[Petition Nos. P82–93, P83–93, P84–93 and P85–93]

Petition for Temporary Exemption From Electronic Tariff Filing Requirements

Notice is hereby given of the filing of petitions by the above named petitioners, pursuant to 46 CFR 514.8(a), for temporary exemption from electronic tariff filing requirements of the Commission's ATFI System.

To facilitate thorough consideration of the petitions, interested persons are requested to reply to the petition no later than November 2, 1993. Replies shall be directed to the Secretary, Federal Maritime Commission, Washington, DC 20573–0001, shall consist of an original and 15 copies, and shall be served as follows:

P82–93—Wayne R. Rohde, Esq., Sher & Blackwell, 1255 Twenty-third Street, NW., Suite 500, Washington, DC 20037–1194.

P83–93—Mr. James C. Olsson, President, Pacific Coast Tariff Bureau, 221 Main Street, Suite 530, San Francisco, California 94105–1915.

P84–93—Mr. Robert Hadow, Director, World Tariff Services, Inc., 14 Commerce Drive, Cranford, New Jersey 07016.

P85–93—Ms. Meiko Geyer, Pricing Supervisor, Trans-American Steamship Agency, 140 W. 6th Street, San Pedro, California 90731.

Copies of the petitions are available for examination at the Washington, D.C. office of the Secretary of the Commission, 800 N. Capitol Street, NW., room 1046.

Joseph C. Polking,

Secretary.

[FR Doc. 93–26218 Filed 10–25–93; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Creditanstalt-Bankverein, et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question 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, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 15, 1993.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. Creditanstalt-Bankverein, Vienna, Austria; to engage *de novo* through its subsidiary, Steinberg Asset Management Company, L.P., New York, New York, in investment advisory activities, pursuant to § 225.25(b)(4) of the Board's Regulation Y.

B. Federal Reserve Bank of Philadelphia (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. Keystone Financial, Inc., Harrisburg, Pennsylvania; to engage *de novo* through its subsidiary, Keystone Brokerage, Inc., Williamsport, Pennsylvania, in full service brokerage activities, pursuant to § 225.25(b)(15)(ii) of the Board's Regulation Y.

C. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Star Banc Corporation, Cincinnati, Ohio; to engage *de novo* through its subsidiary, Star Bank, FSB, Lexington, Kentucky, in owning, controlling and operating a federal savings association, pursuant to § 225.25(b)(9) of the Board's Regulation Y.

D. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. The Alan J. Lewis Financial Services Trust, Road Town, Tortola, British Virgin Islands; to engage *de novo* through its subsidiary, Anglo-American Bancshares Corporation, Baton Rouge, Louisiana, in making, acquiring and servicing loans or other extensions of credit, pursuant to § 225.25(b)(1) of the Board's Regulation Y. These activities will be conducted throughout the United States and the United Kingdom.

2. Barnett Banks, Inc., Jacksonville, Florida; to engage *de novo* through its subsidiaries, Barnett Subsidiary, Jacksonville, Florida, and Main America Capital, L.C., Atlanta, Georgia, in the acquisition, through the lending of money or otherwise, of mortgages and mortgage notes encumbering commercial and multi-family real estate, and such other activities as are incidental to the foregoing, pursuant to § 225.25(b)(1) of the Board's Regulation Y. These activities will be conducted through a joint venture with Mac Partners, Atlanta, Georgia.

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

1. Cass Commercial Corporation, St. Louis, Missouri; to engage *de novo* through its subsidiary, Cass Logistics, Inc., Bridgeton, Missouri, in providing data processing and data trasmission services, facilities, data bases, and access thereto, pursuant to § 225.25(b)(7) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, October 20, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-26294 Filed 10-25-93; 8:45 am]

BILLING CODE 6210-01-F

Lee D. Cameron, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of

Governors. Comments must be received not later than November 15, 1993.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Lee D. Cameron, Trustee, the Trust of Louise Cameron to retain 50 percent, and the Trust of Robert B. Cameron to retain 50 percent, of the voting shares of First National Agency Company of Deer River, Inc. and thereby indirectly acquire First National Bank of Deer River, all of Deer River, Minnesota.

B. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Aaron S. Kaufman, Richardson, Texas; to acquire an additional 15 percent, for a total of 24.99 percent, of the voting shares of Texas Community Bancshares, Inc., Dallas, Texas, and thereby indirectly acquire First Lakewood National Bank, Dallas, Texas.

Board of Governors of the Federal Reserve System, October 20, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-26295 Filed 10-25-93; 8:45 am]

BILLING CODE 6210-01-F

Firstbank of Illinois Co.; Formation of, Acquisition by, or Merger of Bank Holding Companies; and Acquisition of Nonbanking Company

The company listed in this notice has applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed company has also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question 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.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 19, 1993.

A. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Firstbank of Illinois Co., Springfield, Illinois; to acquire 100 percent of the voting shares of Colonial Bancshares, Inc., Des Peres, Missouri.

In connection with this application, Applicant also proposes to acquire Guido Insurance Agency, Des Peres, Missouri, and thereby engage in credit-related insurance agency activities, pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, October 20, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-26296 Filed 10-25-93; 8:45 am]

BILLING CODE 6210-01-F

The Magnolia State Corporation, et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question 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, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than November 19, 1993.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. The Magnolia State Corporation, Bay Springs, Mississippi; to acquire Jones County Finance Company, Laurel, Mississippi, and thereby engage in selling as agent credit life, credit accident, and health and property insurance in connection with extensions of credit made, acquired, or serviced by the bank holding company, pursuant to §§ 225.25(b)(8)(i) and (ii) of the Board's Regulation Y.

B. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. ABN AMRO Bank N.V., Amsterdam, The Netherlands; ABN AMRO Holding N.V., Amsterdam, The Netherlands; Stichting Administratiekantoor ABN AMRO Holding, Amsterdam, The Netherlands; Stichting Prioriteit ABN AMRO Holding, Amsterdam, The Netherlands; and ABN AMRO North America, Inc., Chicago, Illinois, to acquire Cragin Financial Corp., Chicago, Illinois, and thereby engage in operating a thrift, pursuant to § 225.25(b)(9) of the Board's Regulation Y; CAAC, Chicago, Illinois, and thereby engage in the sale of credit life insurance, pursuant to §

225.25(b)(8)(i) of the Board's Regulation Y; CSC, Chicago, Illinois, and thereby engage in the securities brokerage activities and investment advisory services to the general public through a relationship with Laughlin Group Advisors, Inc., Beaverton, Oregon, pursuant to § 225.25(b)(15) of the Board's Regulation Y; and a 5 percent interest in Savings and Loan Network, Inc., Chicago, Illinois, and thereby engage in the development and construction of affordable housing in low- and moderate-income neighborhoods and rehabilitation, marketing and management of low- and moderate-income rental housing, pursuant to § 225.25(b)(6) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, October 20, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-26297 Filed 10-25-93; 8:45 am]

BILLING CODE 6210-01-F

Peoples Savings Financial Corporation, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than November 19, 1993.

A. Federal Reserve Bank of Philadelphia (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. Peoples Savings Financial Corporation, Ridgway, Pennsylvania; to become a bank holding company by acquiring 100 percent of the voting shares of Peoples Savings Bank, Ridgway, Pennsylvania.

B. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. East Side Financial, Inc., Chicago, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of East Side Savings Bank, Chicago, Illinois, formerly known as East Side Savings and Loan Association, Chicago, Illinois.

2. First Park Ridge Corporation, Chicago, Illinois; to acquire 100 percent of the voting shares of Stanford State Bank, Morton Grove, Illinois.

3. Lea County Bancshares, Inc., Hobbs, New Mexico; to become a bank holding company by acquiring 100 percent of the voting shares of Lea County State Bank, Hobbs, New Mexico.

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

1. First Commercial Corporation, Little Rock, Arkansas; to acquire at least 80 percent of the voting shares of Clinton Bancshares, Inc., Clinton, Arkansas, and thereby indirectly acquire Clinton State Bank, Clinton, Arkansas.

D. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. BNCCORP, Inc., Bismarck, North Dakota; to merge with Farmers and Merchants, Inc., Beach, North Dakota, and thereby indirectly acquire Farmers and Merchants Bank, Beach, North Dakota.

2. Northwest Wisconsin Bancorp, Inc., Chippewa Falls, Wisconsin; to become a bank holding company by acquiring 100 percent of the voting shares of BCB Bancorp, Inc., Chippewa Falls, Wisconsin, and thereby indirectly acquire Bank of Barron, Barron, Wisconsin, and Chetek State Bank, Chetek, Wisconsin.

E. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Clatonia Bancshares, Inc., Clatonia, Nebraska; to become a bank holding company by acquiring 100 percent of the voting shares of Farmers Bank of Clatonia, Clatonia, Nebraska.

F. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Intercontinental Bank Shares Corporation, San Antonio, Texas; to acquire 99 percent of the voting shares of Garden Ridge State Bank, San Antonio, Texas.

Board of Governors of the Federal Reserve System, October 20, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-26298 Filed 10-25-93; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93F-0358]

Cytec Industries; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cytec Industries has filed a petition proposing that the food additive regulations be amended to provide for the safe use of *meta*-tetramethylxylene diisocyanate for reaction with one or more of the polyols and polyesters listed in the adhesive regulations and with dimethylolpropionic acid and triethylamine, *N*-methyldiethanolamine, 2-dimethylaminoethanol, 2-dimethylamino-2-methyl-1-propanol, and/or 2-amino-2-methyl-1-propanol in the production of polyurethane resins intended for use as components of adhesive formulations used in food packaging applications.

DATES: Written comments on the petitioner's environmental assessment by November 26, 1993.

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

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9500.

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 3B4401) has been filed by Cytec Industries, c/o Keller and Heckman, 1001 G St., NW., suite 500 West, Washington, DC 20001. The petition proposes that the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of *meta*-tetramethylxylene diisocyanate for reaction with one or

more of the polyols and polyesters listed in § 175.105 and with dimethylolpropionic acid and triethylamine, *N*-methyldiethanolamine, 2-dimethylaminoethanol, 2-dimethylamino-2-methyl-1-propanol, and/or 2-amino-2-methyl-1-propanol in the production of polyurethane resins intended for use as components of adhesive formulations used in food packaging applications.

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 display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before November 26, 1993, 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: October 14, 1993.

Douglas L. Archer,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–26274 Filed 10–25–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0267]

Medical Device Reference List

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its "Medical Device Reference List" (hereinafter referred to as the Reference List) procedures. This document sets forth the circumstances under which manufacturers of medical devices are placed on the Reference List and the effect of such action on the agency's normal scientific review and clearance of premarket notification (510(k)) submissions. It also describes the actions manufacturers must take before the agency will resume processing affected applications and delineates the responsibilities of various FDA offices in this effort.

DATES: The procedures have been in effect since April 1992. Comments may be submitted at any time.

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

FOR FURTHER INFORMATION: Marje Hoban, Office of Compliance (HFZ–331), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4695.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, increased attention has been drawn to the issue of medical device manufacturers seeking FDA clearance to market new products irrespective of their compliance standing with the agency with respect to current good manufacturing practices (CGMP) requirements. In response to this problem, in December 1990, FDA's Center for Devices and Radiological Health (CDRH) increased its commitment to a program linking CGMP inspections with premarket approval decisions. This program entails: (1) Review of a firm's inspectional history and, (2) inspection of the site of manufacture prior to approval of the product for marketing. Under this program, agency field investigators inspect a firm's manufacturing operations and verify CGMP compliance for virtually all original PMA's, as well as for PMA supplements involving manufacturing site changes for which no recent CGMP inspection of a similar manufacturing process has been performed.

The main purpose of these inspections is to ensure, prior to approval, that applicants are in conformance with all production specifications contained in pending PMA's and with applicable CGMP requirements. The program also provides for a subsequent site inspection within 1 year following product marketing to confirm that production plans reviewed at the preapproval inspection stage are being fully and responsibly carried out.

Following the agency's effort to increase its emphasis on the PMA preapproval program, in February 1992, the General Accounting Office submitted a report to the House of Representatives' Subcommittee on Oversight and Investigations. The report, entitled "Medical Technology—Quality Assurance Needs Stronger Management Emphasis and Higher Priority," stated:

> The coordination of GMP inspections with premarket approval is important because, according to the literature on manufacturing reliability, the frequency of design and manufacturing defects is greatest when a product is first manufactured. However, the coordination with premarket approval contrasts with the lack of coordination for devices that reach the market through the 510(k) review. The overwhelming majority of all classes of devices reach the market through the 510(k) or "substantially equivalent" route, which does not require a GMP inspection.
>
> When the Office of Device Evaluation (in the Center for Devices and Radiological Health) completes its review of a 510(k) application with a finding of substantial equivalence, the appropriate district office receives a copy of the letter sent to the manufacturer. However, the letter does not help the district office to identify GMP risks in changing technology and to target inspections accordingly."

(GAO/PEMD–92–10, pg. 32.)

To rectify this situation, in April 1992, CDRH expanded the scope of its CGMP compliance verification program to encompass 510(k) submissions, and PMA supplements not covered by the PMA preapproval inspection program described above. As with the preapproval inspection program for PMA's and PMA supplements involving changes in manufacturing sites, the primary objective of this program is to prevent market clearances of devices manufactured by companies with significantly noncompliant CGMP conditions that might result in unsafe or ineffective devices.

The processes under which a device is manufactured have a significant impact on the safety and effectiveness of the device. Consequently, both a change in manufacturing processes and the violation of CGMP's may have a significant impact on the question of substantial equivalence. A device that is manufactured under processes that constitute significant CGMP violations does not satisfy the criteria for a finding of substantial equivalence under section 513(i) (A) of the Federal Food, Drug, and Cosmetic Act (the act) for two reasons. First, because manufacturing processes affect the technological characteristics of a device, a device manufactured

under violative manufacturing conditions may not have "the same technological characteristics as the predicate device." Second, a device manufactured under violative conditions would "raise different questions of safety and efficacy than the predicate device." The significance of manufacturing processes with respect to the equivalency of a device is reflected in 21 CFR 807.81(a) (3) (i), which requires that a new 510(k) be submitted for changes or modifications in an existing device "that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in * * * manufacturing process."

Because of the sheer volume of 510(k) submissions it receives, FDA cannot practically conduct preclearance inspections for all 510(k)'s and, therefore, is pursuing a dual approach. In the case of 510(k)'s for devices claiming substantial equivalence to a class III preamendments device, the agency is following the inspectional history review/site inspection process employed for PMA's. For these 510(k)'s, an inspection of the applicant firm will be conducted unless an inspection has been conducted within 2 years prior to agency action on the pending 510(k) submission. The CGMP program for class III 510(k)'s began on March 9, 1993.

If an inspection has been conducted within that time, and for all other 510(k)'s (approximately 6,500 annually) the agency will utilize the Reference List as a compliance "screen." FDA believes this approach is appropriate because it puts premarket submissions for all class III devices on an equal footing with respect to CGMP compliance verification. This approach is also practical for the agency because of the manageable number of class III 510(k) submissions (approximately 200 annually) received by the agency.

The major source of information for the Reference List is FDA's Compliance Status Information System (COMSTAT), formerly known as the firm profile system. Under COMSTAT, inspectional and compliance status information for every registered device, drug facility, and foreign facility FDA inspects, is compiled and maintained by the Office of Regulatory Affairs in a central database. One of the purposes of this database is to assure that FDA administrative approvals for medical devices and drugs are not granted to companies that are in serious violation of FDA statutes or regulations. Device companies in the COMSTAT database that have serious CGMP violations are used to make up the Reference List. These companies account for more than 95 percent of the companies on the Reference List. The remaining companies on the Reference List are companies that have been entered into the COMSTAT database for other regulatory violations.

A device manufacturer is placed on the Reference List whenever the most recent FDA inspection reveals violative conditions that are classified as "Official Action Indicated" (OAI) or "Voluntary Action Indicated–3" (VAI–3) accompanied by the issuance of a warning letter. Thus, a medical device company knows it is on the Reference List if it has received a warning letter from the agency citing CGMP deficiencies.

The Reference List process has two significant steps. The first step is simply to determine, prior to giving marketing clearance to a 510(k) submission, whether the applicant is identified on the Reference List. If the applicant is not on the Reference List, the process is complete and 510(k) clearance may be given. In these cases, the initial "screen" will have served its purpose.

If one of the manufacturing sites identified in the application is on the Reference List, this triggers a further check. In that case, CDRH contacts the appropriate district office as to the nature and status of the violation(s) and their relevance to the pending 510(k). Thus, clearance of a 510(k) will not be held up solely because a firm is included on the Reference List. Rather, CDRH will postpone clearance of a 510(k) only when the FDA district office has confirmed that: (1) The site conditions leading to an OAI or VAI–3 with warning letter classification were the result of CGMP noncompliance and the violative conditions have not been corrected; and (2) the deficiencies are relevant to the application pending before the agency. Under these circumstances, the agency will notify the applicant in writing of its decision to postpone final processing of the 510(k) submission and will inform the firm of the steps necessary to permit resumption of the final clearance process.

When a company's CGMP violations are corrected and the agency documents such corrections through an inspection, the applicant company will be removed from the Reference List. In some circumstances, a written reply may satisfactorily resolve the CGMP problem(s), obviating the need for a reinspection. FDA field offices are required to promptly update the COMSTAT database.

Since the Reference List has been in operation, and through August 1993, more than 640 510(k)'s have undergone the full gamut of CGMP compliance review—from initial "screening" of the Reference List by FDA headquarters personnel to verification by agency field investigators—resulting in the postponement of 179 submissions due to CGMP problems. During that same time period, the agency granted marketing clearance for more than 5,300 510(k) submissions.

Publication of this notice is in keeping with the spirit of openness in Government. It also responds to concerns raised over the past year by representatives of the medical device industry and others regarding the need for universal access to information concerning FDA's increased enforcement of Federal medical device statutes and applicable regulations.

II. Reference List

The Reference List procedure applies to all generic types of devices manufactured by domestic and foreign firms. At the discretion of the directors of CDRH's Office of Device Evaluation (ODE) and Office of Compliance (OC), selected class I devices may be exempt from coverage under this program due to their low risk potential. "Special" PMA supplements (as defined in 21 CFR 814.39(d)) will not be subject to this process.

III. Terminology

The terms "applicant" and "application" are used broadly. References to the "applicant" include any person within the meaning of section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e)), who submits to FDA data or other information to influence or support an agency decision regarding clearance to market a medical device. References to "application" include any premarket notification submission, PMA, or supplement to a PMA.

IV. Implementation

Three FDA offices are responsible for the coordination and implementation of this procedure: ODE, OC, and FDA's Office of Regulatory Affairs (ORA), as part of the Office of the Commissioner with its network of headquarters and district offices located throughout the United States, and its responsibility for management and operation of the COMSTAT system. Under the terms of an internal working agreement ratified by these three offices referenced above and the Office of General Counsel, the following responsibilities have been assigned to each of these organizations.

A. Office of Device Evaluation, Center for Devices and Radiological Health

1. Prior to final market clearance, ODE will identify any 510(k) submission or PMA supplement (not covered by the PMA preapproval inspection program) for any applicant on the Reference List and send the file for such application to the OC. Inquiries regarding the need to file a 510(k) for certain changes or "add-to" 510(k) will not be referred to OC.

2. ODE will not find any 510(k) submission substantially equivalent, nor approve any PMA supplement, for a firm on the Reference List until notified in writing by OC that the 510(k) or PMA supplement applicant and device manufacturer (if different) and/or contract sterilizer are in compliance with the CGMP regulation.

3. In appropriate cases, ODE will issue a letter to the applicant (with a copy to OC and the appropriate district office) notifying the applicant that agency processing of its 510(k) submission or PMA supplement is being postponed until corrections of outstanding CGMP problems are made, whether at the applicant's own site of manufacture or at contract manufacturing/sterilizing sites. In this letter, ODE will instruct the firm to contact the district office to ascertain what corrective action steps are necessary to overcome the firm's CGMP deficiencies and thus avoid further postponement by CDRH in the processing of the application.

B. Office of Compliance, Center for Devices and Radiological Health

1. OC will maintain the Reference List, with supporting data obtained from the agency's COMSTAT and from compliance status information gathered from FDA's field operations offices. The Reference List will be updated regularly and supplied daily to ODE.

2. Upon receipt of a 510(k) submission file or a PMA supplement file from ODE, if necessary, OC will contact the applicant to identify the manufacturing/sterilizing site(s) of the subject device. At the same time, OC staff will inquire whether the device is to be marketed as sterile; if it is, the location(s) of the sterilizer(s) must be made known, if different from the manufacturing site(s).

3. OC will contact the district office(s) to determine the current state of CGMP compliance of the product manufacturing and/or sterilization site(s).

4. Depending upon the response from the district office, OC will recommend to ODE that the processing of the 510(k) or PMA "proceed" or be "postponed." OC will recommend postponement when the district office informs it that the device manufacturer or sterilizer is in a VAI–3 with warning letter or OAI state of CGMP compliance, and that the noncompliant state is relevant to the manufacture of the subject device. OC will notify ODE in writing of its recommendation upon receipt of the 510(k) or PMA supplement referral from ODE. When postponement is recommended, OC will simultaneously notify the district office of its recommendation to ODE.

5. When normal processing of a 510(k) submission or PMA supplement is postponed, and the manufacturer subsequently corrects the noncompliant CGMP conditions that resulted in the postponement, OC will notify ODE in writing that processing of the 510(k) submission or PMA supplement may be resumed.

C. Office of Regulatory Affairs—District Office In Which the Manufacturer Is Located

1. When a district office receives from OC/CDRH an inquiry concerning the current CGMP status of a device manufacturer with a 510(k) submission or PMA supplement pending before the agency, district officials will respond by facsimile, as to whether the firm has known serious CGMP deficiencies with respect to the device.

2. When serious CGMP deficiencies are found, the district office will also be responsible for notifying OC/CDRH, by facsimile, when a firm has satisfactorily corrected the noncompliant CGMP conditions that initially resulted in the postponement of FDA review of the applicant's 510(k) submission or PMA supplement. Communication will be by facsimile in order that final marketing clearances can be expedited to the maximum extent possible. The district office will also simultaneously update FDA's COMSTAT system to reflect the change in the facility's compliance status to "acceptable."

The procedures described above occur near the end of the normal product review cycle. This is to ensure that a firm is in CGMP compliance at or near the time of an agency decision to grant marketing clearance. Compliance verification by FDA field offices, if necessary, ordinarily has minimal impact on the overall review time.

The exception to this sequence of actions is 510(k) submissions for devices claiming equivalence to class III preamendments devices. Because of the relatively small number of such submissions, and the comparatively larger investment of agency review time due, in general, to product complexity and the frequent necessity for supporting clinical data, for these 510(k)'s, verification of the regulatory compliance status of the applicant firm is made prior to commencement of agency review. This is accomplished either by a preclearance site inspection or a Reference List check as described previously in this notice.

In an effort to further economize and make more efficient use of device evaluation resources, CDRH is presently considering possible mechanisms to employ the Reference List earlier in the review process. Having knowledge about a firm's CGMP compliance status at an earlier stage in the review cycle will allow for more efficient use of resources by permitting allocation of review time to applications from manufacturers in full compliance with CGMP rules.

By these actions, the agency expects to satisfy the dual objectives of protecting consumers from potentially unsafe or ineffective medical devices before they are introduced into commerce, while, at the same time, minimizing unnecessary delays in the approval of important new medical technologies. In addition, these actions have a beneficial effect on the efficiency and productivity of CDRH premarket reviews of medical devices.

V. Public Disclosure of Reference List Entries

In recent years, FDA-regulated industries have questioned the agency's use of mechanisms to verify regulatory compliance as a condition to marketing approval. The industries have expressed concern about the potential for misuse and abuse of such mechanisms, in part because of the prohibition against public disclosure of the identity of firms placed on compliance monitoring "lists" such as the Reference List described in this notice.

The prohibition against public disclosure applies to the Reference List. The Reference List as a predecisional document that contains advisory information that is neither adopted nor incorporated into a final decisional document. The Reference List is intended to provide current information that may be relevant to decisions about clearance or disapproval of industry submissions in the medical device review process. Public disclosure of the list could interfere with the agency's ability to evaluate preliminary recommendations and interfere with the deliberative process. In addition, because the Reference List is a compilation of recommendations for regulatory action in response to inspections made to enforce the act, the

Reference List also constitutes a record compiled for law enforcement purposes, the disclosure of which could reasonably be expected to interfere with enforcement proceedings.

Therefore, the Reference List is exempt from public disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(5) and (b)(7)(A)) as both an intra-agency memorandum and as a law enforcement record. The Department of Health and Human Services' regulations implementing the FOIA, (45 CFR 5.66(a) and 5.68(a)) and applicable FDA regulations, (21 CFR 20.62 and 20.64(a)(1)), provide for exemptions from public disclosure for intra-agency memoranda and records compiled for law enforcement purposes.

The Reference List is intended for internal use only, as described above. It is not intended as a means of communicating FDA's concerns about a particular firm's compliance with CGMP's. Instead, that information will be communicated directly to the firm, as it always has been, through such vehicles as establishment inspection reports and warning letters. Similarly, at any time OC forwards a "postponement" recommendation to ODE, ODE will notify the applicant that a final marketing clearance decision regarding a pending 510(k) or PMA is being withheld until corrections of the CGMP violations have been made. ODE will also advise the applicant to contact the district office to determine what specific remedial actions are necessary for the firm to be in full compliance with the law and thereby avoid further postponement of decisions on pending 510(k)'s or PMA's. The agency believes that taking these actions fulfills all "due process" requirements.

Interested persons may, at any time, submit to the Docket Management Branch (address above) written comments on these procedures. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the name of the device and 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. Comments will be considered in determining whether to revise these procedures.

Dated: October 20, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–26212 Filed 10–25–93; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Division of Research Grants Behavioral and Neurosciences Special Emphasis Panel; Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Division of Research Grants Behavioral and Neurosciences Special Emphasis Panel.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications in the various areas and disciplines related to behavior and neuroscience. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Office of Committee Management, Division of Research Grants, Westwood Building, National Institutes of Health, Bethesda, Maryland 20882, telephone 301–594–7265, will furnish summaries of the meeting and roster of panel members.

Meeting to Review Individual Small Business Innovation Research Program Applications

Scientific Review Administrator: Dr. Keith Murray (301) 594–7145

Date of Meeting: November 12–13, 1993

Place of Meeting: Holiday Inn Chevy Chase, MD

Time of Meeting: 9 a.m.

Meeting to Review Individual Grant Applications

Scientific Review Administrator: Dr. Carol Campbell (301) 594–7165

Date of Meeting: November 16, 1993

Place of Meeting: Westwood Bldg., room 306B, NIH, Bethesda, MD (Telephone Conference)

Time of Meeting: 11 a.m.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–396, 93.837–844, 93.846–878, 93.892–893, National Institutes of Health, HHS)

Dated: October 20, 1993

Susan K. Fieldman,

Committee Management Office, NIH.

[FR Doc. 93–26214 Filed 10–25–93; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

National Center for Health Statistics; The ICD–9–CM Coordination and Maintenance Committee Meeting

AGENCY: National Center for Health Statistics, DHHS.

ACTION: Notice of meeting.

SUMMARY: The ICD–9–CM Coordination and Maintenance Committee (C&M) will be holding its third meeting of the year on December 2, 1993. The C&M is a public forum for the presentation of proposed modifications to the International Classification of Diseases, ninth-revision, clinical modification.

DATES: The meeting will be held on December 2, 1993 from 9:00 a.m.–5:00 p.m.

ADDRESSES: The Hubert H. Humphrey building, rm. 703A, 200 Independence Ave., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Amy Blum, 301–436–4216.

SUPPLEMENTARY INFORMATION: Tentative agenda—Bilateral neoplasms, Obstetrical fifth-digits, Rehabilitation codes, Vitiligo, Toxic effect of second-hand smoke, Chiari malformations, Prophylactic organ removal, Stem-cell transplant, 14C-urea breath teat, Coronary atherectomy, Progesterone-hormone versus steroid, Continuous mechanical ventilation, Addenda.

Sue Meads,

Co-chair, ICD–9–CM Coordination and Maintenance Committee.

[FR Doc. 93–26272 Filed 10–25–93; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–060–5440–10–ZBBB, CACA–30070, CACA–25594, CACA–31926]

Availability of the Record of Decision for the Eagle Mountain Landfill Project

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with section 202 of the National Environmental Policy Act of 1969 (42 U.S.C. 4371 *et seq.*) and in compliance with the regulations contained in 40 CFR part 1505, the Bureau of Land Management (BLM), California Desert District, has completed its environmental review of the above referenced project and has issued a Record of Decision (ROD). This ROD approves a land exchange with Kaiser Eagle Mountain, Inc. and the