• to obtain participation and service use information important to the evaluation's cost-benefit component; and

• to obtain contact information for a future follow-up survey that will be important to achieving high response rates for that survey.

Respondents: The respondents to the 30-month follow-up survey are current and former TANF recipients, or individuals in families at risk of needing TANF benefits (working poor, hard-to-employ) from the two states participating in the evaluation (Illinois and Nebraska). The survey will be administered to both intervention and control groups in each participating site. The estimated sample size for the survey is 984 individuals, including projected samples of 504 in Illinois and 480 in Nebraska. The survey will be conducted primarily by telephone, with field interviews conducted with those individuals who cannot be interviewed by telephone. OMB already approved the process evaluation component and 18-month follow-up survey for this study.

Note: Tennessee has been dropped from the study due to difficulties in recruiting participants to their program. Therefore, the estimated burden is smaller than the one in the first notice.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of esponses per respondent	Average burden hours per response	Total burden hours
30-month follow-up survey	246	1	30 minutes or .5 hours	123

Estimated Total Annual Burden Hours: 123

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *rsargis@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *lauren__wittenberg@omb.eop.gov.*

Dated: November 10, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–28759 Filed 11–17–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0300]

Determination That Diclofenac Potassium 25-Milligram Tablet Was 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) is announcing its determination that diclofenac potassium 25-milligram (mg) tablet (Cataflam) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for diclofenac potassium 25-mg tablet.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 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 under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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, drugs are withdrawn 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 § 314.62 (21 CFR 314.162)). Regulations also provide that the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On June 27, 2003, The Weinberg Group, Inc., submitted a citizen petition (Docket No. 2003P–0300/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether diclofenac potassium 25-mg tablet was withdrawn from sale for reasons of safety or effectiveness. Diclofenac potassium 25-mg tablet is the subject of NDA 20–142, approved in 1993 and held by Novartis Pharmaceuticals Corp. (Novartis). Diclofenac potassium is used for the treatment of osteoarthritis and rheumatoid arthritis. FDA has determined that shortly after the approval of NDA 20–142, Novartis made the decision not to market diclofenac potassium 25-mg tablet in the United States. It was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book. FDA has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is

equivalent to withdrawing the drug from sale.

FDA has reviewed its records and, under § 314.161, has determined that diclofenac potassium 25-mg tablet was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list diclofenac potassium 25-mg tablet in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to diclofenac potassium 25-mg tablet may be approved by the agency.

Dated: November 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28742 Filed 11–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthetic and Life Support Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Anesthetic and Life Support Drugs Advisory Committee. This meeting was announced in the **Federal Register** of October 8, 2003 (68 FR 58115). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Johanna Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 8, 2003, FDA announced that a meeting of the Anesthetic and Life Support Drugs Advisory Committee would be held on November 18 and 19, 2003. On pages 58115–58116, in the third column, the *Agenda* portion of the meeting is amended to read as follows:

Agenda: On November 18, 2003, the committee will discuss the evaluation and communication of risk related to QTc prolongation by Droperidol (INAPSINE) Akorn, Inc.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: November 14, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–28870 Filed 11–14–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs 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: Cardiovascular and Renal Drugs 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 8, 2003, from 8:30 a.m. to 5 p.m. and on December 9, 2003, from 8 a.m. to 4:30 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Dornette Spell-LeSane, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *spelllesaned@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 8, 2003, the committee will discuss whether aspirin should be recommended for primary prevention of myocardial infarction. Professional labeling for aspirin currently recommends its use for prevention of a second myocardial infarction. On December 9, 2003, the committee will discuss new drug application (NDA) 21–526, proposed trade name Ranexa (ranolazine) 375 milligrams (mg) and 500 mg Tablets, CV Therapeutics Inc., for the proposed indication of treatment of chronic stable angina.

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 December 2, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 2, 2003, 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 Dornette Spell-LeSane 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: November 10, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–28686 Filed 11–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management Advisory Committee.