

Dated: September 11, 1987.

Kay McMurray,

Director, Federal Mediation and Conciliation Service.

[FR Doc. 87-21457 Filed 9-16-87; 8:45]

BILLING CODE 6372-01-M

FEDERAL RESERVE SYSTEM

Formations of; Acquisitions by; and Mergers of Bank Holding Companies; Dublin Bancshares, Inc., et al.

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 October 6, 1987.

A. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Arkard Street, Dallas, Texas 75222:

1. *Dublin Bancshares, Inc.*, Dublin, Texas; to become a bank holding company by acquiring 80 percent of the voting shares of First National Bank of Dublin, Dublin, Texas.

2. *First Canyon Bancorporation, Inc.*, Canyon, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of First Canyon Bancshares, Inc., Canyon, Texas, and thereby indirectly acquire The First National Bank in Canyon, Canyon, Texas.

Board of Governors of the Federal Reserve System, September 11, 1987.

James McAfee,

Association Secretary of the Board.

[FR Doc. 87-21401 Filed 9-16-87; 8:45 am]

BILLING CODE 6210-01-M

Formations of; Acquisitions by; and Mergers of Bank Holding Companies; Marion Bancshares Inc., et al.

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 October 6, 1987.

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

1. *Marion Bancshares Incorporated*, Marion, Alabama; to become a bank holding company by acquiring 100 percent of the voting shares of Marion Bank and Trust Company, Marion, Alabama.

B. Federal Reserve Bank of Chicago (David S. Epstein, Assistant Vice President) 320 South LaSalle Street, Chicago, Illinois 60690:

1. *Oxford Financial Corporation*, Elmhurst, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of Addison State Bank, Addison, Illinois. Comments on this application must be received by September 30, 1987.

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

1. *Elkcorp, Inc.*, Clyde, Kansas; to become a bank holding company by acquiring 80 percent of the voting shares of The Elk State Bank, Clyde, Kansas.

Board of Governors of the Federal Reserve System, September 11, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-21402 Filed 9-16-87; 8:45]

BILLING CODE 6210-01-M

Acquisition of Company Engaged in Permissible Nonbanking Activities; Nationwide Bankshares, Inc.

The organization listed in this notice has 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.

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 October 6, 1987.

A. Federal Reserve Bank of Kansas City (Thomas M. Hoenig, Vice President)

925 Grand Avenue, Kansas City, Missouri 64198:

1. *NationWide BankShares, Inc.*, West Point, Nebraska; to acquire Charter West Agency, Inc., West Point, Nebraska, and thereby engage in general insurance agency activities in a town with a population of less than 5,000 pursuant to § 225.25(b)(8)(iii)(A) of the Board's Regulation Y. This activity will be conducted in the town of West Point, Nebraska, and the immediate vicinity.

Board of Governors of the Federal Reserve System, September 11, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-21403 Filed 9-16-87; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 87F-0269]

Filing of Food Additive Petition; Ciba-Geigy Corp.

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 5-[(2,3-dihydro-6-methyl-2-oxo-1H-benzimidazol-5-yl)azo]-2,4,6(1H, 3H, 5H)-pyrimidinetrione as a colorant in all polymers.

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

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 7B4016) has been filed by Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, proposing that § 178.3297 *Colorants for polymers* (21 CFR 178.3297) be amended to provide for the safe use of 5-[(2,3-dihydro-6-methyl-2-oxo-1H-benzimidazol-5-yl)azo]-2,4,6(1H, 3H, 5H)-pyrimidinetrione as a colorant in all polymers.

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: September 3, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-21426 Filed 9-16-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86P-0369]

Canned Pacific Salmon Deviating From Identity Standard; Amendment of Temporary Marketing Permit

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit, issued to Bumble Bee Seafoods, Inc., to market test canned skinless and boneless chunk salmon is being amended to add another test product manufacturer.

FOR FURTHER INFORMATION CONTACT: Karen L. Carson, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0110.

SUPPLEMENTARY INFORMATION: A temporary permit was issued under the provisions of 21 CFR 130.17 to Bumble Bee Seafoods, Inc., San Diego, CA 92123, to market test canned skinless and boneless chunk salmon to test consumer acceptance of the new style pack. The permit was issued in order to facilitate market testing of foods that deviate from the requirements of the standard of identity for canned Pacific salmon (21 CFR 161.170), which was promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). Notice of issuance of the temporary permit to Bumble Bee Seafoods, Inc., was published in the **Federal Register** of September 16, 1986 (51 FR 32344), and amended in the **Federal Register** of May 29, 1987 (52 FR 20147). The expiration date of the permit is December 29, 1987.

In accordance with § 130.17(f) Bumble Bee Seafoods, Inc., has requested that British Columbia Packers, Ltd., 4300 Moncton St., Richmond, British Columbia, Canada be added to the permit as a test product manufacturer. Accordingly, FDA is amending the temporary permit to reflect this change.

Therefore, FDA is amending the permit to add British Columbia Packers, Ltd., Richmond, British Columbia, Canada as a test product manufacturer. All other conditions and terms of this permit remain the same.

Dated: September 8, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-21422 Filed 9-16-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87D-0279]

Revised Forms for Investigational New Drug Applications; Availability

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of revised forms for investigational new drug applications. Two new forms are being made available: (1) A revised investigational new drug application (IND) (Form FDA-1571); and (2) a revised statement of investigator (Form FDA-1572). The revised statement of investigator form replaces previously used forms FDA-1572 and FDA-1573. The forms have been prepared by FDA's Center for Drugs and Biologics.

ADDRESS: Requests for forms may be made in writing to the Forms and Publications Distribution Center (HFA-268), 12100 Parklawn Dr., Rockville, MD 20852. Requests for forms should include the FDA form number, the form title, the quantity required, the name of the firm, and the address to which the shipment is to be sent.

FOR FURTHER INFORMATION CONTACT: Darlene Burgess, Center for Drugs and Biologics (HFN-46), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4320.

SUPPLEMENTARY INFORMATION: The two revised forms are designed to be used with the newly revised investigational new drug regulations (the "IND Rewrite") published in the **Federal Register** of March 19, 1987 (52 FR 8798). These forms have been approved by the Office of Management and Budget (OMB) under The Paperwork Reduction Act of 1980 and assigned OMB control number 0910-0014. Because a limited number of the forms are available, sponsors are requested to limit their requests to 200 copies of each form.

Dated: September 10, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-21423 Filed 9-16-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87M-0271]

Premarket Approval of Aerosol Services, Inc., Sterile Unpreserved Aerosol Pressurized Spray**AGENCY:** Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Aerosol Services, Inc., City of Industry, CA, for premarket approval, under the Medical Device Amendments of 1976, of AEROSOL SERVICES, INC., STERILE UNPRESERVED AEROSOL PRESSURIZED SPRAY. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant on July 31, 1987, by letter of the approval of the application.

DATE: Petitions for administrative review by October 19, 1987.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7940.

SUPPLEMENTARY INFORMATION: On July 6, 1987, Aerosol Services, Inc. (Aerosol), City of Industry, CA 91746, submitted to CDRH an application for premarket approval of AEROSOL SERVICES, INC., STERILE UNPRESERVED AEROSOL PRESSURIZED SPRAY. The device is indicated for use in the rinsing, heat disinfection and storage of soft (hydrophilic) contact lenses. The application includes authorization from Steridyne Laboratories, Inc. (Steridyne), Hollywood, CA, to incorporate the information contained in its approved premarket approval application for the STERIDYNE DYNASPRAY STERILE SALINE SOLUTION [Docket No. 87M-0159], a product that is identical to the Aerosol device.

On February 27, 1987, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the Steridyne application. On July 31, 1987 CDRH approved Aerosol's application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH

based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ-460), address above.

The labeling of AEROSOL SERVICES, INC., STERILE UNPRESERVED AEROSOL PRESSURIZED SPRAY states that the solution is indicated for use in the rinsing, heat disinfection and storage of soft (Hydrophilic) contact lenses. Manufacturers of soft (hydrophilic) contact lenses that have been approved for marketing are advised that whenever CDRH publishes a notice in the *Federal Register* of the approval of a new solution for use with an approved soft contact lens, the manufacturer of each lens shall correct its labeling to refer to the new solution at the next printing or at such other time as CFRH prescribes by letter to the applicant.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) [21 U.S.C. 360e(d)(3)] authorizes any interested person to petition, under section 515(g) of the act [21 U.S.C. 360e(g)], for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the *Federal Register*. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the person who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before October 19, 1987, file with the Dockets Management Branch (address above) two copies of each petition and

supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: September 3, 1987.

John C. Villforth,
Director, Center for Devices and Radiological Health.

[FR Doc. 87-21421 Filed 9-16-87; 8:45 am]

BILLING CODE 4169-01-M

Advisory Committees; Meetings

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

Meetings: The following advisory committee meetings are announced:

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. October 13, 1987, 8:30 a.m., Auditorium, Lister Hill Center, Bldg. 38A, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD.

Type of meeting and contract person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5:30 p.m.; Joan C. Standaert, Center for Drugs and Biologics (HFN-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4730 or 419-259-6211.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of cardiovascular disorders and diseases.

Agenda—Open public hearing. Interested persons requesting to present data, information, or views, orally or in

writing, on issues pending before the committee should communicate with the committee contract person.

Open committee discussion. The committee will discuss (NDA 18-998) Merck and Co., Vasotech (enalapril) for treatment of congestive heart failure; (NDA 19-558) Merck and Co., Prinivil (lisinopril) for treatment of congestive heart failure; and (NDA 18-343) Squibb and Co., Capoten (captopril) for congestive heart failure.

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. October 22, and 23, 1987, 8:30 a.m., Conference Rms. G and H, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.

Type of meeting and contact person. Open public hearing, October 22, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5:00 p.m.; open committee discussion, October 23, 8:30 a.m. to 2:30 p.m.; Isaac F. Roubein, Center for Drugs and Biologics (HFN-32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of pulmonary disease and diseases with allergenic and/or immunologic mechanisms.

Agenda—Open public hearing. Interested persons requesting to present data, information, or views, orally or in writing, on issues pending before the committee should communicate with the committee contract person.

Open committee discussion. On October 22, the committee will discuss the following: (1) Surfactant replacement therapy, (2) effect of theophylline on school performance, (3) rationality of antitussive-expectorant combinations, and (4) adverse reactions of beta-agonists. On October 23, the committee will discuss NDA 19-658 (loratidine, Schering-Plough Corp.).

Anti-Infective Drugs Advisory Committee

Date, time, and place. October 26 and 27, 1987, 8:30 a.m., Conference Rms. D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.

Type of meeting and contract person. Open public hearing, October 26, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 4:30 p.m.; October 27, 8:30 a.m. to 12:30 p.m.; Thomas E. Nightingale, Center for Drugs and Biologics (HFN-32), Food and

Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in infectious disease.

Agenda—Open public hearing. Interested persons requesting to present data, information, or views, orally or in writing, on issues pending before the committee should communicate with the committee contract person.

Open committee discussion. The committee will discuss the safety and efficacy of ganciclovir, also as DHPG, and the drug ramantadine.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meeting announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (Subpart C of 21 CFR Part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR Part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral

presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

Details on the agenda, questions to be addressed by the committee, and a current list of committee members are available from the contact person before and after the meeting. Transcripts of the open portion of the meeting will be available from the Freedom of Information Office (HFI-35), Food and Drug Administration, Rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA's regulations (21 CFR Part 14) on advisory committees.

Dated: September 9, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-21425 Filed 9-16-87; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

[BERC-406-CN]

Medicare Program; Payments Under Medicare and Awards Under the Federal Tort Claims Act; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of HCFAR Ruling; Correction.

SUMMARY: In the July 10, 1987 issue of the Federal Register (FR Doc. 87-15581), beginning on page 26088, we set forth a