

arrangements have a daily average dollar value larger than \$100,000, so the arrangements would not be considered to give rise to systemic risk.

Example #2

An ACH clearinghouse with more than 100 members, net settlement debits averaging less than \$500 million per day, and a netting factor of five would not be considered to raise significant credit, liquidity, or systemic risks. Such a system would likely not involve settlement guarantees or mutualization of losses, and without high netting factors or similar concerns, it would not be likely to lead to significant liquidity risks. Given the large number of participants, it is unlikely that participants would be able to resolve a settlement failure among themselves without prior coordinated procedures. The system would need to have reliable operational procedures to resolve a settlement failure in a timely manner on the settlement date, such as through a recast of settlements. The rules of the system would need to specify settlement failure procedures, including those for identifying and reversing non-settled entries under applicable rules.

Example #3

A foreign exchange clearinghouse that clears and settles contracts that average more than \$100,000 through a central counterparty arrangement would be required to address potential credit, liquidity, and legal risks, as well as systemic risks. Netting and novation of transactions, for example, would shift credit risk to the central counterparty. Legal risk could exist if the arrangements to implement the netting of underlying foreign exchange contracts could be invalidated or ineffective in the event of bankruptcy of the central counterparty. Given that the arrangement exceeds or plans to exceed the base criteria for potential systemic risk, and serves a key financial market, it would be required to implement robust risk controls and fully meet the Lamfalussy Minimum Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Meeting of the National Advisory Council for Health Care Policy, Research, and Evaluation

AGENCY: Agency for Health Care Policy and Research, HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the National Advisory Council for Health Care Policy, Research, and Evaluation.

DATES: The meeting will be held on Friday, November 21, 1997 from 9:00 a.m. to 4:00 p.m.

ADDRESSES: The meeting will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Nancy Foster, Coordinator of the Advisory Council at the Agency for Health Care Policy and Research, 2101 East Jefferson Street, Suite 502, Rockville, Maryland 20852, (301) 594-1349 ext. 1307.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Linda Reeves, Assistant Administrator for Equal Opportunity, AHCP, on (301) 594-6665 ext. 1055 no later than November 14, 1997.

SUPPLEMENTARY INFORMATION:

I. Purpose

Section 921 of the Public Health Service Act (42 U.S.C. 299c) establishes the National Advisory Council for Health Care Policy, Research, and Evaluation. The Council provides advice to the Secretary and the administrator, Agency for Health Care Policy and Research (AHCP), on matters related to AHCP activities to enhance the quality, appropriateness, and effectiveness of health care services and access to such services through scientific research and the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.

The Council is composed of members of the public appointed by the Secretary and Federal ex-officio members. The Council will be chaired by Harold S. Luft, Ph.D.

II. Agenda

On Friday, November 21, 1997, the meeting will begin at 9:00 a.m., with the call to order by the Council Chairman. The Administrator, AHCP, will update the status of current Agency programs and initiatives. The Council will then discuss strategic directions for the Agency, how the Agency can most productively advance outcomes research, and the U.S. Preventive Services Task Force.

The meeting will adjourn at 4:00 p.m. Agenda items are subject to change as priorities dictate.

Dated: November 3, 1997.

John M. Eisenberg,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0438]

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 Form FDA 3397, User Fee Cover Sheet that must be submitted along with certain drug and biologic product applications and supplements.

DATES: Submit written comments on the collection of information by January 12, 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