Board of Governors of the Federal Reserve System, October 27, 2006.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E6–18346 Filed 10–31–06; 8:45 am]

BILLING CODE 6210–01–S

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 Web site at *http://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 27, 2006.

A. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Capitol Bancorp Ltd., Lansing, Michigan; to indirectly acquire 51 percent of the voting shares of Bank of Tacoma (in organization), Tacoma, Washington.

In connection with this Application, Capitol Development Bancorp Limited VI, Lansing, Michigan, has applied to become a bank holding company by acquiring 51 percent of the voting shares of Bank of Tacoma (in organization), Tacoma, Washington.

2. Bank of Montreal, Montreal, Canada, Harris Financial Corp., Chicago, Illinois, and Harris Bankcorp, Inc., Chicago, Illinois; to acquire 100 percent of the voting shares of First National Bank & Trust, Kokomo, Indiana.

3. QCR Holdings, Inc., Moline, Illinois; to acquire 100 percent of the voting shares of Ridgeland Bancorp, Inc., Tony, Wisconsin, and thereby indirectly acquire voting shares of Farmers State Bank, Ridgeland, Wisconsin.

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BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Improving Health and Accelerating Personalized Health Care Through Health Information Technology and Genomic Information in Population- and Community-Based Health Care Delivery Systems

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Advances in medicine, biomedical science, and technology present opportunities for enabling health care practices to be increasingly patient-specific by taking into account individual differences in health states, disease processes, and outcomes from interventions. Often referred to as personalized health care, the desired impact of these types of health practices is improved effectiveness and safety of medical practices. These health benefits may be manifested through new approaches for predicting disease risk at an early time point, enabling preemption of disease processes prior to full manifestation of symptoms, analyzing the effectiveness of different interventions in specific populations based on their genetic makeup, and preventing the progression of disease and the related complications.

For the purpose of achieving a broader understanding of rapid changes occurring in the health care setting that may have an impact on the future of personalized health care, the Department of Health and Human Services (HHS) requests input from the public and private sectors on plans for developing and using resources involving health information technology (IT) and genetic and molecular medicine, with specific reference to incorporating these capacities in evidence-based clinical practice, health outcomes evaluations, and research.

DATES: Responses should be submitted to the Department of Health and Human Services on or before 5 p.m., EDT, January 2, 2007.

ADDRESSES: Electronic responses are preferred and may be addressed to *PHCRFI@hhs.gov.* Written responses should be addressed to Department of Health and Human Services, 200 Independence Avenue, SW., Room 434E, Washington, DC 20201, Attention: Personalized Health Care RFI.

A copy of this RFI is also available on the HHS Web site at *http://www.aspe.hhs.gov/PHC/rfi.* Please follow the instructions for submitting responses.

The submission of written materials in response to the RFI should not exceed 75 pages, not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit key concepts of their written responses.

Public Access: Responses to this RFI will be available to the public in the HHS Public Reading Room, 200 Independence Avenue, SW., Washington, DC 20201. Please call (202) 690–7453 between 9 a.m. and 5 p.m. to arrange access. The RFI and all responses will also be made available on the HHS Web site at *http://www.aspe.hhs.gov/PHC/rfi.* Any information you submit will be made public.

Do not send proprietary, commercial, financial, business confidential, trade secret, or personal information that should not be made public.

FOR FURTHER INFORMATION CONTACT: Dr. Gregory Downing, Personalized Health Care Initiative, (202) 260–1911.

SUPPLEMENTARY INFORMATION: Advances in medicine, biomedical science, and technology present opportunities for enabling health care practices to be increasingly patient-specific by taking into account individual differences in health states, disease processes, and outcomes from interventions. Often referred to as personalized health care, the desired impact of these types of health practices is improved effectiveness and safety of medical practices. These health benefits may be manifested through new approaches for predicting disease risk at an early time point, enabling preemption of disease processes prior to full manifestation of

symptoms, analyzing the effectiveness of different interventions in specific populations, and preventing the progression of disease and the related complications.

The application of interoperable electronic information technologies (IT) in the health care setting provides new opportunities to collect and analyze information about diagnostic and therapeutic interventions, as well as health care outcomes. With many potential applications, integrated data analysis of multiple parameters of health care practices has the potential to support new approaches to evaluating health outcomes, developing the evidence base for best practices, identifying individual differences in response to therapies, supporting research on new interventions, automating the process of detecting and reporting notifiable disease conditions and health care-associated infections to public health surveillance systems, and enhancing safety.

In the past year, the American Health Information Community (AHIC), a chartered Federal advisory committee, has made recommendations to the Secretary to advance the development of electronic health records (EHR). AHIC's activities and recommendations support a nationwide approach to developing digital and interoperable health IT systems that ensure the privacy and security of patient information. Already underway are efforts to support consumer empowerment, health safety and improvement, and public health protection through broadly deployed, harmonized information systems. As a result of the deployment of these capabilities throughout the health care system, new avenues are emerging to apply information about individual health experiences toward improved transparency about the quality and cost of health care and transformation of health care delivery, as well as decision support for health practitioners.

Occurring in parallel with the advances in health IT are advances in molecular and genetic medicine. This science-based approach to medicine is now in the early stages of entry in health care through the introduction of diagnostics and treatments that target specific genetic and molecular features of disease processes. Applications of this science and technology provide useful information to aid in patient care through more accurate diagnosis and treatment at an individual level. The availability of genetic information (especially the availability of this information as part of the EHR), and the ability to aggregate these data and correlate them with outcomes or other relevant findings from multiple sources, could greatly expand our capacity for personalized health care, providing more specific individual information for prevention, diagnosis, and treatment; pointing toward clinically useful markers; enabling safer and more effective use of existing therapies; and identifying potential fruitful areas for development of new or refined therapies.

New pathways are emerging for affordable and more effective health care practices through personalized health care. The ability to integrate new scientific knowledge, especially our growing understanding of the human genome, into the health care setting in an efficient and timely fashion will rely on robust, reliable and secure information sources in electronically interoperable systems. Many public and private organizations are engaged in the planning for future collections and integration of health data for this purpose. This request seeks information that will facilitate a broader understanding of directions being taken and the productive role that Federal health agencies might play in facilitating progress, avoiding unnecessary barriers, and achieving optimal benefit from the opportunities now before us.

Information Requested

For the purpose of achieving a broader understanding of rapid and emerging changes occurring in the health care setting that may have an impact on the future of personalized health care, HHS requests input from interested parties on plans for developing and using resources involving health IT and genetic and molecular medicine, with specific reference to incorporating these capacities in evidence-based clinical practice, health outcomes evaluations, research, and transformation of health care delivery.

Input is sought on the interest and current planning activities of health care systems and related organizations on the needs and applications of these transformative aspects of personalized health care. Specific areas for comment include:

- Concepts on anticipated approaches for the use of EHR and population- and community-based health care system databases for longitudinal data collection in addressing:

—Disease susceptibility.
—Clinical course and outcomes.
—Treatment response.
—Evidenced-based clinical decision support.
—Optimal healthcare delivery systems.

- Anticipated applications of genomic-based clinical testing in medical decision-making, safety assessment, and risk management.
- Establishment of biospecimen resources obtained from clinical medical services for application in research, clinical trials, health services planning, clinical effectiveness, and health outcomes evaluations.
- Organizational or institutional practices to address ethical, legal, and social implications regarding the use of patient information, including genetic data, to support personalized health care.
- Examples of utilizing large clinical data repositories for practical clinical research to discover effective technologies, therapeutics, diagnostics, and prevention strategies for different populations.
- Issues and challenges associated with incorporating genomic information as a part of a broad longitudinal data collection.
- Needs for community-wide standards or best practices that will facilitate large-scale data integration and exchange to benefit personalized health care.
- Feasibility and potential benefits for establishing linkages of institutional or organizational data resources with private and publicly available health databases.
- Development of ontologies across different clinical data repositories that will facilitate the utility of the data for answering clinical research questions.
- Models for linking clinical data repositories across disparate care providers.
- Examples of the use of disease registries to track specific diseases and response to drug therapies across different subpopulations.
- Models for prioritizing analyses to fill gaps in evidence of effectiveness of therapeutic interventions for different populations.
- Strategies for accumulating patient data necessary for research that may not be available through EHRs.
- Concepts or models on the potential use of clinical data and related resources for research applications.
- Models of cost-benefit analysis for integrated data systems, EHR, and clinical resources to inform medical decision-making.
- Opportunities and challenges for the development of electronic tools to aid in the integration and analysis of large datasets of clinical parameters to assist in outcomes evaluations.

Potential Responders

HHS anticipates responses from a broad range of individual organizations

that have interests in health systems change and personalized health care. Some examples of these organizations include:

- Community health delivery systems.
- Health maintenance organizations.
- University-based health systems.
- State and local public health departments.
- Other Federal agencies.
- Advocacy groups and public interest organizations.
- Consumer and patient interests groups.
- Health care professional societies.
- Trade industry organizations.
- Purchasers of health care.
- Health information technology industry vendors.

Dated: October 26, 2006.

John O. Agwunobi,

Assistant Secretary for Health, Office of Public Health and Science.

[FR Doc. E6–18371 Filed 10–31–06; 8:45 am]

BILLING CODE 4150–26–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0478]

Marketed Unapproved Drugs; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on issues related to the application process for seeking approval for marketed unapproved drugs. This will be a 1-day workshop involving FDA staff and representatives from businesses currently marketing unapproved drugs. The purpose of the workshop is to provide clarification and direction to businesses on how to seek approval to legally market drugs through the new drug application (NDA) and abbreviated new drug application (ANDA) processes and how to legally market drugs through compliance with the over-the-counter (OTC) monographs.

DATES: The public workshop will be held on January 9, 2007, from 9 a.m. to 4 p.m. Registration is open until November 15, 2006. Submit requests for specific discussion topics by November 15, 2006.

ADDRESSES: The public workshop will be held in the Center for Drug Evaluation and Research Advisory Committee conference room, 5630 Fishers Lane, rm. 1066, Rockville, MD. The agenda for the meeting will be posted at *http://www.fda.gov/cder/drug/unapproved_drugs*.

Submit topics by mail to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit topics electronically to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed topics, except that individuals may submit one paper copy. All requests for discussion topics should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Kirchberg, Center for Drug Evaluation and Research (HFD–330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8916, e-mail: *karen.kirchberg@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 9, 2006 (71 FR 33466), FDA announced the availability of a guidance entitled ''Marketed Unapproved Drugs—Compliance Policy Guide'' (the Marketed Unapproved Drugs CPG). The guidance describes how FDA intends to exercise its enforcement discretion with regard to drugs marketed in the United States that do not have required FDA approval for marketing. The guidance explains that FDA intends to continue to give priority to enforcement actions involving unapproved drugs that have potential safety risks, lack evidence of effectiveness, and constitute health fraud, among other categories. The Marketed Unapproved Drugs CPG also explains how the agency intends to address those situations in which a company obtains approval to sell a drug that other companies have sold without FDA approval for some time. In the Marketed Unapproved Drugs CPG, FDA encourages companies to comply with the drug approval requirements of the Federal Food, Drug, and Cosmetic Act.

Following the publication of the Marketed Unapproved Drugs CPG, a number of drug companies have contacted FDA seeking clarification about how to obtain approval to legally market their unapproved drug products and whether applications for marketing are subject to user fees, among other issues. The agency is committed to working with companies to facilitate the process of ensuring that products are safe and effective and meet appropriate standards for manufacturing and labeling.

II. Scope of the Public Workshop

As part of FDA's goal to ensure that all marketed drugs comply with appropriate FDA requirements to ensure their safety and efficacy, FDA is holding a public workshop to educate businesses on the drug application and OTC monograph processes and to discuss issues of interest to participants.

Topics for discussion include the following: (1) The various routes for legal marketing—NDAs, ANDAs, and OTC monographs; (2) application processes; (3) user fee applicability and waivers; and (4) market exclusivity for newly-approved drugs. The information provided during registration will help us determine additional topics for discussion and how to further focus the workshop.

III. Participation in the Public Workshop

A. Registration

Register via e-mail to *CDER_330CATS@cder.fda.gov* by providing complete contact information for each attendee (including name, title, affiliation, e-mail address, and phone number(s)) by November 15, 2006. Please indicate ''Workshop—Unapproved Products'' in the ''subject'' line of the e-mail. FDA intends to respond to registration requests by e-mail after November 15, 2006. There is no registration fee to attend. Space is limited; therefore, interested parties are encouraged to register early and FDA may need to limit the number of attendees from each firm or organization. If you need special accommodations due to a disability, please e-mail your request at least 7 days before the meeting.

B. Suggested Topics

If you would like to request discussion of a specific topic for the workshop, submit it to the Division of Dockets Management (see **ADDRESSES**) using the docket number, found in brackets in the heading of this document, by November 15, 2006. We may not be able to include all submitted topics in the workshop agenda.

C. Parking, Transportation, and Security

Limited visitor parking is available for a fee, and the Twinbrook Metro station is within walking distance. Early arrival is encouraged, as there will be security screening. Workshop participants will be asked for government-issued picture identification by the security officers.

IV. Transcripts

Following the workshop, transcripts will be available for review at the