FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have 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 the 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. The notices also will be available for inspection at the office 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 January 20, 2004.

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

1. Marantz Group, LP, Springfield, Illinois and its general partner, Tom E. Marantz, Springfield, Illinois; to retain voting shares of Staun Bancorp, Inc., Staunton, Illinois, and thereby indirectly retain voting shares of First Community State Bank, Staunton, Illinois.

2. Joseph Thomas McLane, Poplar Bluff, Missouri; to become a trustee of Midwest Bancorporation Inc. and Affiliates Employee Stock Ownership Plan, Poplar Bluff, Missouri, and thereby indirectly gain control of Midwest Bancorporation, Inc., Poplar Bluff, Missouri, First Midwest Bank of Carter County, Van Buren, Missouri, First Midwest Bank of Dexter, Dexter, Missouri, and First Midwest Bank of Piedmont, Piedmont, Missouri.

Board of Governors of the Federal Reserve System, December 31, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–249 Filed 1–6–04; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Medicare and Medicaid Services

[Document Identifier: CMS–37]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

Agency: Center for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320. We cannot reasonably comply with the normal clearance procedures because of possible public harm.

CMS is proposing to minimize disruption to State operations and the reduction of unnecessary expenditures to the Federal government by modifying the collection requirements associated with the CMS–37 information collection package. In particular, CMS will begin to require the States to submit up-front documentation to support the budget and expenditure information currently captured on the CMS–37 ''Medicaid Program Budget Report''. This will enable CMS to identify and resolve any potential funding and/or expenditure issues with the States prior to the budget actually being formulated and/or implemented and the expenditures actually paid and claimed by the States.

CMS is requesting OMB review and approval of this collection by January 9, 2004, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by January 8, 2004.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Medicaid Program Budget Report; *Form No.:* CMS–37, OMB # 0938–0101; *Use:* The Medicaid Program Budget Report is prepared by the State Medicaid Agencies and is used by CMS for (1) developing National Medicaid Budget estimates, (2) qualification of Budget Assumptions, (3) the issuance of quarterly Medicaid Grant Awards, and (4) collection of projected State receipts of donations and taxes; *Frequency:* Quarterly; *Affected Public:* State, local, and/or tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 8,064.

We have submitted a copy of this notice to OMB for its review of these information collections. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Jburke3@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–4194.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by January 8, 2004:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Julie Brown, CMS–37, Room C5–16–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167, Attn: Brenda Aguilar, CMS Desk Officer (CMS–37).

Dated: December 29, 2003.

John P. Burke III,

CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–382 Filed 1–5–04; 3:11 pm]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0424]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by February 6, 2004.

ADDRESSES: The Office of Management and Budget is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514 (OMB Control Number 0910–0356)—Extension

Congress enacted the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) on October 9, 1996. As directed by ADAA, FDA published a regulation under § 514.4(a) (21 CFR 514.4(a)), to further define substantial evidence in a manner that encourages the submission of new animal drug applications (NADAs) and supplemental NADAs and encourages dose range labeling. Under ADAA, substantial evidence is the standard that a sponsor must meet to demonstrate the effectiveness of a new animal drug for its intended use under the conditions suggested in its proposed labeling. Section 514.4(a) gives FDA greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective. FDA believes this regulation will reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs, will eliminate the need for an adequate and well-controlled dose titration study, and may, in limited instances, reduce or eliminate the number of adequate and well-controlled field investigations necessary to demonstrate by substantial evidence the effectiveness of a new animal drug. Table 1 of this document represents the estimated burden of meeting the substantial evidence standard.

In the **Federal Register** of September 19, 2003 (68 FR 54905), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.4(a)	190	4.5	860	632.6	544,036

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–256 Filed 1–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0565]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Food and Drug Administration Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of rapid response surveys to obtain data on safety information to support quick-turnaround decision making about potential safety problems or risk management solutions from health care professionals, hospitals and other user-facilities (e.g., nursing homes, etc.), consumers, manufacturers of biologics, drugs and medical devices, distributors, and importers when FDA must quickly determine whether or not a problem with a biologic, drug, or medical device impacts the public health.

DATES: Submit written or electronic comments on the collection of information by March 8, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the