

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 Karen Abraham-Burrell 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: November 5, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-26868 Filed 11-8-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0001]

#### Circulatory System 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:* Circulatory System 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 December 11, 2013, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

*Contact Person:* Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver

Spring, MD 20993, 301-796-3063, 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:* On December 11, 2013, the committee will discuss, make recommendations, and vote on information related to the premarket approval application regarding the Boston Scientific WATCHMAN Left Atrial Appendage (LAA) Closure Technology. The WATCHMAN LAA Closure Technology is a percutaneously delivered permanent cardiac implant placed in the left atrial appendage. This device is intended to prevent thrombus embolization from the left atrial appendage, thereby preventing the occurrence of ischemic stroke and systemic embolism, and reduce the risk of life-threatening bleeding events in patients with non-valvular atrial fibrillation who are eligible for warfarin therapy.

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 November 27, 2013. 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 November 19, 2013. 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 November 20, 2013.

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 [AnnMarie.Williams@fda.hhs.gov](mailto:AnnMarie.Williams@fda.hhs.gov) or 301-796-5966 at least 7 days in advance of the meeting.

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

Dated: November 5, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-26891 Filed 11-8-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-1361]

#### Determination That Adderall (Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate) Tablet and 13 Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:**

Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993-0002, 301-796-5418.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which

authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is generally known as the “Orange Book.” Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA

for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 011522 .....	ADDERALL (amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextro-amphetamine sulfate) Tablet; Oral, 5 milligrams (mg), 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg.	Teva Womens Health Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355.
NDA 011601 .....	KENALOG (triamcinolone acetonide) Cream; Topical, 0.025%, 0.1%.	Apothecon Pharmaceuticals, General Offices, P.O. Box 4500, Princeton, NJ 08543-4500.
NDA 013601 .....	MUCOMYST (acetylcysteine) Solution; Inhalation, Oral, 10%, 20%.	Do.
NDA 018531 .....	NITROGLYCERIN (nitroglycerin) Injectable; Injection, 5mg/milliliter (mL).	Hospira Inc., 275 North Field Dr., Bldg. H2, Lake Forest, IL 60045-5046.
NDA 018726 .....	WESTCORT (hydrocortisone valerate) Ointment; Topical, 0.2%.	Ranbaxy Inc., 600 College Rd., East Princeton, NJ 08540.
NDA 018830 .....	TAMBOCOR (flecainide acetate) Tablet; Oral, 50 mg, 100 mg, 150 mg.	Medicis Pharmaceutical Corp., 7720 North Dobson Rd., Scottsdale, AZ 85256.
NDA 020336 .....	DYNACIRC CR (isradipine) Tablet; Extended Release, Oral, 5 mg, 10 mg.	GlaxoSmithKline LLC., 2711 Centerville Rd., Ste. 400, Wilmington, DE 19808.
NDA 020518 .....	RETROVIR (zidovudine) Tablet; Oral, 300 mg .....	ViiV Healthcare, 5 Moore Dr., Research Triangle Park, NC 27709.
NDA 021745 .....	RYZOLT (tramadol HCl) Tablet; Extended Release, Oral, 100 mg, 200 mg, 300 mg.	Purdue Pharma Products LP, 1 Stamford Forum, Stamford, CT 06901.
NDA 022021 .....	ALTACE (ramipril) Tablet; Oral, 1.25 mg, 2.5 mg, 5 mg, 10 mg.	Pfizer Inc., 501 5th St., Bristol, TN 37620.
NDA 050808 .....	SOLODYN (minocycline HCl) Tablet; Extended Release; Equivalent to (EQ) 45 mg Base, EQ 90 mg Base, EQ 135 mg Base.	Medicis Pharmaceutical Corp., 7720 North Dobson Rd., Scottsdale, AZ 85256.
ANDA 081295 .....	ESTRACE (estradiol) Tablet; Oral, 0.5 mg .....	Bristol Myers Squibb, P.O. Box 4000, Princeton, NJ 08543.
ANDA 084499 .....	ESTRACE (estradiol) Tablet; Oral, 1 mg .....	Do.
ANDA 084500 .....	ESTRACE (estradiol) Tablet; Oral, 2 mg .....	Do.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the “Discontinued Drug Product List” section of the Orange Book. The

“Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs.

Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 5, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-26856 Filed 11-8-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

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

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this Information Collection Request must be received within 60 days of this notice.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov)

or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

#### Information Collection Request Title: Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements

##### OMB No. 0915-0307—Revision

**Abstract:** Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program), Part A section 2604(c), Part B section 2612(b), and Part C section 2651(c), requires that grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs for individuals with HIV/AIDS, identified and eligible under the legislation. In order for grantees under Parts A, B, and C to be exempted from the 75 percent core medical services requirement, they must request and receive a waiver from HRSA, as required in the Act.

On October 25, 2013, HRSA published revised standards for core medical services waiver requests in the **Federal Register** (78 FR 63990). These revised standards will allow grantees more flexibility to adjust resource allocation based on the current situation in their local environment. These standards ensure that grantees receiving waivers demonstrate the availability of core medical services, including antiretroviral drugs, for persons with HIV/AIDS served under Title XXVI of the PHS Act. The core medical services waiver uniform standard and waiver request process will apply to Ryan White HIV/AIDS Program Grant Awards under Parts A, B, and C of Title XXVI of the PHS Act. Core medical services

waivers will be effective for a 1-year period that is consistent with the grant award period. Grantees may submit a waiver request before the annual grant application, with the application, or up to 4 months after the grant award has been made.

**Need and Proposed Use of the Information:** HRSA uses the documentation submitted in core medical services waiver requests to determine if the applicant/grantee meets the statutory requirements for waiver eligibility including: (1) No waiting lists for AIDS Drug Assistance Program (ADAP) services; and (2) evidence of core medical services availability within the grantee's jurisdiction, state, or service area to all individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act. See sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of the PHS Act.

**Likely Respondents:** Ryan White HIV/AIDS Program Part A, B, and C grantees.

**Burden Statement:** Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Waiver Request .....	20	1	20	5.5	110
Total .....	20	1	20	5.5	110

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques

or other forms of information technology to minimize the information collection burden.

Dated: November 4, 2013.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2013-26974 Filed 11-8-13; 8:45 am]

**BILLING CODE 4165-15-P**