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 May 29, 1987.

A. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *Central Bancshares of the South, Inc.*, Birmingham, Alabama; to acquire 100 percent of the voting shares of Central Bank of Shelby County, Shelby County, Alabama, a *de novo* bank.

2. *E.C.S.B. Holding Company, Inc.*, Mary Esther, Florida; to become a bank holding company by acquiring 100 percent of the voting shares of Emerald Coast State Bank, Mary Esther, Florida, a *de novo* bank.

3. *Jefferson Bancorp, Inc.*, Miami Beach, Florida; to merge with Broward Bancorp, Lauderdale Lakes, Florida, and thereby indirectly acquire The Broward Bank, Lauderdale Lakes, Florida.

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

1. *Butler Point, Inc.*, Catlin, Illinois; to become a bank holding company by acquiring 80 percent of the voting shares of The First National Bank of Catlin, Catlin, Illinois.

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

1. *Greenfield Bancshares, Inc.*, Greenfield, Tennessee; to become a bank holding company by acquiring at least 80 percent of the voting shares of Greenfield Banking Company, Greenfield, Tennessee.

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

1. *Central Bank Corporation*, Sault Ste. Marie, Michigan; to become a bank holding company by acquiring 100 percent of the voting shares of Central Savings Bank, Sault Ste. Marie, Michigan. Comments on this application must be received by May 27, 1987.

2. *First BancShares, Inc. of Cold Spring*, Cold Spring, Minnesota; to become a bank holding company by acquiring 100 percent of the voting shares of The First National Bank of Cold Spring, Cold Spring, Minnesota.

E. **Federal Reserve Bank of San Francisco** (Harry W. Green, Vice President) 101 Market Street, San Francisco, California 94105:

1. *National Security Bank Holding Company*, Newport, Oregon; to become a bank holding company by acquiring 100 percent of the voting shares of National Security Bank, Newport, Oregon.

2. *United Valley Financial*, Lemoore, California; to become a bank holding company by acquiring 66.4 percent of the voting shares of Farmers State Bank, Farmersville, California.

Board of Governors of the Federal Reserve System, May 4, 1987.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 87-10447 Filed 5-7-87; 8:45 am]

BILLING CODE 6210-01-M

## Change in Bank Control Notice; Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has 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 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 May 22, 1987.

A. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *B.D. Fairchild*, Tonkawa, Oklahoma; to acquire 6.33 percent of the voting shares of Service Bancshares Limited, Inc., Tonkawa, Oklahoma, and thereby indirectly acquire The Service Bank of Tonkawa, Tonkawa, Oklahoma.

Board of Governors of the Federal Reserve System, May 4, 1987.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 87-10488 Filed 5-7-87; 8:45 am]

BILLING CODE 6210-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMG) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on May 1, 1987.

**Public Health Service (PHS)**

(Call Reports Clearance Officer on 202-245-2100 for copies of Package)

**Alcohol, Drug Abuse and Mental Health Administration**

*Subject:* Confidentiality of Alcohol and Drug Abuse Records—NPRM—Reinstatement—(0930-0099)
*Respondents:* Federal agencies or employees; Non-profit institutions; Small businesses or organizations
*Subject:* Annual Census of Patient Characteristics in State and County Mental Hospital Inpatient Services—Reinstatement—(0930-0093)
*Respondents:* State or local governments

**National Institutes of Health**

*Subject:* Factors Associated with Premature Births: Missouri Followback Survey—NEW—
*Respondents:* Individuals or households; State or local governments

**Assistant Secretary for Health**

*Subject:* 1988 National Maternal and Infant Health Survey and 1987 Pretest—NEW—
*Respondents:* Individuals or households; Businesses or other for-profit; Non-profit institutions
*OMB Desk Officer:* Shannah Koss

**Health Care Fanancing Administration**

(Call Reports Clearance Officer on 301-594-8650 for copies of package)
*Subject:* Monthly Contractor Financial Report Contractor Draws on letter of Credit—Extension—(0938-0361)-HCFA-1522-1521

*Respondents:* Businesses or other for-profit; Non-profit institutions
*Subject:* Medicare Contractor Administrative Budget and Cost Reporting System—Revision—(0938–0350)–HCFA–1523/1524
*Respondents:* Businesses or other for-profit; Non-profit institutions
*Subject:* Request for Information—Medicare Payment for Services to Patients now Deceased—Reinstatement—(0938–0020)–HCFA–1660
*Respondents:* Individuals or households; Businesses or other for-profit
*Subject:* Intermediary Benefit Payment Report—Extension—(0938–0371)–HCFA–456
OMB Desk Officer: Allison Herron

As mentioned above, copies of the information collection clearance packages can be obtained by calling the Reports Clearance Officer, on one of the following numbers:

PHS: 202–245–2100
HCFA: 301–594–8650

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, DC 20503.

ATTN: (name of OMB Desk Officer)

Dated: May 4, 1987.

**James F. Trickett,**

*Deputy Assistant Secretary, Administrative and Management Services.*

[FR Doc. 87–10491 Filed 5–7–87; 8:45 am]

BILLING CODE 4150–04–M

## Food and Drug Administration

**[Docket No. 87F–0086]**

### McNeil Specialty Products Co.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that McNeil Specialty Products Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sucralose as a non-nutritive sweetener in food.

**FOR FURTHER INFORMATION CONTACT:** Blondell Anderson, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–5487.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 7A3987) has been filed by McNeil Specialty Products Co., Division of McNeilab, Inc., a wholly owned subsidiary of Johnson & Johnson, P.O. Box 3000, Grandview Rd., Skillman, NJ 08558–3000, proposing the issuance of a food additive regulation providing for safe use of sucralose, 1,6-dichloro-1,6-dideoxy-*beta*-D-fructofuranosyl-4-chloro-4-deoxy-*alpha*-D-galactopyranoside, as a non-nutritive sweetener in food, where standards of identity do not preclude such use.

The potential environmental impact of this action is being reviewed. If 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: May 1, 1987.

**Richard J. Ronk,**

*Acting Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 87–10471 Filed 5–7–87; 8:45 am]

BILLING CODE 4160–01–M

**[Docket No. 87E–0095]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; Atrovent

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) had determined the regulatory review period of Atrovent and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims this human drug product.

**ADDRESS:** Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fihsers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Michael W. Cogan, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under the act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase market with the initital submission of an application to market the human drug product and continues until FDA grants permission to start the drug product. Although only a portion of a regulatory review period may count toward the actural amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B)

FDA recently approved for marketing the human drug product Atrovent, an inhalation aerosol drug indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. Folloiwng FDA's approval, Boehringer Ingelheim International GmbH filed a patent term restoration application with the U.S. Patent and Trademark Office, which then requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated April 7, 1987, FDA advised the Patent Office that the product had undergone a regulatory review period and that Atrovent represented the first commercial marketing or use of its active ingredient, ipratropium bromide. Shortly thereafter, the Patent Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Atrovent is 4,942 days. Of this time, 3,695 days occurred during the testing phase of the regulatory review period, while 1,247 days occurred during the approval phase. These periods of time were derived from the folloiwng dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug,*

*and Cosmetic Act became effective:* June 20, 1973. FDA has verified that the investigational new drug application became effective on June 20, 1973 (30 days after its receipt by the agency; see 21 CFR 312.1(b)(4)).

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* August 1, 1983. FDA has verified that the new drug application (NDA 19–085) was initially submitted on August 1, 1983.

3. *The date the application was approved:* December 29, 1986. FDS has verified that NDA 19–085 was approved on December 29, 1986.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actural period for patent extension. In its application for patent extension, this applicant seeks 2 years of patent extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 7, 1987, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested peson may petition FDA, on or before November 4, 1987, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 1, 1987.

**Stuart L. Nightingale,**

*Associate Commissioner for Health Affairs.*

[FR Doc. 87–10469 Filed 5–7–87; 8:45 am]

BILLING CODE 4160–01–M

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**[Docket No. 87E–0071]**

## Determination of Regulatory Review Period for Purposes of Patent Extension; Unasyn

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Unasyn and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims this human drug product.

**ADDRESS:** Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Michael W. Cogan, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Unasyn, an injectable antibacterial combination drug for treatment of infections due to susceptible strains of designated microorganisms in skin and suture infections, intra-abdominal infections, and gynecological infections. Following FDA's approval, Pfizer Inc. field a patent term restoration application with the U.S. Patent and Trademark Office, which then requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated April 2, 1987, FDA advised the Patent Office that the product had undergone a regulatory review period and that Unasyn represented the first commercial marketing or use of one of its active ingredients, sulbactam sodium. Shortly thereafter, the Patent Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Unasyn is 3,310 days. Of this time, 2,687 days occurred during the testing phase of the regulatory review period, while 623 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 507(i) of the Federal Food, Drug, and Cosmetic Act became effective:* December 10, 1977. FDA has verified that the investigational new drug application became effective on December 10, 1977 (30 days after its receipt by the agency; see 21 CFR 312.1(b)(4)).

2. *The date the application was initially submitted with respect to the human drug product under section 507(b) of the Federal Food, Drug, and Cosmetic Act:* April 18, 1985. FDA has verified that the new drug application (NDA 50,608) was initially submitted on April 18, 1985.

3. *The date the application was approved:* December 31, 1986. FDA has verified that NDA 50,608 was approved on December 31, 1986.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2 years of patent extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 7, 1987, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 4, 1987, for a determination regarding whether the applicant for extension acted with due diligence during the regualtory review period. To meet its burden, the petition