

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**
**Cardiovascular and Renal Drugs Advisory Committee; Cancellation**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is canceling the meeting of the Cardiovascular and Renal Drugs Advisory Committee scheduled for April 5, 2005. This meeting was announced in the **Federal Register** of March 9, 2005 (70 FR 11678).

**FOR FURTHER INFORMATION CONTACT:** Cathy A. Groupe, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, rm. 1093, Rockville, MD 20857, 301-827-7001, e-mail: [Groupc@cder.fda.gov](mailto:Groupc@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 3014512533.

Dated: March 24, 2005.

**Sheila Dearybury Walcott,**  
*Associate Commissioner for External Relations.*

[FR Doc. 05-6331 Filed 3-25-05; 3:50 pm]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**
**Science Board to the Food and Drug Administration; 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:* Science Board to the Food and Drug Administration.

*General Function of the Committee:* The Board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the Board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on

upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs

*Date and Time:* The meeting will be held on April 15, 2005, 8:30 a.m. to 5 p.m.

*Location:* Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

*Contact Person:* Jan Johannessen, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687, e-mail: [jjohannessen@fda.gov](mailto:jjohannessen@fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The Board will hear about and discuss the following topics: (1) The agency's pre- and postmarketing safety programs for drugs and biologics and (2) Good Manufacturing Practices for vaccines, blood, and cell, tissue, and gene products.

*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 April 8, 2005. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 8, 2005, 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 Jan Johannessen 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: March 24, 2005.

**Sheila Dearybury Walcott,**  
*Associate Commissioner for External Relations.*

[FR Doc. 05-6333 Filed 3-25-05; 3:51 pm]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**
**Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for AGRYLIN (anagrelide), CLOLAR (clofarabine), and DIFLUCAN (fluconazole). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

**ADDRESSES:** Submit written requests for single copies of the summaries to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

**FOR FURTHER INFORMATION CONTACT:** Grace Carmouze, Center for Drug Evaluation and Research (HFD-960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-7337, e-mail: [carmouzeg@cder.fda.gov](mailto:carmouzeg@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:**
**I. Background**

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for AGRYLIN (anagrelide), CLOLAR (clofarabine), and DIFLUCAN (fluconazole). The summaries are being made available

consistent with section 9 of the BPCA (Public Law 107-109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet (<http://www.fda.gov/cder/pediatric/index.htm>) summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for AGRYLIN (anagrelide), CLOLAR (clofarabine), and DIFLUCAN (fluconazole). Copies are also available by mail (see **ADDRESSES**).

## II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/pediatric/index.htm>.

Dated: March 22, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-6332 Filed 3-30-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0317] (formerly Docket No. 03D-0317)

#### Guidance for Review Staff and Industry on Good Review Management Principles and Practices for Prescription Drug User Fee Act Products; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the

availability of a guidance for review staff and industry entitled "Good Review Management Principles and Practices for PDUFA Products." This is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Food and Drug Administration, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The guidance may also be obtained from CBER by mail by calling 1-800-835-4709, or 301-827-1800. Submit electronic comments to <http://www.fda.gov/dockets/comments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** John Jenkins, Center for Drug Evaluation and Research (HFD-020), Food and Drug Administration, suite 7215, 5515 Security Lane, Rockville, MD 20852, 301-594-3937; or Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301-827-0373.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for review staff and industry entitled "Good Review Management Principles and Practices for PDUFA Products." In conjunction with the June 2002 reauthorization of PDUFA, FDA agreed to meet specific performance goals (PDUFA Goals). The PDUFA Goals include providing guidance to industry and review staff in CDER and CBER on the good review management principles and practices (GRMPs) for the conduct of the first cycle review of a new drug application (NDA), a biologics license

application (BLA), or an efficacy supplement under PDUFA.

The GRMPs in this guidance are based on the collective experience of CDER and CBER with review of applications for PDUFA products and are intended to promote efficient and consistent management of application reviews. The GRMPs also clarify roles and responsibilities of review staff in managing the review process and identify ways in which NDA and BLA applicants may further the effectiveness and efficiency of the review process.

In the **Federal Register** of July 28, 2003 (68 FR 44345), FDA published a notice announcing the availability of a draft version of this guidance. FDA received a number of comments when it issued the draft version of this guidance. We have considered the comments on the draft guidance carefully and have made some changes to address those comments. The guidance has been revised to clarify the principles on which our current and developing practices are based. We have also added general internal timelines for important milestones associated with the review process.

The GRMPs also include the agency's current best practices, as well as goals for review management improvements. The GRMPs are an important foundational component of FDA's program to more fully implement a quality systems approach for the new drug and biologics review and approval process.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on GRMPs for PDUFA products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.