions of the forms. Information concerning the reuse of the product (new question D8) and the name and address of the reprocessor (new question D9) can be provided in section H10 on the prior version of form 3500A (OMB approval date, November 2002). Reporters may continue to use the prior version of Forms 3500 and 3500A until [*insert date 6 months after date of publication in the* **Federal Register**]. During this 6-month period, the prior versions and the instructions will be available on FDA's Center for Devices and Radiological Health MDR Web site at *http://www.fda.gov/cdrh/mdr/mdr-forms.html*.

III. Availability of Forms

The newly revised MedWatch forms are available at FDA Form 3500 *http://www.fda.gov/medwatch/safety/3500.pdf* and FDA Form 3500A *http://www.fda.gov/medwatch/safety/3500a.pdf*.

The instructions for the revised forms are available at FDA Form 3500 *http://www.fda.gov/medwatch/report/consumer/instruct.htm* and FDA Form 3500A *http://www.fda.gov/medwatch/report/instruc.htm*.

Dated: January 30, 2004.

Beverly Chernaik Rothstein,

Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.

[FR Doc. 04–3333 Filed 2–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0834]

Draft Guidance for Industry on Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling.'' The draft guidance is intended to assist applicants in developing labeling for new drug applications (NDAs) for such drug products. This is the third draft of the guidance, which initially issued in September 1999.

DATES: Submit written or electronic comments on the draft guidance by April 19, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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 draft guidance to the Division of Dockets Management (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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Margaret Kober, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4243.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling.'' The draft guidance describes the recommended labeling for health care providers and patient instructions for inclusion in NDAs. A draft of this guidance was first issued on September 27, 1999 (64 FR 52100). However, on September 10, 2002, the agency withdrew the draft guidance (67 FR 57432), pending consideration of the results from the National Institutes of Health (NIH) Women's Health Initiative (WHI). In the **Federal Register** of February 3, 2003 (68 FR 5300), the agency issued a second draft reflecting the agency's thinking after considering the results of the WHI substudy concerning overall risks and benefits of hormone therapy for postmenopausal symptoms.

The agency is issuing this third draft guidance to address comments received, to incorporate new study results from the WHI, and to better inform prescribers and patients regarding the availability of the lowest effective dose for these drug products. This third draft supersedes the second draft and reflects the agency's thinking after considering these issues. Further revisions to the guidance may be necessary as additional information becomes available.

On May 31, 2002, the WHI study of conjugated estrogens 0.625 milligram (mg)/day (CE) plus medroxyprogesterone acetate 2.5 mg/day (MPA) in postmenopausal women was stopped after a mean of 5.2 years of followup because the test statistic for invasive breast cancer exceeded the stopping boundary for this adverse effect and the global index statistic supported risks exceeding benefits. Data on the major clinical outcomes through April 30, 2002, regarding increased risks for invasive breast cancer, heart attacks, strokes, and venous thromboembolism rates, including pulmonary embolism, became available July 17, 2002. On March 17, 2003, additional information was published about health-related quality of life.

The Women's Health Initiative Memory Study (WHIMS), a substudy of the WHI, was published on May 28, 2003. It concluded that women treated in the study with conjugated estrogens 0.625 mg combined with medroxyprogesterone acetate 2.5 mg have a greater risk of developing probable dementia than those on placebo. Detailed information about WHIMS is available at *http://www.nih.gov/PHTindex.htm*.

This third draft of the guidance retains and updates the labeling recommendations regarding the results of the WHI study and recommends adding risk information related to the results of the WHIMS study to appropriate sections of the labeling, including the boxed warning. It also adds to the WARNINGS section that use of estrogen-containing products may increase the risk of mammographic abnormalities. In addition, because it is unknown whether risks for postmenopausal women prescribed estrogen-containing products for the treatment of moderate to severe vasomotor symptoms and moderate to severe symptoms of vulvar and vaginal atrophy differ depending on the dose prescribed, the guidance recommends