

**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