Board of Governors of the Federal Reserve System, July 28, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–19814 Filed 8–2–99; 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, including the companies listed below, 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 August 26, 1999.

A. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. Central Illinois Bancorp, Inc., Sidney, Illinois; to establish a *de novo* subsidiary, Marine Bank, Omaha, Nebraska (in organization), and thereby engage in operating a savings association, pursuant to § 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, July 28, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–19815 Filed 8–2–99; 8:45 am]

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FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, August 9, 1999.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: July 30, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–20014 Filed 7–30–99; 2:45 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2250]

Agency Information Collection Activities: Proposed Collection; Comment Request; Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection

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 collection 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 information collection provisions relating to the regulation of FDA's current good manufacturing practices for blood and blood components; notification of consignees receiving blood and blood components at increased risk for transmitting human immunodeficiency virus (HIV) infection.

DATES: Submit written comments on the collection of information by October 4, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the

burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection—21 CFR 606.100, 606.160, 610.46, and 610.47 (OMB Control Number 0910–0336)—Extension

Under the biologics licensing and quarantine provisions of the Public Health Service Act (42 U.S.C. 262–264) and the general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351–353, 355–360, and 371–374), FDA has the authority to issue regulations designed to protect the public from unsafe or ineffective biological products and to issue regulations necessary to prevent the introduction, transmission, or spread of communicable diseases.

FDA has implemented an extensive system of donor screening and testing procedures performed by blood establishments before, during, and after donation, to help prevent the transfusion of blood products that are at increased risk for transmitting HIV. HIV is the virus that causes acquired immune deficiency syndrome (AIDS), a communicable disease that can be transmitted through transfusion. Despite the best practices of blood establishments, however, a person may donate blood early in infection, during the period when the antibody to HIV is not detectable by a screening test, but HIV is present in the donor's blood (a so-called ''window'' period). If the donor attempts to donate blood at a later date, the test for antibody to HIV may, at that time, be repeatedly reactive. Therefore, FDA believes such circumstances require clarification of the donor's status through testing with a more specific antibody test and procedures to ''lookback'' at prior collections.

FDA issued regulations that require blood establishments to follow written standard operating procedures (SOP's) when the blood establishments have collected Whole Blood, blood components, Source Plasma, and Source Leukocytes later determined to be at increased risk for transmitting HIV. When a donor who previously donated blood is tested on a later donation, and tests repeatedly reactive for antibody to HIV, the regulations require blood establishments to perform more specific testing using a licensed test, and notify consignees who received Whole Blood, blood components, Source Plasma, and Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees are required to quarantine previously collection Whole Blood, blood components, Source Plasma, and Source Leukocytes from such donors, and if appropriate, notify transfusion recipients. Upon completion of more specific testing, hospital transfusion services that do not participate in Medicare, and are therefore not subject to Health Care Financing Administration's (HCFA's) regulations, are required to take steps to notify transfusion recipients, as appropriate. These regulations are intended to help ensure the continued safety of the blood supply by providing necessary information is provided to users of blood and blood components and appropriate notification of recipients of transfusion at increased risk for transmitting HIV infection.

Section 606.100(b)(19) (21 CFR 606.100(b)(19)) requires written SOP's for the following procedures: (1) Review prior donations of blood and blood products from donors with no previous history of antibody to HIV who subsequently test repeatedly reactive for the antibody to HIV; (2) quarantine in-house blood and blood products; (3) notify consignees regarding the need to quarantine such products; (4) determine the suitability for release of such products from quarantine; (5) notify consignees of such products with antibody testing results from ''lookback'' donors; and (6) notify attending physicians so that transfusion recipients are informed that they may have received blood and blood components at increased risk for transmitting HIV. Section 606.160(b)(1)(vii) (21 CFR 606.160(b)(1)(vii)) requires records to relate the donor with the unit number of each previous donation from that donor. Section 606.160(b)(1)(viii) requires records of quarantine, notification, testing, and disposition performed under §§ 610.46 and 610.47 (21 CFR 610.46 and 610.47). Section 610.46(a) requires blood establishments to notify consignees, within 72 hours, of repeatedly reactive tests results so that previously collected blood and blood components are appropriately quarantined. Section 610.46(b) requires blood establishments to notify consignees of licensed, more specific test results for HIV within 30 calendar days after the donors's repeatedly reactive test. Section 610.47(b) requires transfusion services not subject to HCFA regulations to notify physicians of prior donation recipients or to notify recipients themselves of the need for HIV testing and counseling.

There are approximately 3,076 registered blood establishments that annually collect an estimated 24,000,000 units of Whole Blood and Source Plasma, and that are required to follow FDA ''lookback'' procedures. Of these establishments, approximately 180 are registered transfusion services that are not subject to HCFA's ''lookback'' regulations.

The following reporting and recordkeeping estimates are based on information provided by industry, and FDA experience. In Table 1, it is estimated that an average of 60 repeat donors per establishment will test repeatedly reactive annually. This estimate results in a total number of 184,560 notifications of these test results to consignees by blood establishments for the purpose of quarantine of affected products, and another 184,560 notifications to consignees of subsequent test results. It is estimated that transfusion services not subject to HCFA regulations will need to notify physicians, or in some cases recipients, an average of 16 times per year resulting in a total number of 2,880 notifications. FDA estimates an average of 10 minutes per notification of consignees, physicians, and recipients. The estimate of one-half hour for § 610.47(b) is based on the minimum requirement of three attempts to notify recipients by transfusion services. In Table 2, the estimate of 154 recordkeepers and 160 records is based on the estimate that the requirement is already implemented voluntarily by more than 95 percent of the facilities, which collect 98 percent of the Nation's blood supply. FDA estimates that it takes approximately 5 minutes to document and maintain the records to relate the donor with the unit number of each previous donation. The establishment of SOP's under § 606.100(b)(19) is a one-time burden. The maintenance of the SOP's is considered usual and customary business practice, therefore no burden is calculated for the preparation and updating of the SOP.

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
610.46(a)	3,076	60	184,560	0.17	31,375
610.46(b)	3,076	60	184,560	0.17	31,375
610.47(b)	180	16	2,880	0.5	1,440
Total					64,190

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.160(b)(1)(vii)	154	160	24,640	12.8	1,971
606.160(b)(1)(viii)	3,076	60	184,560	4.8	14,765
Total					16,736

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

Dated: July 27, 1999

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–19794 Filed 8–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1387]

Agency Information Collection Activities; Announcement of OMB Approval; Survey of Licensed Biologics Manufacturers and Registered Blood Establishments for Year 2000 Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Survey of Licensed Biologics Manufacturers and Registered Blood Establishments for Year 2000 Compliance'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 25, 1999 (64 FR 28203), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0408. The approval expires on November 30, 1999. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: July 27, 1999

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–19792 Filed 8–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0670]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Labeling Requirements for Color Additives (Other Than Hair Dyes) Petitions; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 8, 1999 (64 FR 36885). The document announced that the proposed collection of information had been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The document published with an inadvertent error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 99–17242, appearing on page 36885, in the **Federal Register** of Thursday, July 8, 1999, the following correction is made:

In the third column, in the next to the last line of the document ''$14,200 (2 x $2,600 + x $3,000 listing fees = $14,200).'' is corrected to read ''$14,200 (2 x $2,600 + 3 x $3,000 listing fees = $14,200).''

Dated: July 28, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–19793 Filed 8–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0811]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.