

governmental services and certain unrated municipal revenue bonds (including unrated public ownership and private ownership industrial development bonds). These activities have been previously approved by the Board by order to be so closely related to banking as to be proper incident thereto within the meaning of section 4(c)(8) of the BHC Act. See *Bank South Corporation*, 81 Fed. Res. Bull. 1,116 (1995)(private ownership industrial development bonds); *Letter Interpreting Section 20 Orders*, 81 Fed. Res. Bull. 198 (1995) (unrelated municipal revenue bonds). Applicant previously received the Board's approval to engage through SouthTrust Securities in, among other things, underwriting and dealing in municipal revenue bonds, including public ownership industrial development bonds. See *SouthTrust Corporation*, 75 Fed. Res. Bull. 647 (1989).

Board of Governors of the Federal Reserve System, July 9, 1996.

Jennifer J. Johnson,

*Deputy Secretary of the Board.*

[FR Doc. 96-17899 Filed 7-12-96; 8:45 am]

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### **Federal Open Market Committee; Domestic Policy Directive of May 21, 1996**

In accordance with § 271.5 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on May 21, 1996.<sup>1</sup> The directive was issued to the Federal Reserve Bank of New York as follows:

The information reviewed at this meeting suggests that, on balance, economic activity has grown moderately in recent months. Nonfarm payroll employment changed little in April after rising substantially in the first quarter; the civilian unemployment rate fell to 5.4 percent. Industrial production increased sharply in April, largely reflecting a rebound in motor vehicle assemblies after a strike in March. Retail sales declined somewhat in April after posting a strong gain in the first quarter. Single-family housing starts rose considerably in April. Orders and contracts point to some deceleration in spending on business equipment and

nonresidential structures after a very rapid expansion in the first quarter. The nominal deficit on U.S. trade in goods and services widened significantly in the first quarter from its rate in the fourth quarter of last year. Upward pressures on food and energy prices have led to somewhat larger increases in the consumer price index over recent months.

Short-term market interest rates have changed little while long-term rates have risen somewhat further since the Committee meeting on March 26. In foreign exchange markets, the trade-weighted value of the dollar in terms of the other G-10 currencies has appreciated considerably over the intermeeting period.

Growth of M2 and M3 slowed substantially in April after recording sizable increases earlier in the year. For the year through April, both aggregates grew at rates somewhat above the upper bounds of their respective ranges for the year. Expansion in total domestic nonfinancial debt remained moderate on balance over recent months.

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. In furtherance of these objectives, the Committee at its meeting in January established ranges for growth of M2 and M3 of 1 to 5 percent and 2 to 6 percent respectively, measured from the fourth quarter of 1995 to the fourth quarter of 1996. The monitoring range for growth of total domestic nonfinancial debt was set at 3 to 7 percent for the year. The behavior of the monetary aggregates will continue to be evaluated in the light of progress toward price level stability, movements in their velocities, and developments in the economy and financial markets.

In the implementation of policy for the immediate future, the Committee seeks to maintain the existing degree of pressure on reserve positions. In the context of the Committee's long-run objectives for price stability and sustainable economic growth, and giving careful consideration to economic, financial, and monetary developments, slightly greater reserve restraint or slightly lesser reserve restraint would be acceptable in the intermeeting period. The contemplated reserve conditions are expected to be consistent with moderate growth in M2 and M3 over coming months.

By order of the Federal Open Market Committee, July 8, 1996.

Donald L. Kohn,

*Secretary, Federal Open Market Committee.*

[FR Doc. 96-17835 Filed 7-12-96; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Agency for Health Care Policy and Research**

#### **Contract Review Meeting**

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C. appendix 2), announcement is made of the following advisory subcommittee scheduled to meet during the month of July 1996:

*Name:* Subcommittee on Request for Proposal No. AHCPR-96-0004, Planning, Evaluation and Analyses.

*Date and Time:* July 18-19, 1996, 8:30 a.m.-5:00 p.m.

*Place:* Agency for Health Care Policy and Research, Executive Office Center, 6th Floor Conference Room, 2101 East Jefferson Street, Rockville, Maryland 20852.

This meeting will be closed to the public.

*Purpose:* The Subcommittee's charge is to provide, on behalf of the Health Care Policy and Research Contracts Review Committee, advice and recommendations to the Secretary and to the Administrator, Agency for Health Care Policy and Research (AHCPR), regarding the scientific and technical merit of contract proposals submitted in response to a specific Request for Proposals. The purpose of this task order contract is to provide focused, high-priority planning, evaluation, and other types of analytical products to various AHCPR components on a short turnaround basis as the need arises. Multiple awards are anticipated with individual tasks orders to be competed among awardees. Task orders are anticipated to last no longer than 18 months at an estimated cost of \$10,000-\$250,000 each.

*Agenda:* The session of the Subcommittee will be devoted entirely to the technical review and evaluation of contract proposals submitted in response to a specific Request for Proposals. The Administrator, AHCPR, has made a formal determination that this meeting will not be open to the public. This is necessary to protect the free exchange of views and avoid undue interference with Committee and Department operations, and safeguard confidential proprietary information and personal information concerning individuals associated with the proposals that may be revealed during the sessions. This is in accordance with section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. appendix 2, Department regulations, 45 CFR section 11.5(a)(6), and procurement regulations, 48 CFR section 315.604(d). Anyone wishing to obtain information regarding this meeting should contact Sharon Williams, Office of Management, Contracts Management Staff, Agency for Health Care

<sup>1</sup> Copies of the Minutes of the Federal Open Market Committee meeting of May 21, 1996, which include the domestic policy directive issued at that meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

Policy and Research, Executive Office Center, 2101 East Jefferson Street, Suite 601, Rockville, Maryland. 20852, (301) 594-1445.

Dated: July 8, 1996.

Clifton R. Gaus,  
Administrator.

[FR Doc. 96-17879 Filed 7-12-96; 8:45 am]

BILLING CODE 4160-90-M

## Food and Drug Administration

[Docket No. 90F-0063]

### Henkel Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to future filing, of a food additive petition (FAP 0B4194) proposing that the food additive regulations be amended to provide for the safe use of a mixed ester product resulting from the reaction of pentaerythritol and dipentaerythritol with C<sub>14</sub>-C<sub>22</sub> fatty acids as a release agent for ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers, polyethylene phthalate polymers, and poly(tetramethylene terephthalate) intended to contact food.

**FOR FURTHER INFORMATION CONTACT:** Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3083.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of March 15, 1990 (55 FR 9772), FDA announced that a food additive petition (0B4194) had been filed by Henkel Corp., Organic Products Division, 300 Brookside Ave., Ambler, PA 19002, (Currently c/o Bruce A. Schwemmer, Bruce EnviroExcel Group, Inc., 94 Buttermilk Bridge Rd., Washington, NJ 07882). The petition proposed to amend the food additive regulations in § 178.3860 *Release agents* (21 CFR 178.3860) to provide for the safe use of a mixed ester product resulting from the reaction of pentaerythritol and dipentaerythritol with C<sub>14</sub>-C<sub>22</sub> fatty acids as a release agent for ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers, polyethylene phthalate polymers, and poly(tetramethylene terephthalate) intended to contact food. Henkel Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: June 25, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval,  
Center for Food Safety and Applied Nutrition.

[FR Doc. 96-17826 Filed 7-12-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 86D-0380]

### Medical Devices; Medical Software Devices; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) and the National Library of Medicine (NLM) are announcing a public workshop to discuss definitions of medical software devices, criteria for defining risk categories, software quality audits and premarket notification, commercial distribution of software, and the options available for regulating medical software devices. FDA has noted some confusion among manufacturers regarding which requirements apply to medical software devices and accessories. This workshop will help to clarify the requirements, and provide FDA with information to better assess the risks to public health associated with different types of medical software devices.

**DATES:** The workshop will be held on September 3 and 4, 1996, from 9:30 a.m. to 4:30 p.m. Participants and other persons who want to present data or information must be present by 9 a.m. Written notices of participation must be submitted on or before August 5, 1996.

**ADDRESSES:** The workshop will be held at the National Institutes of Health, Natcher Conference Center, 45 Center Dr., Bethesda, MD 20892. Written comments, identified with the docket number found in brackets in the heading of this document, regarding the subjects being discussed at the workshop may be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. A more detailed listing of the workshop topics, issues, background information, as well as registration forms, can be obtained after August 1, 1996, through the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system. To receive the public workshop on medical software devices documents to your FAX machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second

voice prompt press 2, and then enter the document number, 1072, followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. The information will be sent by FAX. All workshop-related information can also be obtained by using the World Wide Web. FDA's home page address may be accessed at <http://www.fda.gov>.

**FOR FURTHER INFORMATION CONTACT:** Charles S. Furfine, Center for Devices and Radiological Health (HFZ-143), 12720 Twinbrook Pkwy., Rockville, MD 20852, 301-443-2536, ext. 16; FAX 301-443-9101; or EMail [csf@fdadr.cdrh.fda.gov](mailto:csf@fdadr.cdrh.fda.gov).

Registration forms should be sent to Charles Furfine (address above). There is no registration fee but advance registration is required. Interested persons are encouraged to register early because space is limited. If you have a disability that affects your attendance at, or participation in, this meeting, please contact Charles S. Furfine (address above) in writing and identify your needs. The availability of appropriate accommodations cannot be assured unless prior written notification is provided.

#### SUPPLEMENTAL INFORMATION:

##### I. Background

On September 25, 1987 (52 FR 36104), FDA published a notice of availability of a "Draft Policy Guidance for Regulation of Computer Products," which the agency was making available for comment. The guidance was intended to provide software developers and manufacturers of medical devices with guidance about which software products were regulated as medical devices and which might be exempt from particular regulatory controls, such as premarket notification. A 1989 draft of the FDA software policy reiterated the basic statements of the 1987 draft, but also addressed specific issues related to blood-bank software products. The 1989 draft also addressed the issue of which medical software devices should be exempt from general controls, including the current good manufacturing practice regulations. The agency stated in the 1989 draft that medical software devices (unclassified medical software devices that are not components, parts, or accessories to classified devices) would not be subject to active regulatory oversight if they "are intended to involve competent human intervention before any impact on human health occurs (e.g., where clinical judgment and experience can be used to check and interpret a system's output) \* \* \*."

Since 1989, FDA has gained experience in applying the criterion of