

and 312.82). The information collection provisions in § 312.47 concerning End-of-Phase 2 meetings and Pre-NDA meetings have been approved by OMB (OMB control number 0910 0014). However, the guidance provides

additional recommendations for submitting information to FDA in support of a meeting request.

In the **Federal Register** of March 20, 2012 (77 FR 16235), FDA published a 60-day notice requesting public

comment on the proposed collection of information. FDA received no comments on the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

| Meeting requests and information packages | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Meeting Requests:                         |                       |                                    |                        |                             |             |
| CDER .....                                | 975                   | 2.06                               | 2,014                  | 10                          | 20,140      |
| CDER .....                                | 127                   | 1.99                               | 253                    | 10                          | 2,530       |
| Total .....                               |                       |                                    |                        |                             | 22,670      |
| Information Packages:                     |                       |                                    |                        |                             |             |
| CDER .....                                | 756                   | 1.84                               | 1,394                  | 18                          | 25,092      |
| CDER .....                                | 112                   | 1.81                               | 203                    | 18                          | 3,654       |
| Total .....                               |                       |                                    |                        |                             | 28,746      |
| Grand Total .....                         |                       |                                    |                        |                             | 51,416      |

Dated: July 13, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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:** Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

**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 August 8, 2012, from 8 a.m. to 5 p.m.

**Location:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/>

[AdvisoryCommittees/default.htm](#); under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

**Contact Person:** Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [ACPS-CP@fda.hhs.gov](mailto:ACPS-CP@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**Agenda:** During the first session, the committee will discuss the uses and limitations of in vitro dissolution testing and propose future direction for evaluation including possible research. During the second session, the committee will receive an update on the FDA's recently posted draft guidances for industry on biosimilar products. This will be an awareness topic and

there will not be formal Committee discussion or recommendation.

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/AdvisoryCommittees/Calendar/default.htm>. 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 August 1, 2012. Oral presentations from the public will be scheduled between approximately 11 a.m. to 12 noon for the first session, and 3:45 p.m. to 4:15 p.m. for the second session. Those individuals interested in making 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 July 24, 2012. 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 July 25, 2012.

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 Yvette Waples 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.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: July 16, 2012.

**Jill Hartzler Warner,**  
*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012-17667 Filed 7-19-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA

Reports Clearance Office on (301) 443-1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### **Proposed Project: Enrollment and Recertification of Entities in the 340B Drug Pricing Program (OMB No. 0915-0327)—[Revision]**

Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities which choose to participate in the section 340B Drug Pricing Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(9) of the PHS Act to notify manufacturers of the identities of covered entities and the mandate of section 340B(a)(5)(A)(ii) to establish a mechanism to ensure against duplicate discounts and the ongoing responsibility to administer the 340B Drug Pricing Program while maintaining efficiency, transparency and integrity, the HRSA Office of Pharmacy Affairs (OPA) developed a process of registration of covered entities to enable it to address those mandates.

#### **Enrollment/Registration**

To enroll and certify the eligible federally funded grantees and other safety net health care providers, OPA

requires entities to submit administrative information (e.g. shipping and billing arrangements, Medicaid participation), certifying information and signatures from appropriate grantee level or entity level authorizing officials and state/local government representatives. The purpose of this registration information is to determine eligibility for the 340B Drug Pricing Program. This information is entered into the 340B database by entities and verified by OPA staff according to 340B Drug Pricing Program requirements. Accurate records are critical to implementation of the 340B Drug Pricing Program legislation, especially to prevent diversion and duplicate discounts. To maintain accurate records, 340B statute also requires that entities recertify eligibility annually and that they notify the program of updates to any administrative information that they submitted when initially enrolling into the program. The burden requirement is low for recertification and for submitting change requests.

#### **Contract Pharmacy Self-Certification**

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are also required to submit general information about the arrangements and to certify that signed agreements are in place with those contract pharmacies.

#### **Pharmaceutical Pricing Agreement**

In accordance with the guidance found in the May 7, 1993, **Federal Register**, Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage.

The estimates of annualized burden are as follows:

| Reporting requirement   | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|-----------------------|--------------------------|-----------------|--------------------|--------------------|
| <b>HOSPITAL ENROLLMENT, ADDITIONS &amp; RECERTIFICATIONS</b>    |                       |                          |                 |                    |                    |
| 340B Program Registrations & Certifications for Hospitals ..... | 546                   | 1                        | 546             | 2.0                | 1,092.0            |
| Certifications to Enroll Hospital Outpatient Facilities .....   | 606                   | 1                        | 606             | 0.5                | 303.0              |
| Hospital Annual Recertification .....                           | 4,842                 | 1                        | 4,842           | 0.5                | 2,421.0            |