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FDA has reviewed its records and, under § 314.161, has determined that diclofenac potassium 25-mg tablet was not withdrawn from sale for reasons of safety or effectiveness.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.