

unfair competition, conflicts of interests, or unsound banking practices" (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 3, 1997.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Mercantile Bancorporation Inc.*, St. Louis, Missouri, and Ameribanc, Inc., St. Louis, Missouri; to acquire and merge with Regional Bancshares, Inc., Alton, Illinois, and thereby indirectly acquire Bank of Alton, Alton, Illinois.

Board of Governors of the Federal Reserve System, December 6, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96-31491 Filed 12-11-96; 8:45 am]

BILLING CODE 6210-01-F

[Docket No. R-0937]

Policy Statement on Payments System Risk; Modified Procedures for Measuring Daylight Overdrafts; Correction

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Policy statement; correction.

SUMMARY: This document corrects the announced effective date of recent amendments to the Policy Statement on Payments System Risk, which established daylight overdraft posting times for payments associated for Treasury investments resulting from electronic federal tax payments. These amendments were effective under the Small Business Regulatory Enforcement Fairness Act of 1996, on December 9, 1996. The amendments to the policy statement as published at 61 FR 58691, however, incorrectly stated that they were effective November 18, 1996, the date of publication in the Federal Register.

EFFECTIVE DATE: Effective November 18, 1996, the effective date for the

amendments to the policy statement is corrected to be December 9, 1996.

FOR FURTHER INFORMATION CONTACT: Paul Bettge, Manager (202/452-3174), Heidi Richards, Senior Financial Services Analyst (202/452-2598), Division of Reserve Bank Operations and Payment Systems; for the hearing impaired only: Telecommunications Device for the Deaf, Dorothea Thompson (202/452-3544).

By order of the Board of Governors of the Federal Reserve System, December 9, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96-31577 Filed 12-11-96; 8:45 am]

BILLING CODE 6210-01-P

Sunshine Act Meeting

AGENCY HOLDING THE MEETING:

Committee on Employee Benefits of the Federal Reserve System*.

TIME AND DATE: 3:00 p.m., Tuesday, December 17, 1996.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposals relating to Federal Reserve System benefits.
2. Proposals regarding actuarial assumptions in the Federal Reserve System benefit plans.
3. Proposal regarding selection of a financial auditor for the Office of Employee Benefits.
4. Proposed committee for the Office of Employee Benefits.
5. Any items carried forward from a previously announced meeting.

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* The Committee on Employee Benefits considers matters relating to the Retirement, Thrift, Long-Term Disability Income, and Insurance Plans for Employees of the Federal Reserve System.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: December 10, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96-31761 Filed 12-10-96; 3:13 pm]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96F-0477]

Elf Atochem North America, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Elf Atochem North America, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyamide/polyether block copolymers prepared by reacting a copolymer of *omega*-laurolactam and adipic acid with poly(tetramethylene ether glycol) for use in the manufacture of rubber articles intended for repeated use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by January 13, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4528) has been filed by Elf Atochem North America, Inc., 2000 Market St., Philadelphia, PA 19103-3222. The petition proposes to amend the food additive regulations in § 177.2600 *Rubber articles intended for repeated use* (21 CFR 177.2600) to provide for the safe use of polyamide/polyether block copolymers prepared by reacting a copolymer of *omega*-laurolactam and adipic acid with poly(tetramethylene ether glycol) for use in the manufacture of rubber articles intended for repeated use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets

Management Branch (address above) for public review and comment. Interested persons may, on or before January 13, 1997, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: November 25, 1996.

George H. Pauli,
Acting Director, Office of Premarket
Approval, Center for Food Safety and Applied
Nutrition.

[FR Doc. 96-31574 Filed 12-11-96; 8:45 am]

BILLING CODE 4160-01-F

Health Resources and Services Administration

Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA- 19

AGENCY: Health Resources and Services
Administration, HHS.

ACTION: Final notice.

INFORMATION: Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act (the "PHS Act"), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services ("HHS") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the amount determined under a statutory formula.

Section 340B(a)(5) of the PHS Act identifies certain requirements for covered entities concerning potential double price reductions and drug diversion. A covered entity must permit

the manufacturer of a covered outpatient drug to audit the records of the covered entity directly pertaining to the entity's compliance with the requirements of section 340B(a)(5) (A) and (B) as to drugs purchased from the manufacturer. These audits must be conducted in accordance with guidelines established by the Secretary, acting through the Health Resources and Services Administration, Bureau of Primary Health Care, the Office of Drug Pricing (the "Department"). Section 340B(a)(5)(C) states that the Secretary shall establish guidelines relating to the number, scope and duration of the audits. The Department has defined these terms and provided suggested audit steps.

Further, the Department anticipates that disputes may arise between covered entities and participating manufacturers regarding implementation of the provisions of section 340B. To resolve these disputes in an expeditious manner, the Department has developed a voluntary dispute resolution process.

The purpose of this notice is to inform interested parties of final program guidelines concerning manufacturer audit guidelines and the dispute resolution process.

FOR FURTHER INFORMATION CONTACT:

Director, Office of Drug Pricing, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, West Towers, 10th Floor, Bethesda, Maryland 20814, Phone: (301) 594-4353.

EFFECTIVE DATE: January 13, 1997.

SUPPLEMENTARY INFORMATION:

(A) Background

Proposed manufacturer audit guidelines and the proposed informal dispute process were announced in the Federal Register at 59 FR 30021 on June 10, 1994. A comment period of 30 days was established to allow interested parties to submit comments. The ODP received comments from 12 sources including pharmaceutical manufacturers, a covered entity, organizations representing pharmaceutical manufacturers or covered entities, and the American Institute of Certified Public Accountants.

The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered in developing this final notice. Changes were also made to increase clarity and readability.

(B) Comments and Responses— Manufacturer Audit Guidelines

Comment: A number of commenters addressed the requirement that a manufacturer establish reasonable cause and obtain approval from the Department before conducting an audit. While some commenters believe that the statute gives manufacturers the right to routinely conduct an audit as a normal business practice without the need for Departmental approval, other commenters indicated that manufacturers should be required to provide objective documentation that a violation has occurred before being granted permission to audit.

Response: Section 340B(a)(5)(C) provides that audits will be performed in accordance with procedures established by the Secretary relating to the number, duration, and scope of the audits. These audits must pertain directly to the entity's compliance with the prohibitions against drug diversion and the generation of duplicate drug rebates and discounts with respect to drugs of the manufacturer. See Section 340B(a)(5)(A) & (B). In order to ensure that the audits pertain to compliance with the prohibitions in the aforementioned subparagraphs, it is appropriate to require manufacturers to submit an audit work plan for the Department's review and to establish reasonable cause. Although the Department will not require pre-approval of the plan, this will ensure that the audits are performed where there are valid business concerns and are conducted with the least possible disruption to the covered entity. Significant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity may be a basis for establishing reasonable cause.

Comment: Omit the requirement to submit an audit plan for the Department's approval.

Response: The requirement for approval of an audit plan has been dropped. The Department's review of the audit workplan is necessary to ensure that audit work performed is relevant to the audit objectives while protecting patient confidentiality and information of the covered entity which is considered proprietary. If after this review the Department has concerns regarding the audit plan it will work with the manufacturer to incorporate mutually agreed-upon revisions to the plan.

Comment: Commenters indicated that audits would not be meaningful without