Board of Governors of the Federal Reserve System, March 18, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–6917 Filed 3–21–96; 8:45 am]

BILLING CODE 6210–01–F

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are 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 standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act, including whether the acquisition of the nonbanking company 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'' (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 15, 1996.

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

1. Absarokee Bancorporation, Absarokee, Montana; to acquire 100 percent of the voting shares of United Bank of Columbus, N.A., Columbus, Montana, a *de novo* bank.

Board of Governors of the Federal Reserve System, March 18, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–6918 Filed 3–21–96; 8:45 am]

BILLING CODE 6210–01–F

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. Once the notice 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 the proposal complies with the standards of section 4 of the BHC Act, including 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'' (12 U.S.C. 1843). 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 April 5, 1996.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Heritage Bancshares Group, Inc., Minneapolis, Minnesota; to engage in making and servicing loans, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, March 18, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–6919 Filed 3–21–96; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0008]

John W. Bushlow; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying a hearing for and is issuing a final order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. John W. Bushlow, 9704 Tartuffe Dr., Richmond, VA 23233, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Bushlow was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Bushlow has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action.

EFFECTIVE DATE: March 22, 1996.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tamar S. Nordenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On February 21, 1992, the United States District Court for the District of Maryland entered judgment against Mr. John W. Bushlow, former Vice President of Manufacturing and plant manager of Vitarine Pharmaceuticals, Inc., for one count of failing to establish and maintain records, with the intent to mislead, a Federal felony offense under 21 U.S.C. 331(e) and 333(a)(2). As a result of this conviction, FDA served Mr. Bushlow by certified mail on April 9, 1993, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application, and offered him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Mr. Bushlow was convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

The certified letter informed Mr. Bushlow that his request for a hearing could not rest upon mere allegations or denials, but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also notified Mr. Bushlow that if it conclusively appeared from the face of the information and factual analyses in his request for a hearing that there was no genuine and substantial issue of fact which precluded the order of debarment, FDA would enter summary judgment against him and deny his request for a hearing.

In a letter dated May 4, 1993, Mr. Bushlow requested a hearing. The letter in its entirety is as follows:

> In accordance with the requirements of 21 U.S.C. 335a(i), I set forth below the information relied upon to justify a hearing on the Food and Drug Administration's Proposed Notice to Debar, dated February 5, 1993.
>
> I. The Proposal to Permanently Debar Violates the Double Jeopardy Clause of the Fifth Amendment
>
> II. The Proposed Notice to Permanently Debar violates the Ex Post Facto Clause of the Constitution
>
> III. The Proposed Notice to Permanently Debar violates the Constitution in that it is too broad, too vague and too unspecific.
>
> In accordance, and within the required 60 days from receipt of the Proposal to Debar Notice, additional information will be filed to justify a hearing.

Despite his stated intention, Mr. Bushlow did not follow up with additional information to justify a hearing.

The Deputy Commissioner for Operations has considered Mr. Bushlow's letter and concludes that it is unpersuasive and fails to raise a genuine and substantial issue of fact requiring a hearing. The constitutional claims that Mr. Bushlow offers do not create a basis for a hearing because hearings are not granted on matters of policy or law, but only on genuine and substantial issues of fact (21 CFR 12.24(b)(1)). The constitutional arguments are, in any event, unconvincing, for the reasons discussed below.

II. Mr. Bushlow's Arguments in Support of a Hearing

Mr. Bushlow states that the debarment proposal violates the Ex Post Facto Clause and Double Jeopardy Clause of the U.S. Constitution. Mr. Bushlow was convicted on February 21, 1992, prior to the enactment of the Generic Drug Enforcement Act (GDEA) on May 13, 1992.

An ex post facto law is one that reaches back to punish acts that occurred before enactment of the law or that adds a new punishment to one that was in effect when the crime was committed. (*Ex Parte Garland*, 4 Wall. 333, 377, 18 L. Ed. 366 (1866); *Collins* v. *Youngblood*, 497 U.S. 37 (1990).)

The Double Jeopardy Clause states that no person shall ''be subject for the same offense to be twice put in jeopardy of life or limb.''

In determining whether a statutory provision such as the one being challenged is unconstitutional under the Ex Post Facto Clause or Double Jeopardy Clause, the critical consideration is whether the provision is remedial or punitive in nature. The intent of debarment under the GDEA is not to punish, but rather to remedy the past fraud and corruption in the drug industry. In upholding the GDEA against an ex post facto challenge, the court in *Bae* v. *Shalala* stated,

> Without question, the GDEA serves compelling governmental interests unrelated to punishment. The punitive effects of the GDEA are merely incidental to its overriding purpose to safeguard the integrity of the generic drug industry while protecting public health.

(*Bae* v. *Shalala*, 44 F.3d 489, 493 (7th Cir. 1995); see also, *Manocchio* v. *Kusserow*, 961 F.2d 1539, 1542 (11th Cir. 1992); *Hawker* v. *New York*, 170 U.S. 189, 190 (1898); *DeVeau* v. *Braisted*, 373 U.S. 154 (1960).) Therefore, Mr. Bushlow's claim that the GDEA violates the Ex Post Facto Clause and Double Jeopardy Clause is unpersuasive.

Mr. Bushlow also asserts that the proposal to debar him is unconstitutional because it is ''too broad, too vague, and too unspecific.'' Such an argument does not provide the basis for a hearing.

Neither the proposal to debar nor the act's debarment provisions, on which the proposal to debar was based, are vague or unspecific. The debarment proposal sets forth expressly the conduct on which the proposal is based, the findings of FDA, the agency's proposed action, and the procedure for requesting a hearing. Section 306(a)(2)(B) of the act clearly mandates the debarment of an individual who has been convicted of a Federal felony for conduct relating to the regulation of any drug product. The act defines the conduct and felony conviction that lead to debarment. The period of debarment is also set forth in section 306(c)(2) of the act, which states that the debarment is permanent.

Finally, Mr. Bushlow does not explain his argument that the debarment proposal is over broad. In fact, the debarment provisions are narrowly drawn to accomplish the legitimate government purposes of ensuring the integrity of the drug regulatory process and protecting the public health. The debarment provisions further the compelling governmental interest of ''restor[ing] consumer confidence in generic drugs by eradicating the widespread corruption in the generic drug approval process.'' (*Bae* v. *Shalala*, 44 F.3d 489, 493 (7th Cir. 1995).)

Mr. Bushlow does not dispute the fact that he was convicted as alleged by FDA in its proposal to debar him, and he has raised no genuine and substantial issue of fact regarding this conviction. Also, Mr. Bushlow's legal arguments do not create a basis for a hearing and, in any event, are unpersuasive. Accordingly, the Deputy Commissioner for Operations denies Mr. Bushlow's request for a hearing.

III. Findings and Order

Therefore, the Deputy Commissioner for Operations, under section 306(a) of the act, and under authority delegated to him (21 CFR 5.20), finds that Mr. John W. Bushlow has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)(B)).

As a result of the foregoing findings, Mr. John W. Bushlow is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective March 22, 1996, (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the

services of Mr. Bushlow, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6)). If Mr. Bushlow, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications from Mr. Bushlow during his period of debarment.

Any application by Mr. Bushlow for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 93N–0008 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 3, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–6941 Filed 3–21–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

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.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. April 10 and 11, l996, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms III and IV, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open committee discussion, April 10, 1996, 8 a.m. to 8:15 a.m.; open public hearing, 8:15 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 10:45 a.m.; closed committee deliberations, 10:45 a.m. to 3 p.m.; open public hearing, 3 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 6 p.m.; open committee discussion, April 11, l996, 8 a.m. to 10:30 a.m.; open public hearing, 10:30 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 11:30 a.m.; closed committee deliberations, 11:30 a.m. to 1 p.m.; open committee discussion, 1 p.m. to 2:30 p.m.; closed committee deliberations, 2:30 p.m. to 3:30 p.m.; Nancy T. Cherry or Sandy M. Salins, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 3, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On April 10, 1996, the committee will discuss data issues pertaining to pediatric studies using vaccines for the prevention of Lyme disease. The committee will also review safety and efficacy data pertaining to a Bacille Calmette-Guerin (BCG) vaccine from Connaught Laboratories, Ltd., for the prevention of tuberculosis. On April 11, l996, the committee will: (1) Discuss vaccine safety issues, (2) review a research program in the Division of Viral Products, and (3) hear a briefing on reverse transcriptase in avian cells.

Closed committee deliberations. On April 10 and 11, l996, the committee will review trade secret and/or confidential commercial information relevant to pending investigational new drug applications, product licensing applications, or approved products. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)). On April 11, l996, the committee will also discuss personal information concerning an individual associated with a research program at the center, disclosure of which would constitute a clearly unwarranted invasion of personal privacy. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(6)).

Anesthetic and Life Support Drugs Advisory Committee

Date, time, and place. April 29 and 30, 1996, 8:30 a.m., Holiday Inn—Bethesda, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, April 29, 1996, 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 p.m.; open committee discussion, April 30, 1996, 8:30 a.m. to 2 p.m.; closed committee deliberations, 2 p.m. to 5 p.m.; Stephen P. Pollitt, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Anesthetic and Life Support Drugs Advisory Committee, code 12529.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the field of anesthesiology and surgery.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make