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, AHCPR, 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 (AHCPR), on matters related to AHCPR 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, AHCPR, 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.

[FR Doc. 97–29660 Filed 11–10–97; 8:45 am]
BILLING CODE 4160–90–M

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

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.

User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910–0297)—Reinstatement

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), FDA has the authority to assess and collect user fees for certain drug and biologic product applications and supplements. Under this authority, pharmaceutical companies pay a fee for each new drug application, biologic product license application, biologic license application, or supplement submitted for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. Form FDA 3397 is the user fee cover sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application with the actual application by utilizing a unique number tracking system. The information collected is used by FDA, Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, new biologic product license applications, and supplemental applications.

Respondents to this collection of information are drug and biologic product applicants.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	200	9.44	1,888	.15	283

There are no capital costs or operating and maintenance costs associated with this collection.

Based on the agency's experience of 4 years, FDA estimates there are approximately 200 manufacturers of products subject to Prescription Drug User Fee Act. Of the 200 manufacturers, CDER estimates 141 are drug manufacturers and CBER estimates 59 are biologics manufacturers. CDER estimates 1,721 annual responses that include the following: 125 new drug applications, 1,098 chemistry supplements, 400 labeling supplements, and 98 efficacy supplements. CBER estimates 167 annual responses that include the following: 157 annual product supplements, and 10 original license applications.

Dated: November 3, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–29710 Filed 11-10-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0436]

Bottled Water Study: Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting public comment on what are feasible methods for providing people who purchase bottled water with information about the contents of that bottled water and on what information should be provided. FDA will consider the information that it receives in response to this notice in conducting a study of the feasibility of appropriate methods, if any, for informing customers about the contents of bottled water. FDA is required to conduct the feasibility study under the Safe Drinking Water Act Amendments of 1996 (SDWA Amendments).

DATES: Written comments by December 12, 1997.

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

FOR FURTHER INFORMATION CONTACT: Henry Kim, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–0631.

SUPPLEMENTARY INFORMATION:

I. Background

On August 6, 1996, Congress passed, and the President signed into law, the SDWA Amendments (Pub. L. 104–182). Under the SDWA Amendments' Public Notification (section 114) provisions designed to further public awareness about the quality of their drinking water, section 114(a) mandates that, not later than 24 months after the date of enactment of this law, the Environmental Protection Agency (EPA) issue regulations requiring community water systems to provide their customers with an annual report, referred to as a consumer confidence report (CCR), that contains information on the level of contaminants in drinking water purveyed by the systems.

Parallel to this requirement, section 114(b) of the SDWA Amendments requires that not later than 18 months after the date of its enactment, FDA in