

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

*Date and Time:* The meeting will be held on May 5 and 6, 2008, from 8 a.m. to 4:30 p.m.

*Location:* Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD. The hotel telephone number is 301-948-8900.

*Contact Person:* Teresa Watkins, 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: [Teresa.Watkins@fda.hhs.gov](mailto:Teresa.Watkins@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in Washington, DC area), codes 3014512529 and 3014512535. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory hotline/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On May 5, 2008, the committees will discuss new drug application (NDA) 22-272, OXYCONTIN (oxycodone hydrochloride controlled-release) Tablets, Purdue Pharma L.P., and its safety for the proposed indication of management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. The sustained-release characteristics of this formulation are purportedly less easily defeated than other formulations of OXYCONTIN. On May 6, 2008, the committees will discuss supplemental new drug application (sNDA) 21-947/s-005, FENTORA (fentanyl buccal tablet), Cephalon, Inc., and its safety for the proposed indication of breakthrough pain in opioid tolerant non-cancer patients with chronic pain.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at [\[dockets/ac/acmenu.htm\]\(http://www.fda.gov/ohrms/dockets/ac/acmenu.htm\), click on the year 2008 and scroll down to the appropriate advisory committee link.](http://www.fda.gov/ohrms/</a></p>
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*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 on or before April 21, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Those desiring to make formal oral presentations should notify the contact person 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 on or before April 11, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 14, 2008.

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 Teresa Watkins at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: March 20, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Obstetrics and Gynecology 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:* Obstetrics and Gynecology 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 May 16, 2008, from 8 a.m. to 5:30 p.m.

*Location:* Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Michael Bailey, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4100, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area), code 3014512524. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss, make recommendations, and vote on a premarket approval application for the FC2 Female Condom, sponsored by the Female Health Co. This device is indicated to help prevent HIV/AIDS and unintended pregnancy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after

the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

*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 on or before May 2, 2008. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m., and between 3:30 p.m. and 4 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before April 24, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 25, 2008.

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 Ann Marie Williams, Conference Management Staff, at 240-276-8932, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: March 20, 2008.

**Randall W. Lutter,**  
Deputy Commissioner for Policy.  
[FR Doc. E8-6290 Filed 3-26-08; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

**Proposed Project: The Nurse Faculty Loan Program (NFLP): Program Specific Data Form (NEW)**

The Nurse Faculty Loan Program (NFLP) is authorized under Title VIII of the Public Health Service Act, Section 846A, as amended by the Nurse Reinvestment Act, Public Law 107-205

to increase the number of qualified nurse faculty. The HHS, acting through HRSA, may enter into an agreement with schools of nursing and make an award to establish and operate a distinct NFLP loan fund. The NFLP loan fund is used by the applicant School of Nursing to make loans to eligible students pursuing an advanced nursing degree program that will prepare the student to become qualified as a nursing faculty.

The NFLP Program Specific Data Form will capture program-related information provided by the applicant. NFLP applicants will complete and submit the Program Specific Data Form as an electronic attachment with the required application materials. The form will provide the Federal Government with specific data from the applicant to specify: (1) The amount of the Federal funds requested by the applicant, (2) the expected contribution from the applicant, (3) the student enrollment and graduation data based on current and prospective NFLP loan recipients, (4) the graduate nursing education programs supported under NFLP, (5) the program accreditation status, (6) the current tuition and fee information for graduate nursing education programs, and (7) the projected NFLP loan fund balance that may be considered as part of the award determination. The data provided in the form are essential for the formula-based criteria used to determine the award amount to the applicant schools. The new Program Specific Data Form will facilitate the current effort to develop an automated data collection capability for the NFLP. The electronic data collection capability will streamline the application submission process, enable an efficient award determination process, and serve as a data repository to facilitate reporting on the use of funds and analysis of program outcomes. Additionally, the data will be used to ensure programmatic compliance with the legislative authority and program guidance, to report program accomplishments to policy makers and Congress, and to formulate and justify the appropriation to the Office of Management and Budget and Congress.

The estimate of burden for this form is as follows:

| Form  | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|-----------------------|--------------------------|-----------------|--------------------|--------------------|
| Nurse Faculty Loan Program Annual Operating Report (AOR). | 150                   | 1                        | 150             | 8 hours .....      | 1200 hours         |
| Total Burden .....  | 150                   | 1                        | 150             | 8 hours .....      | 1200 hours         |