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Board of Governors of the Federal
Reserve System, June 1, 1998.

Jennifer J. Johnson,
Secretary of the Board.

[FR Doc. 98-14955 Filed 6-4-98; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Notice of Meeting of Consumer Advisory Council

The Consumer Advisory Council will
meet on Thursday, June 25. The

meeting, which will be open to public
observation, will take place at the
Federal Reserve Board's offices in
Washington, D.C., in Dining Room E of
the Martin Building (Terrace level). The
meeting will begin at 9:00 a.m. and is
expected to continue until 4:00 p.m.,
with a lunch break between
approximately 1:00 and 2:00 p.m. The
Martin Building is located on C Street,
Northwest, between 20th and 21st
Streets.

The Council's function is to advise
the Board on the exercise of the Board's
responsibilities under the Consumer
Credit Protection Act and on other
matters on which the Board seeks its
advice. Time permitting, the Council
will discuss the following topics:

*Possible Revisions to Regulation B
(Equal Credit Opportunity) and
Regulation C (Home Mortgage
Disclosure).* The Bank Regulations
Committee and Community Affairs and
Housing Committee will lead a joint
discussion about members'
recommendations for revising
Regulations B and C, in connection with
the Board's review of the regulations
under its Regulatory Improvement
Program.

CRA Assessment Area Issues. The
Bank Regulations Committee will lead a
discussion of issues related to the
implementation of the Community
Reinvestment Act, focusing in particular
on the delivery of banking products and
CRA regulations' treatment of the
"assessment area"—the primary
geographic area in which an
institution's record is evaluated.

TLA/RESPA Proposals. The
Consumer Credit Committee will lead a
discussion on legislative proposals to
simplify, consolidate, and streamline
the provisions of the Boards Regulation
Z (Truth in Lending) and HUD's
Regulation X (Real Estate Settlement
Procedures) affecting the mortgage
lending process.

Electronic Communication. The
Depository and Delivery Systems
Committee and the Consumer Credit
Committee will jointly lead a discussion
of members' recommendations
regarding Board proposals to permit
electronic delivery of notices and
disclosures in substitution for paper
communications under regulations that
implement the Electronic Fund
Transfer, Truth in Lending, Consumer
Leasing, Truth in Savings, and Equal
Credit Opportunity statutes.

Governor's Report. Federal Reserve
Board Member Edward M. Gramlich
will report on economic conditions,
recent Board initiatives, and issues of
concern, with an opportunity for
questions from Council members.

Members Forum. Individual Council
members will present views on
economic conditions present within
their industries or local economies.

Reports. Council committees will
report on their work.

Other matters previously considered
by the Council or initiated by Council
members also may be discussed.

Persons wishing to submit views to
the Council regarding any of the above
topics may do so by sending written
statements to Deanna Aday-Keller,
Secretary, Consumer Advisory Council,
Division of Consumer and Community
Affairs, Board of Governors of the
Federal Reserve System, Washington,
D.C. 20551. Information about this
meeting may be obtained from Ms.
Aday-Keller, 202-452-6470.
Telecommunications Device for the Deaf
(TDD) users may contact Diane Jenkins,
202-452-3544.

Board of Governors of the Federal Reserve
System, June 1, 1998.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 98-14911 Filed 6-4-98; 8:45AM]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

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

TIME AND DATE: 10:00 a.m., Wednesday,
June 10, 1998.

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 matters 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.bog.frb.fed.us> for an electronic
announcement that not only lists
applications, but also indicates
procedural and other information about
the meeting.

Dated: June 3, 1998.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 98-15158 Filed 6-3-98; 2:12 pm]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0192]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 reinstatement 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 establishment license application (ELA) and product license application (PLA) forms by manufacturers of biological products.

DATES: Submit written comments on the collection of information by August 4, 1998.

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

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.

Establishment and Product License Applications: Forms FDA 2599, 2599a, 2600, 2600b, 3066, 3086, 3096, 3098, 3098a, 3098b, 3098c, 3098d, 3098e, 3210, 3213, 3214, and 3314—21 CFR 601.2 and 601.12—(OMB Control Number 0910-0124—Reinstatement)

FDA is the Federal agency charged with responsibility for determining that drugs and biological products are safe and effective. Manufacturers of biological products for human use must file an application for FDA approval of the product prior to introducing it into interstate commerce. The information provided by manufacturers on these license application forms is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that biologics for human use have been shown to be safe and effective. The uniform format of the forms provides for orderly, efficient review by the Center for Biologics Evaluation and Research (CBER) staff and expedites the licensing process as well as documenting for future reference the methods and procedures that have been approved for use at each manufacturing location. Statutory authority for the collection of this information is provided by section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262).

Section 601.2 (21 CFR 601.2) requires that manufacturers of biological

products regulated under the PHS act submit an ELA and a PLA, or a biologic license application (BLA) to CBER for review and approval prior to marketing a biological product in interstate commerce. Blood and blood components fall within the category of biological products. All establishments collecting and/or preparing blood and blood components for sale or distribution in interstate commerce are subject to the licensing application provisions of section 351 of the PHS Act. Section 601.12 (21 CFR 601.12) requires manufacturers of a biologic for human use to file supplemental applications for all important changes to applications previously approved prior to implementing such changes. In addition to §§ 601.2 and 601.12, other regulations provide additional standards for human blood and blood products, which require submission of certain information in a license application, including 21 CFR 640.17, 640.21(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), and 680.1(b)(2)(iii) and (c). The information collection requirements in the preceding regulations and their associated reporting burdens are provided under the burden estimated for §§ 601.2 and 601.12 and the application form in approved OMB control number 0910-0338.

As outlined in the President's November 1995 National Performance Review's document entitled "Reinventing the Regulation of Drugs Made From Biotechnology," FDA intends to use a single harmonized application form for all drug and licensed biological products. FDA revised Form FDA 356h, "Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use," for this purpose and announced its availability in the **Federal Register** of July 8, 1997 (62 FR 36558). This notice described FDA's intent to phase in the use of the new Form FDA 356h for all biological products and stated that applicants submitting new drug applications (NDA's), abbreviated new drug applications (ANDA's), abbreviated antibiotic drug applications (AADA's), and BLA's for biologic products specified in § 601.2(c) could begin to use the new Form FDA 356h immediately. The notice also advised such applicants that they will be required to use revised Form FDA 356h beginning January 8, 1998. In the interim period, the old Form FDA 356h and the new Form FDA 356h were to be acceptable alternatives for NDA's, ANDA's, AADA's, and BLA's.