

each respondent 1.5 hours annually to maintain the records.

The Agency has estimated that on average, 220 user facilities, importers, and manufacturers would annually be required, under § 803.17, to establish new procedures, or revise existing procedures, in order to comply with this

provision. We estimate that it will take each respondent 10 hours annually to establish new procedures, or revise existing procedures.

### Third-Party Disclosure Burden

Under §§ 803.40 and 803.42, device importers report deaths and serious injuries to the manufacturers and FDA.

Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA. We estimate that it will take respondents 1 hour annually to report the information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemptions—803.19 .....	.....	57	4	228	3	684
User Facility Reporting—803.30 and 803.32 .....	.....	544	9	4,896	1	4,896
User Facility Annual Reporting—803.33 .....	3419	195	1	195	1	195
Importer Reporting, Death and Serious Injury—803.40 and 803.42 .....	.....	1	1	1	1	1
Manufacturer Reporting—803.50, through 803.53 .....	.....	1,239	243	301,077	1	301,077
Supplemental Reports—803.56 .....	.....	124	302	37,448	1	37,448
Total .....	.....	.....	.....	.....	.....	344,301

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record	Total hours
MDR Procedures—803.17 .....	220	1	220	10	2,200
MDR Files—803.18 .....	30,000	1	30,000	1.5	45,000
Total .....	.....	.....	.....	.....	47,200

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Importer Reporting, Malfunctions—803.40 and 803.42 .....	1	25	25	1	25

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

### Joint Meeting of the Bone, Reproductive, and Urologic Drugs Advisory Committee, and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of two public advisory committees of the Food and Drug

Administration (FDA). The meeting will be open to the public.

**Name of Committees:** Bone, Reproductive, and Urologic Drugs Advisory Committee, and the Drug Safety and Risk Management Advisory Committee.

**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 June 4, 2015, 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. Answers to commonly asked questions

including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**Contact Person:** Kalyani Bhatt, 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: [BRUDAC@fda.hhs.gov](mailto:BRUDAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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:** The committees will discuss new drug application (NDA) 022526, flibanserin 100 milligram (mg) tablets, submitted by Sprout Pharmaceuticals Inc., proposed for the treatment of hypoactive sexual desire disorder (HSDD) in premenopausal women.

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 meeting 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 20, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 May 12, 2015. 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 May 13, 2015.

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 Kalyani Bhatt 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: May 4, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-11013 Filed 5-6-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

**[Document Identifier: HHS-OS-0990-0424-60D]**

### Agency Information Collection Activities; Proposed Collection; Public Comment Request

**AGENCY:** Office of the Assistant Secretary for Health, Office of Adolescent Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the

Office of Management and Budget (OMB). Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on the ICR must be received on or before July 6, 2015.

**ADDRESSES:** Submit your comments to [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or by calling (202) 690-6162.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier HHS-OS-0990-0424-60D for reference.

**Information Collection Request Title:** Positive Adolescent Futures (PAF) Study.

**Abstract:** The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting approval by OMB on a revised data collection. The Positive Adolescent Futures (PAF) Study will provide information about program design, implementation, and impacts through a rigorous assessment of program impacts and implementation of two programs designed to support expectant and parenting teens. These programs are located in Houston, Texas and throughout the state of California. The revision to this information collection request includes the 12-month follow-up survey instrument related to the impact study. The collected data from this instrument will provide a detailed understanding of the program impacts within the two study sites about one year after youth are enrolled in the study. Plus, have first access to the programming offered by each site. Clearance is requested for three years.

**Need and Proposed Use of the Information:** The data will serve two main purposes. First, the data will be used to determine program effectiveness by comparing outcomes on repeat pregnancies, sexual risk behaviors, health and well-being, and parenting behaviors between treatment (program) and control youth. Second, the data will be used to understand whether the programs are more effective for some youth than others. The findings from these analyses of program impacts will be of interest to the general public, to policymakers, and to organizations interested in supporting expectant and parenting teens.

**Likely Respondents:** 1,913 study participants.