

Ritchie County, Harrisville, West Virginia, The Dime Bank, Marietta, Ohio, Union Bank Of Tyler County, Middlebourne, West Virginia, The Community Bank, Pennsboro, West Virginia, and Gateway Bancshares, Inc., McMechen, West Virginia, and thereby indirectly acquire The Bank of McMechen, McMechen, West Virginia.

In connection with this application, Applicant also has applied to acquire Commbanc Investment, Inc., Marietta, Ohio, and Hometown Finance Co., Inc., Parkersburg, West Virginia, and thereby engage in securities brokerage activities pursuant to § 225.28(b)(7)(i) of the Board's Regulation Y, in financial and advisory activities pursuant to § 225.28(b)(6) of the Board's Regulation Y; extending credit and servicing loans pursuant to § 225.28(b)(1) of the Board's Regulation Y; and acting as agent for the sale of death and disability insurance directly related to its consumer lending activities pursuant to § 225.28(b)(11)(ii) of the Board's Regulation Y.

B. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. *Regions Financial Corporation*, Birmingham, Alabama; to merge with Key Florida Bancorp, Inc., Bradenton, Florida, and thereby indirectly acquire Liberty National Bank, Bradenton, Florida.

C. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. *Community Bank Shares of Indiana, Inc.*, New Albany, Indiana; to acquire 100 percent of the voting shares of NCF Financial Corporation, Bardstown, Kentucky, and thereby indirectly acquire NCF Bank & Trust Company, Bardstown, Kentucky.

2. *Union Planters Corporation*, Memphis, Tennessee; to acquire 100 percent of the voting shares of Security Bancshares, Inc., Des Arc, Arkansas, and thereby indirectly acquire Farmers & Merchants Bank, Des Arc, Arkansas, and Merchants & Farmers Bank, West Helena, Arkansas.

D. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 90 Hennepin Avenue, P.O. Box 291, Minneapolis, Minnesota 55480-0291:

1. *Forstrom Bancorporation, Inc.*, Clara City, Minnesota; to merge with First Valley Bankcorp, Seeley Lake, Montana, and thereby indirectly acquire First Valley Bank, Seeley Lake, Montana.

Board of Governors of the Federal Reserve System, January 9, 1998.

Jennifer J. Johnson,
Deputy Secretary of the Board.

[FR Doc. 98-1001 Filed 1-14-98; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

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 § 225.28 of Regulation Y (12 CFR 225.28) 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. The notice also will 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.

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 January 29, 1998.

A. Federal Reserve Bank of San Francisco (Maria Villanueva, Manager of Analytical Support, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. *Banque Nationale de Paris*, Paris, France; to engage *de novo* through its subsidiary BNP Securities (U.S.A.), Inc., Radnor, Pennsylvania, in buying and selling in the secondary market all types of securities on the order of customers as a "riskless principal" to the extent of engaging in a transaction in which the company, after receiving an order to buy (or sell) a security from a customer, purchases (or sells) the security for its own account to offset a contemporaneous sale to (or purchase from) the customer, pursuant to § 225.28(b)(7)(ii) of the Board's Regulation Y. The proposed activities will be conducted worldwide.

Board of Governors of the Federal Reserve System, January 9, 1998.

Jennifer J. Johnson,
Deputy Secretary of the Board.

[FR Doc. 98-1002 Filed 1-14-98; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Commission on Consumer Protection and Quality in the Health Care Industry; Notice of Public Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given of the meeting of the Advisory Commission on Consumer Protection and Quality in the Health Care Industry. This two-day meeting will be open to the public, limited only by the space available.

Place of meeting: William Natcher Conference Center, National Institutes of Health (Building 45), 45 Center Drive; Bethesda, MD, 20892. Exact locations of the sessions will be available at the conference center (lower level) and on the Commission's web site, "www.hcqualitycommission.gov".

Times and Dates: The public meeting will span two days. On Tuesday, January 27, 1998, the subcommittee break-out sessions will take place from 8:00 a.m. until 4:30 p.m. On Wednesday, January 28, 1998, the general plenary session will begin at 8:00 a.m. and it will continue until 4:00 p.m.

Purpose/Agenda: To hear testimony and continue formal proceedings of the Commission's three (3) remaining subcommittees (Subcommittee on Consumer Rights has completed its work). Agenda items are subject to change as priorities dictate.

Contact Person: For more information, including substantive program information and summaries of the meeting, please contact: Edward (Chip) Malin, Hubert Humphrey Building, Room 118F, 200 Independence Avenues, S.W., Washington, DC 20201; [202/205-3333].

Dated: January 8, 1998.

Janet Corrigan,

Executive Director, Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

[FR Doc. 98-962 Filed 1-14-98; 8:45 am]

BILLING CODE 4110-60-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-07-98]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of

information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Projects

1. The Tri-State Mining District: Lead Exposure and Immunotoxic Effects Study in the Tri-State District—New—The proposed study evaluates associations between immune system dysfunction/damage and exposure to

lead among children in the Tri-State Mining District. This district encompasses several contaminated areas including three Superfund sites: The Oronogo-Duenweg Mining Belt site in Jasper County, Missouri; the Cherokee County Site in Kansas; and the Tar Creek, Ottawa County Site in Oklahoma.

The proposed study consists of two repeated in-person interviews and biological testing for blood lead and immune function among participants of the ongoing lead screening programs in the Tri-State Mining district. Approximately 50 children identified as having blood lead >10 micrograms per deciliter and 50 children with blood lead levels <5 micrograms per deciliter will constitute the study and comparison groups respectively. Blood specimens will be obtained to measure

lead, complete blood count, EP, ZPP, antibody titers, and the CDC/ATSDR recommended immune panel. A second blood drawn a month later will examine intra-personal immune tests stability and will help evaluate the relationship between immune results and recent illness. Parents will be interviewed using a children's health questionnaire that solicits information on demographics, the medical history of each child and the occurrences of recent illness. Statistical analyses will compare health outcome measures (symptoms, illness, change in immune parameters) to blood lead levels. Other than their time, there will be no cost to the respondents. The length of clearance requested is for 1 year. Total annual burden hours are 125.

Form name	Number of respondents	Number of responses/respondent	Average burden/response (in hrs)	Total burden (in hrs.)
Verification	500	1	0.5	25
Pediatric Immune Questionnaire	100	2	0.05	100

2. National Childhood Blood Lead Surveillance System—(0920-0337)—Reinstatement—Lead poisoning is a common and societally devastating environmental disease of young children in the United States. In response to the call for a national surveillance program of lead levels made in the HHS publication, *Strategic Plan for the Elimination of Childhood Lead Poisoning* (February 1991), CDC established the National Childhood Blood Lead Surveillance System. In

FY92, CDC awarded funds to eight states to assist them in developing a complete childhood lead surveillance activity. In FY96, CDC provided funding for childhood blood lead surveillance activity in 31 states and the District of Columbia. Sixteen of these states submitted 1995 (calendar year) data to the national database. Information from this national surveillance system may be used by Federal and state agencies to (1) more accurately estimate the number of children with elevated lead levels; (2)

monitor short-term trends; (3) identify clusters of cases; (4) determine geographic distribution of cases; (5) examine risk factors among children with elevated lead levels; (6) identify risk factors for elevated lead levels among specific population groups; (7) target intervention programs to groups at risk for elevated lead levels; and (8) track national progress in eliminating childhood lead poisoning. Total annual burden hours are 456.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
State Health Departments:				
(a) Annual Report	20	1	10	200
(b) Quarterly Report	32	4	2	256

3. Risk And Protective Factors of Intimate Partner Violence Survey—New—The purpose of the project is to identify early warning signs and protective factors in intimate violence prevention by conducting a random-digit-dial national survey. Findings from a preliminary focus group study reveal that: (1) There may exist a pattern of early warning signs that women can use to avoid intimate partner violence, (2) certain individual and societal characteristics (which we call risk and protective factors), such as family history of abuse or the support of friends or institutions, may increase or

reduce the risk of violence in women's lives, (3) these risk and protective factors may influence women's ability to detect early warning signs for physical violence perpetrated by an intimate partner, and (4) there may be differences between African-American, Caucasian, and Hispanic women regarding helping relationships and services utilized by abused women.

The survey will include a stratification methodology to include six specific categories of women across the United States who are over 18 years of age. The six categories of women are African-American, Caucasian, and

Hispanic women who: (1) Have never been in a violent relationship, (2) are currently in a violent relationship, and (3) have previously been in a violent relationship, but have been living free of violence for at least one year. The survey will gather data from approximately 1,800 women using an interview protocol which was developed and pilot tested in conjunction with the focus group study and has been refined by experts and CDC program staff. Total annual burden hours are 630.

Respondents	Number of respondents	Number of responses/respondent	Average burden/ response (in hrs.)	Total burden (in hrs.)
Never Abused in a Relationship:			12 min.	
—African Am.	300	1	.2	60
—Caucasian	300	1	.2	60
—Hispanic	300	1	.2	60
Currently in Abusive Relationship:			15 min.	
—African Am.	300	1	.25	75
—Caucasian	300	1	.25	75
—Hispanic	300	1	.25	75
Formerly in Abusive Relationship:			15 min.	
—African Am.	300	1	.25	75
—Caucasian	300	1	.25	75
—Hispanic	300	1	.25	75

Dated: January 9, 1998.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-1016 Filed 1-14-98; 8:45 am]

BILLING CODE 4163-18-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D-0236]

International Conference on Harmonisation; Guidance on Data Elements for Transmission of Individual Case Safety Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled "E2B Data Elements for Transmission of Individual Case Safety Reports." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is intended to facilitate the standardization of the data elements for the transmission of individual case safety reports for both preapproval and postapproval reporting periods.

DATES: Effective January 15, 1998. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Copies of the guidance are

available from the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), or by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Copies may be obtained from CBER's FAX Information System at 1-888-CBER-FAX or 301-827-3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Marcel E. Salive, Center for Biologics Evaluation and Research (HFM-220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3974.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry

representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of October 1, 1996 (61 FR 51287), FDA published a draft tripartite guideline entitled "Data Elements for Transmission of Individual Case Safety Reports" (E2B). The notice gave interested persons an opportunity to submit comments by December 30, 1996.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on July 17, 1997.

In accordance with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997), this document has