Federal Communications Commission.

James D. Schlichting,

Deputy Chief, Wireless Telecommunications Bureau.

[FR Doc. 02–27647 Filed 10–30–02; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

PREVIOUSLY ANNOUNCED DATE: Tuesday, October 29, 2002 the closed meeting scheduled for that day was cancelled.

DATE AND TIME: Tuesday, November 5, 2002 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

PERSON TO CONTACT FOR INFORMATION: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 02–27896 Filed 10–29–02; 2:59 pm]

BILLING CODE 6715–01–M

FEDERAL RESERVE SYSTEM

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. The application also will 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 (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

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 November 25, 2002

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Gravett Bancshares, Inc., Gravette, Arkansas; to become a bank holding company by acquiring 100 percent of the voting shares of Bank of Gravett, Gravette, Arkansas.

B. Federal Reserve Bank of Minneapolis (Julie Stackhouse, Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. Merchants Financial Group, Inc., Winona, Minnesota; to acquire 100 percent of the voting shares of Merchants Bank, National Association, La Crescent, Minnesota, a de novo bank, in connection with the relocation of the charter of the existing Merchants Bank, National Association, La Crescent, Minnesota, to Onalaska, Wisconsin.

Board of Governors of the Federal Reserve System, October 25, 2002.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 02–27653 Filed 10–30–02; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health and Science and Food and Drug Administration

[Docket No. 02N–0466]

Solicitation of Public Review and Comment on Research Protocol: A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Response of Dryvax® Administered to Children 2 to 5 Years of Age

AGENCY: Office of Public Health and Science and Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA), HHS are soliciting public review and comment on a proposed research protocol entitled ''A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Response of Dryvax® Administered to Children 2 to 5 Years of Age.'' The proposed research would be supported by a contract awarded by the National Institutes of Health (NIH) and conducted under an Investigational New Drug Application (IND) filed with the FDA. Public review and comment is solicited regarding the proposed research protocol pursuant to the requirements of HHS regulations at 45 CFR 46.407 and FDA regulations at 21 CFR 50.54.

DATES: To be considered, written or electronic comments on the proposed research must be received on or before 4:30 p.m. December 2, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Docket Number 02N–0466, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* All comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be viewed on the FDA Web site at: *http://www.fda.gov/ohrms/dockets/dockets/02n0466/02n0466.htm* or may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Leslie K. Ball, Office for Human Research Protection, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone

301–496–7005; fax 301–402–0527; e-mail: *LBall@osophs.dhhs.gov;* or Ms. Patricia M. Beers Block, Office for Good Clinical Practice, OSHC, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, HF–34, Rockville, MD 20857; telephone 301–827–3340; fax 301–827–1169; *e-mail: pbeersblock@oc.fda.gov.*

SUPPLEMENTARY INFORMATION: All studies conducted or supported by HHS which are not otherwise exempt and which propose to involve children as subjects require Institutional Review Board (IRB) review in accordance with the provisions of HHS regulations at 45 CFR part 46, subpart D. Under FDA's Interim Final Rule effective April 30, 2001 (21 CFR part 50, subpart D), FDA adopted similar regulations to provide safeguards for children enrolled in clinical investigations of FDA-regulated products.

Pursuant to HHS regulations at 45 CFR 46.407 and FDA regulations at 21 CFR 50.54, if an IRB reviewing a protocol conducted or supported by HHS for a clinical investigation regulated by FDA does not believe that the proposed research or clinical investigation involving children as subjects meets the requirements of HHS regulations at 45 CFR 46.404, 46.405, or 46.406, and FDA regulations at 21 CFR 50.51, 50.52, or 50.53, respectively, the research or clinical investigation may proceed only if the following conditions are met: (a) The IRB finds and documents that the research or clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children; and (b) the Secretary (HHS) and the Commissioner (FDA), respectively, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment determine either:

(1) That the research or the clinical investigation in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406 under HHS regulations, and 21 CFR 50.51, 50.52, or 50.53 under FDA regulations, or (2) that the following conditions are met: (i) The research or clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research or clinical investigation will be conducted in accordance with sound ethical principles; and (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 45 CFR 46.408 and 21 CFR 50.55.

HHS received a request from Harbor-UCLA Medical Center to review a protocol entitled ''A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Response of Dryvax® Administered to Children 2 to 5 Years of Age'' pursuant to the provisions of HHS regulations at 45 CFR 46.407. The sponsor of this research, the National Institute of Allergy and Infectious Diseases (NIAID), NIH, proposes to study the safety and immune response to Dryvax® (vaccinia virus vaccine), when administered to children 2 to 5 years of age. This study proposes to evaluate Dryvax® at its full, licensed strength and at a 1:5 dilution, in children enrolled in a number of sites, including Harbor-UCLA Medical Center and Cincinnati Children's Hospital Medical Center. Use of Dryvax® in this protocol is being performed under an FDA IND primarily because there are no data to support the efficacy of the 1:5 dilution of this product in children. This protocol was developed by NIAID in the context of current HHS bioterrorism preparedness plans, given the potential risk of smallpox being used as a weapon of bioterrorism, and has been approved by two IRBs.

However, after reviewing this research proposal, the Harbor-UCLA Medical Center IRB determined that this study could not be approved under 45 CFR 46.404, 46.405, or 46.406 but was suitable for review under 45 CFR 46.407. Because this clinical investigation is regulated by FDA, FDA's regulations at 21 CFR part 50, subpart D, apply as well. The Harbor-UCLA Medical Center IRB was unable to assess the prospect of direct benefit to the participants but found that the research presented a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children. NIAID has not initiated this clinical trial pending the Secretary's and Commissioner's determination. Experts in relevant disciplines have reviewed this protocol (see discussion below regarding access to each expert's report), but prior to the Secretary and Commissioner making a final determination, public review and comment are hereby solicited pursuant to HHS regulations at 45 CFR 46.407 and FDA regulations at 21 CFR 50.54. In particular, comments are solicited on the following questions: (1) What are the potential benefits of the research, if any, to the subjects and to children in general; (2) what are the types and degrees of risk that this research presents to the subjects; (3) are the risks to the subjects reasonable in relation to the anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result; and (4) does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children?

All written comments concerning this matter should be submitted to FDA's Dockets Management Branch pursuant to 21 CFR 10.20. Received comments may be viewed on the FDA Web site at: *http://www.fda.gov/ohrms/dockets/dockets/02n0466/02n0466.htm* or may be seen in the Dockets Management Branch between the 9 a.m. and 4 p.m., Monday through Friday.

Materials available for review on the OHRP Web page (available at *http://ohrp.osophs.dhhs.gov/dpanel/dpindex.htm)* include: The NIH protocol, site-specific protocol application reviewed by the Harbor-UCLA Medical Center IRB, sample parental permission document, relevant package inserts, and reports of each of the experts pursuant to HHS regulations at 45 CFR 46.407 and FDA regulations at 21 CFR 50.54. A paper copy of the information referenced here is available upon request.

Dated: October 23, 2002.

Lester M. Crawford,

Deputy Commissioner, FDA.

Dated: October 24, 2002.

Eve E. Slater,

Assistant Secretary for Health.

[FR Doc. 02–27769 Filed 10–30–02; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0454]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notice of a Claim for Generally Recognized as Safe Exemption Based on a Generally Recognized as Safe Determination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the