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. 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 February 7, 1997.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Community Bancorp of Louisiana, Inc., Raceland, Louisiana; to merge with American Security Bancshares, Inc., Welsh, Louisiana, and thereby indirectly acquire American Bank, Welsh, Louisiana.

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

1. Damen Financial Corporation, Schaumburg, Illinois; to become a bank holding by acquiring 100 percent of the voting shares of Damen National Bank, Schaumburg, Illinois (in organization).

Board of Governors of the Federal Reserve System, January 7, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–692 Filed 1–10–97; 8:45 am]

BILLING CODE 6210–01–F

GENERAL SERVICES ADMINISTRATION

Information Security Oversight Office; Cancellation of Optional Form

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: Because of low usage the following Optional Form is cancelled: OF 95, Opened/Locked Sign for Restricted Files.

DATES: Effective January 13, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

Dated: December 23, 1996.

Steven Garfinkel,

Director, Information Security Oversight Office.

[FR Doc. 97–713 Filed 1–10–97; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0300]

Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software.'' The guidance document applies to blood establishment software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture. The guidance presents an overview of the type of information, including methods and procedures, that FDA's reviewers should expect to be included in 510(k) submissions for such devices and describes the approach FDA's reviewers should take in reviewing premarket submissions for blood establishment computer software.

DATES: Written comments may be submitted at any time, however, to ensure comments are considered for the next revision they should be submitted by April 14, 1997.

ADDRESSES: Submit written comments and information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written requests for single copies of the guidance entitled ''Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests.

The document may also be obtained by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or FAX at 1–800–CBER–FAX, or 301–827–3844.

Persons with access to the INTERNET may obtain the document using the World Wide Web (WWW), or bounce-back e-mail. For WWW access, connect to CBER at ''http.fda.gov/cber/cberftp.html''. To receive the document by bounce-back e-mail, send a message to ''SWREVIEW@al.cber.fda.gov''.

FOR FURTHER INFORMATION CONTACT: Nancy J. Jensen, Office of Blood Research and Review/Division of Blood Applications, Center for Biologics Evaluation and Research (HFM–385), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3524.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a

''Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software.'' A premarket notification (510(k)) is an application submitted to FDA under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)), to demonstrate that the medical device to be marketed is substantially equivalent to a legally marketed device that was or is currently on the U.S. market.

In a March 31, 1994, letter sent to manufacturers of blood establishment computer software, FDA stated that software products used in the manufacture or maintenance of data for blood and blood components are devices under section 201(h) of the act (21 U.S.C. 321(h)) because these products aid in the prevention of disease by identifying unsuitable donors and by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing use. The original date for submissions was March 31, 1995, but after careful evaluation of the needs expressed by the software manufacturers and the impact of the initiative on blood establishments, FDA concluded that a 1-year extension to March 31, 1996, was warranted. FDA notified known manufacturers of blood establishment computer software of the extension, by letter, the text of which was published in the Federal Register of October 3, 1995 (60 FR 51802). The reviewer guidance was presented and discussed at the Blood Products Advisory Committee meeting held on June 20, 1996.

The content and format required for a 510(k) submission may be found in 21 CFR part 807. FDA intends that the guidance document will be used as a supplement to the ''Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review,'' issued by the Center for Devices and Radiological Health on August 29, 1991. The reviewer guidance announced in this notice contains a description of the content and format that a reviewer should expect in a 510(k) submission for blood establishment computer software.

As with other guidance documents, FDA does not intend this document to be all-inclusive. Moreover, not all information may be applicable to all situations. The reviewer guidance document is intended to provide information and does not set forth requirements. Although this guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, it does represent the agency's current thinking on the review of premarket notification submissions for blood establishment computer software.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the reviewer guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and information are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA anticipates revising the reviewer guidance document periodically, in response to comments received or to reflect advancements in blood establishment computer software.

Dated: December 31, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–715 Filed 1–10–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–882–N]

Notification Procedures for States Implementing ''Alternative Mechanisms'' in the Individual Health Insurance Market

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice generally describes the statutory provisions under section 111 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that guarantee availability of individual health insurance coverage to certain individuals with prior group coverage. It also provides procedural guidance for States that intend to implement an alternative mechanism under section 111 of HIPAA. Finally, this notice describes the statutory provisions that will apply in a State that does not implement an acceptable alternative mechanism.

This notice does not establish new policy or requirements.

FOR FURTHER INFORMATION CONTACT: Gertrude Saunders of the Insurance Reform Implementation Task Force (IRITF), (410) 786–5888 or e-mail (iritf@hcfa.gov).

ADDRESSES: All correspondence regarding this notice should be submitted to the following address: HCFA, Bureau of Policy Development, Office of Chronic Care and Insurance Policy, Insurance Reform Implementation Task Force, S–LL–17, Attention: Marc Thomas, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

SUPPLEMENTARY INFORMATION:

I. Background—Summary of Recent Legislation

The Health Insurance Portability and Accountability Act of 1996 (HIPAA, Pub. L. 104–191) was enacted on August 21, 1996. HIPAA amended the Public Health Service (PHS) Act to provide for, among other things, improved access, portability, and renewability of health insurance in both the group and individual health insurance markets. Group health plans are regulated, in part, by the Federal government under the Employee Retirement Income Security Act of 1974 (ERISA) and the Internal Revenue Code and, to the extent they purchase insurance, in part, by the States under State insurance law. Policies sold in the individual health insurance market are regulated by the States. This notice pertains to only the individual market changes made by section 111 of HIPAA.

Section 2741 of the PHS Act, as added by section 111 of HIPAA, essentially gives a State two options to ensure that ''eligible individuals'' have access to the individual health insurance market. Under the first option, assuming there is appropriate authority in State law, the State may simply enforce the Federal statutory provisions that require all issuers who offer coverage in the individual market to make all their individual policies available to all eligible individuals on a guaranteed basis, without preexisting condition exclusions. (These provisions are commonly referred to as the ''Federal default'' provisions.) If the State chooses this option, individual issuers may elect to impose certain limitations on the policies that they are required to offer under the Federal default provisions. (For additional information on these limitations see section VIII of this notice.)

Under the second option, States may choose to implement an ''alternative mechanism'' to ensure that eligible individuals have access to the individual health insurance market or comparable coverage. States that choose this option must submit to us a timely notice with sufficient documentation to enable us to determine whether it is an acceptable alternative mechanism. (This process is discussed in more detail under section VI of this notice, which includes the address for written submissions.)