

Dated: September 9, 2005.

William P. Nichols,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.*
[FR Doc. 05-18321 Filed 9-14-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0486]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Experimental Study of Health Claims on Food Packages

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Experimental Study of Health Claims on Food Packages" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of April 20, 2005 (70 FR 20568), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0565. The approval expires on August 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: September 7, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.
[FR Doc. 05-18283 Filed 9-14-05; 8:45 am]
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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 November 16, 2005, from 8 a.m. to 5 p.m.

Location: Food and Drug Administration, CDER Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Cathy Groupe, 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, e-mail: GroupeC@cdcr.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21-628, proposed trade name CERTICAN (everolimus) Tablets (0.25 milligrams (mg), 0.50 mg, 0.75 mg, and 1.0 mg), Novartis Pharmaceuticals Corporation, for the proposed indication of prophylaxis of rejection in heart transplantation. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2005 and scroll down to the heading Cardiovascular and Renal Drugs Advisory Committee.)

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 November 8, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each

presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 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 Beverly O'Neil at 301-827-7001, 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: September 6, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.
[FR Doc. 05-18365 Filed 9-14-05; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dental Products 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: Dental Products 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 October 11, 2005, from 9:15 a.m. to 5:45 p.m., and on October 12, 2005, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Ballroom Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ-480), Food and Drug

Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283, ext. 123, e-mail: mea@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512518. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 11, 2005, the committee will hear a presentation on the FDA Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. Subsequently, on October 11 and 12, 2005, the committee will discuss and make recommendations on the classification of the following unclassified dental devices:

- Root canal cleanser, product code KJJ, intended to cleanse a root canal after endodontic instrumentation;
- Retraction cord, product code MVL, intended for temporary retraction and hemostasis of the gingival margin;
- Root apex locator, product code LQY, intended to measure the length of the root canal;
- Dental mouthguards, product code MQC, intended to provide protection against bruxism, teeth clenching, and grinding;
- Artificial saliva, product code LFD, intended for the relief of chronic and temporary xerostomia;
- Oral wound dressing, product code MGQ, intended to provide pain relief from aphthous ulcers, canker sores, and minor oral lesions; and
- Electrical anesthesia, product code LWM, intended, through the application of electrical current, to provide analgesia or anesthesia during dental procedures.

Also, on October 12, 2005, the committee will discuss and make recommendations regarding the over-the-counter (OTC) use of dental mouthguards. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. More information regarding product code classification can be accessed by visiting <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm> or by contact person. Material for the October 11 and 12 sessions will be posted on October 7, 2005.

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 October 3, 2005. On October 11, 2005 and October 12, 2005, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 3, 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 AnnMarie Williams, Conference Management Staff, 301-594-1283, ext. 113, 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: September 6, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05-18363 Filed 9-14-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Nonprescription 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 October 20, 2005, from 8 a.m.

to 5:30 p.m., and on October 21, 2005, from 8 a.m. to 12 noon.

Location: Holiday Inn Washington Silver Spring, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD. The hotel telephone number is 301-589-0800.

Contact Person: Darrell Lyons, Center for Drug Evaluation and Research (HFD-021), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-6760, FAX: 301-827-6778, e-mail: lyonsd@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the benefits and risks of antiseptic products marketed for consumer use (e.g., antibacterial hand-washes and body-washes). The discussion will include topics such as the efficacy of antiseptics intended for use by consumers and potential risks to the individual and the general population from using these products. The background material will become available no later than the day before the meeting and will be posted under the Nonprescription Drugs Advisory Committee (NDAC) on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2005 and scroll down to NDAC).

Procedure: On October 20, 2005, from 8 a.m. to 5:30 p.m., the meeting is open to the public. 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 October 13, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on October 20, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 13, 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.

Closed Committee Deliberations: On October 21, 2005, from 8 a.m. to 12 noon, the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the