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

consultation with EPA publish for notice and comment a draft study on the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water. A final study is to be published not later than 30 months after the date of enactment of the SDWA Amendments.

II. Procedure for the Feasibility Study

In carrying out the provisions of section 114(b) of the SDWA Amendments, FDA intends to: (1) Solicit through this notice information on appropriate methods, if any, that are feasible for conveying information about the contents of bottled water to customers; (2) evaluate the information received to tentatively identify the appropriate methods, if any, that are feasible for conveying information about the contents of bottled water to people who purchase that bottled water; (3) publish for notice and comment a draft feasibility study report in which the agency will present its tentative findings; and (4) consider the comments the agency receives on the draft feasibility study report and publish a final report on the feasibility of appropriate methods, if any, for providing information about the contents of bottled water to customers.

In this notice, FDA is soliciting information that it will use in conducting the feasibility study. FDA is requesting comments about: (1) The methods, if any, that may be appropriate, and why they are appropriate, for conveying information about the contents of bottled water to consumers; (2) whether any appropriate method is feasible as a means of providing information about the contents of bottled water to customers, and the supporting reasons for why the method is feasible; and (3) the type of information about the contents of bottled water that should be provided within the context of the SDWA Amendments.

FDA considers this solicitation of information through this **Federal Register** notice to be the most effective means of obtaining information from all segments of the general public (i.e., industries, trade associations, consumers, consumer advocacy groups, educational institutions) that are interested in the subject of feasibility of appropriate methods of providing information about the contents of bottled water to customers. FDA thus deems this approach to be the most appropriate means of obtaining sufficient and pertinent information from stakeholders for conducting the feasibility study as required by the SDWA Amendments.

III. Request for Information

A. Methods for Conveying Information to Customers

FDA requests comments on what methods, if any, are appropriate for conveying to customers information about the contents of bottled water. FDA also requests for any method identified that the comment state why that method is appropriate for communicating information about the contents of bottled water to people who purchase that product.

For example, for bottled waters that are sold at retail (e.g., grocery stores), comments may wish to address whether it would be appropriate to provide the information directly on the product's label or through an address or a toll-free telephone number on the product's label that customers can write to or call to obtain the information. In the latter instance, would it be appropriate for bottlers to operate a menu driven system for callers to directly access the information? Would it be appropriate for bottlers to take the name and address of the caller and mail the information in the form of a pamphlet, for example? Comments should provide the reasons why any method identified is appropriate.

Noting that the SDWA Amendments require community water systems to mail their annual CCR to customers, comments may wish to address whether it is appropriate for firms that deliver bottled water to customer's homes, office buildings, schools, and hospitals to mail the information to the customer along with the invoice that they normally provide. Why would providing the information in this manner be considered appropriate?

Recognizing the increasing prominence of the Internet as a source of public information, comments may wish to address whether it is appropriate for firms to provide information about bottled water to customers over the Internet. Again, why would this method be deemed appropriate?

FDA also requests comments about other methods that are appropriate for conveying information to customers about the contents of bottled water, and why they are appropriate.

B. Feasibility of Appropriate Methods

For each method identified as being appropriate for conveying information to customers about the contents of bottled water, FDA also requests information on whether the provision of information by such method is feasible, i.e., ''capable of being done or carried out'' (Webster's Third New International Dictionary, 1976). Thus persons who believe that an appropriate method is feasible for a stated purpose should state why the provision of information by that method can be done or carried out, i.e., is feasible. Likewise, interested persons who believe that an appropriate method is not feasible should state why the provision of information by that method cannot be done or carried out. Comments should address the costs to bottlers and all other relevant factors that support the position they take with respect to the feasibility of the method in question.

For example, those who comment on the possibility of providing information directly on a product's label should address the feasibility of doing so in light of the obvious concern about the limited label space available on a bottled water product. Is it feasible to provide the subject information directly on the label of a bottled water product notwithstanding the limited label space, or is the limited label space such a significant obstacle that use of a product's label would not be feasible?

Again, by way of example, comments that address providing the information on the Internet should address feasibility with respect to the cost of establishing and maintaining an Internet site, particularly for small firms.

C. Information on the Contents of Bottled Water

FDA requests comments on the type of information about the contents of bottled water that should be provided to convey to customers, to the extent possible, information analogous to that provided in a CCR. In this regard, FDA notes that a CCR must contain: (1) Information about the source of the drinking water purveyed by the system; (2) definitions for the terms ''maximum contaminant level goal'' (MCLG), ''maximum contaminant level'' (MCL), ''variances,'' and ''exemptions;'' (3) the MCLG, MCL, and the actual level found for contaminants detected in the water and, for any contaminants detected that violated the MCL during the year, information on the health effects that led EPA to regulate that contaminant; (4) information on compliance with EPA's National Primary Drinking Water Regulations, and notice if the system is operating under a variance or an exemption and the basis on which the variance or exemption was granted; (5) information on the levels of unregulated contaminants for which monitoring by the system is required (including levels of cryptosporidium and radon where States determine that they may be found); and (6) a statement that the presence of contaminants in drinking

water does not necessarily indicate that the drinking water poses a health risk, and that more information about contaminants and potential health effects can be obtained by calling the EPA hotline.

What type of information about the contents of bottled water could be provided that would be analogous to the previously described information required in a CCR? For example, because FDA establishes ''allowable levels'' and not MCL's for contaminants in bottled water, would providing information describing the term ''allowable level'' as established in FDA's quality standard regulation for bottled water be analogous to the provision of information about MCL's required in a CCR? Also, by way of an example, for information concerning MCLG's, variances, exemptions that are required in a CCR, are there similar or analogous types of information with respect to bottled water that could be provided to customers?

IV. Comments

Interested persons may, on or before December 12, 1997, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 3, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–29655 Filed 11-10-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; NLM Online Application Packet

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Library of Medicine (NLM), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 10, 1997, page number 37068, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: Title: NLM Online Application Packet. Type of Information Collection Request: Extension of OMB No. 0925–0223. Expires 11/30/97. Need and Use of Information Collection: The NLM uses the information provided by individuals and institutions for MEDLARS online system user code assignments and invoices for system use. Frequency of Response: On occasion. Affected Public: Individuals or households; businesses or other for profit; State or local governments; Federal agencies; Non-profit institutions; Small businesses or organizations. Type of Respondents: Organizations, Health Care Providers, Students. The annual reporting burden is as follows: Estimated Number of Respondents annually: 2,640. Estimated Number of Responses per Respondent: 1; Average Burden Hours Per Response: 0.0833 hours; and Estimated Total Annual Burden Hours Requested: 219. The annualized cost to respondents is estimated at: $11,383. There are no capital costs to report. There are no operating or maintenance costs to report.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the items(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Carolyn Tilley, Head, Medlars Management Section, BSD, LO, NLM, NIH, Building 38A, Room 4N–04, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number (301) 402–1076 or E-mail your request, including your address to: carolyn__tilley@ccmail.nlm.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before December 12, 1997.

Dated: November 3, 1997.

Donald C. Poppke,

Executive Officer, NLM.

[FR Doc. 97–29669 Filed 11–10–97; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to Section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the President's Cancer Panel.

This meeting will be open to the public as indicated below, with attendance by the public limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretatin or other reasonable accommodations, should notify Linda Quick-Cameron, Committee Management Officer, National Cancer Institute, Executive Plaza North, Room 609, 6130 Executive Blvd., MSC 7410, Bethesda, MD 20892–7410 (301/496–5708). A summary of the meeting and the roster of committee members will be provided upon request. Other information pertaining to the meeting may be obtained from the contact person indicated below.

Committee Name: President's Cancer Panel.

Date: November 21, 1997.

Place: Moffitt Cancer Center, Research Center (Across from Cancer Center), 12902 Magnolia Drive, Tampa, FL 33612.

Open: 8:00 a.m. to Adjournment.

Agenda: Concerns of special populations in the National Cancer Program: