Dated: August 18, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–21715 Filed 8–24–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Sanitation Inspections of Cruise Ships

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces fees for vessel sanitation inspections for fiscal year 2001: October 1, 2000, through September 30, 2001.

EFFECTIVE DATE: October 1, 2000.

FOR FURTHER INFORMATION CONTACT: David L. Forney, Chief, Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop F–16, Atlanta, GA 30341–3724, telephone (770) 488–7333, E-mail: Dforney@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose and Background

The fee schedule for sanitation inspections of passenger cruise ships currently inspected under the Vessel Sanitation Program (VSP) was first published in the **Federal Register** (52 FR 45019) on November 24, 1987, and CDC began collecting fees on March 1, 1988. Since then, CDC has published the fee schedule annually. This notice announces fees effective October 1, 2000.

The formula used to determine the fees is as follows:

$$\text{Average cost per inspection} = \frac{\text{Total Cost of VSP}}{\text{Weighted No. of Annual Inspections}}$$

The average cost per inspection is multiplied by a size/cost factor to determine the fee for vessels in each size category. The size/cost factor was established in the proposed fee schedule published in the **Federal Register** (52 FR 27060) on July 17, 1987, and revised in a schedule published in the **Federal Register** (54 FR 48942) on November 28, 1989. The revised size/cost factor is presented in Appendix A.

Fee

The fee schedule is presented in Appendix A and will be effective October 1, 2000, through September 30, 2001. This fee schedule represents a 7% increase over the current fee schedule which became effective October 1, 1997. The increase is primarily due to substantial increases in the cost of air transportation and personnel. If travel expenses continue to increase, it may be necessary to readjust the fees before September 30, 2001, since travel constitutes a sizable portion of the program's costs. If such a readjustment in the fee schedule is necessary, a notice will be published in the **Federal Register** 30 days before the effective date.

Applicability

The fees will be applicable to all passenger cruise vessels for which inspections are conducted as part of CDC's VSP.

Dated: August 21, 2000.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

APPENDIX A.—SIZE/COST FACTOR

Vessel size	GRT [1]	Average cost X
Extra Small	< 3,001	0.25
Small	3,001–15,000	0.50
Medium	15,001–30,000	1.00
Large	30,001–60,000	1.50
Extra Large	60,000	2.00

FEE SCHEDULE OCTOBER 1, 2000—SEPTEMBER 30, 2001

Vessel size	GRT [1]	Fee ($US)
Extra Small	< 3,001	1,150
Small	3,001–15,000	2,300
Medium	15,001–30,000	4,600
Large	30,001–60,000	6,900
Extra Large	60,000	9,200

[1] GRT-Gross Register Tonnage in cubic feet, as shown in Lloyd's Register of Shipping.

Inspections and re-inspections involve the same procedure, require the same amount of time, and are, therefore, charged at the same rate.

[FR Doc. 00–21718 Filed 8–24–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0436]

Food and Drug Administration Final Study Report; Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its final study report on the feasibility of appropriate methods of informing customers of the contents of bottled water, as required by the Safe Drinking Water Act (SDWA) Amendments. This final feasibility study report evaluates and identifies appropriate methods that may be feasible for conveying information about bottled water to customers.

FOR FURTHER INFORMATION CONTACT: Rebecca J. Buckner, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4081.

SUPPLEMENTARY INFORMATION:

I. Background

On August 6, 1996, the President signed into law the SDWA Amendments (Public Law 104–182). Under the Public Notification section of the SDWA Amendments (section 114), the

Environmental Protection Agency (EPA) was required to issue regulations mandating that each community water system mail to each customer of the system an annual report, referred to as a consumer confidence report (CCR), on the level of contaminants in the drinking water purveyed by that system. A complete description of the information contained in a CCR can be found in section II.A of this document.

In the **Federal Register** of February 13, 1998 (63 FR 7606), EPA published a proposed rule to require local water systems to provide an annual CCR to their customers. Based on that proposal, EPA published a final rule on August 19, 1998 (63 FR 44511). Section 114(b) of the SDWA Amendments required that, no more 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. Section 114(b) of the SDWA Amendments also required us to publish a final study not later than 30 months after enactment of the SDWA Amendments.

In the **Federal Register** of November 12, 1997 (62 FR 60721) (hereinafter referred to as the 1997 notice), we published a notice requesting comment on several matters relevant to the feasibility of appropriate methods of informing customers of the contents of bottled water. In the **Federal Register** of February 22, 2000 (65 FR 8718), we published a draft feasibility study report (the draft study). In the draft study we evaluated the information received and identified appropriate methods that may be feasible for conveying information about bottled water to customers. In the draft study, we stated that comments received on the draft study would be evaluated and considered in preparation of the final report. Interested persons were given until April 24, 2000, to comment on the draft study. We received over 250 letters, each containing one or more comments, from government agencies, States, consumer groups, and members of the public in response to the draft study. We have evaluated those comments in preparing this final feasibility study report.

II. Response to Comments

A. Congressional Mandate for Us Under Section 114(b) of the SDWA Amendments

(Comment 1) Several comments maintained that Congress, because of the mandate to us to publish a study on the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water, intended for us to engage in rulemaking on feasible methods, if found.

We disagree with these comments. The plain language in section 114(b) of the SDWA Amendments states that we ''shall publish for public notice and comment a draft study'' and ''shall publish a final study * * *.'' Thus, our charge under the SDWA Amendments is to publish a draft and final study on the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water. There is no language in section 114(b) of the SDWA Amendments requiring us to issue regulations. On the contrary, Congress did clearly express its intent in other sections of the SDWA Amendments where it wanted regulations to be issued. For example, section 114(a) of the SDWA Amendments on consumer confidence reports, states that EPA ''shall issue regulations * * *.'' No such similar intent was expressed in the plain language of the statute, under section 114(b). Therefore, section 114(b) of the SDWA Amendments does not require us to issue regulations; section 114(b) requires us to publish a draft and final feasibility study. Moreover, the Conference Report on the Safe Drinking Water Act Amendments of 1996 (H. Rept. 104–741, at 9701 (1996)) states, ''The study is intended to provide information on the feasibility of informing customers concerning the contents of bottled water, and is not intended to prejudge the question of whether such information requirements are necessary.'' The question about whether information requirements are necessary is outside the scope of this final feasibility study. We plan to consider, based on the findings in the final feasibility study, whether to engage in future rulemaking on information requirements on the contents of bottled water.

(Comment 2) A few comments stated that all of the information outlined by EPA for inclusion in a CCR should be placed on the label of bottled water because consumers have a right to know this information at point of purchase.

A discussion of an individual's right to know certain information on bottled water is beyond the scope of this study. The SDWA Amendments directed us to study the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water, not whether an individual has a right to know information on the contents of bottled water. To the extent that these comments assert that it is an appropriate and feasible method to include all CCR-type information on the label of bottled water, we respond to such assertion in comment 8 of this document.

(Comment 3) Several comments requested that more information on contaminants and their health effects than what is contained in a CCR be placed on the labels of bottled water. Conversely, other comments maintained that it is not necessary to provide any of the CCR-type information on bottled water to customers; the comments further stated that bottled water companies already do provide this information voluntarily to customers who request it. In addition, several comments requested that fluoride and sodium content be provided on labels of bottled water. These comments indicated that fluoride information is important so that customers and health professionals can determine if an individual's fluoride intake is appropriate and information on sodium is important for individuals on a low sodium diet.

A discussion about whether it is necessary to provide, to customers, more information than what is contained in a CCR or more than what is currently required on the contents of bottled water is beyond the scope of this study. The SDWA Amendments directed us to study the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water, not whether information is necessary. Please note that the sodium content of bottled water is already required to be declared on the label, consistent with 21 CFR 101.9(c)(4).

B. Information About the Contents of Bottled Water

We stated in the draft study that we believe that much of the information contained in a CCR is applicable to bottled water (65 FR 8718 at 8721). We note that a CCR, as outlined by EPA, contains the following: (1) Information about the source of drinking water; (2) definitions of ''maximum contaminant level'' (MCL), ''maximum contaminant level goal'' (MCLG), ''exemption'' and ''variance''; (3) the MCL, MCLG, and contaminant level detected in the water for regulated contaminants found in the water during the year and, for any contaminant detected that violates 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 operates 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, for example, levels of *Cryptosporidium* and radon where States determine such levels 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 risks can be obtained by calling the EPA hotline.

In the draft study, we stated that, while much of the information contained in a CCR is applicable to bottled water, we recognize that certain information contained in a CCR is relevant only to public drinking water systems. Such information includes the definition and statement of MCLG's and MCL's and information on public drinking water systems operating under a variance and other information that is relevant only to public drinking water systems regulated by EPA, such as information on EPA's drinking water hotline.

In the draft study, we noted that our intent in the 1997 notice was to solicit information that was analogous to that outlined by EPA for inclusion in a CCR (see above). Although we recognize that the SDWA Amendments provide for States to develop alternative requirements with respect to the form and content of a CCR, it was not our intent to solicit a broad range of information but rather to limit the discussion to information that is analogous to that outlined by EPA for inclusion in a CCR.

(Comment 4) Several comments stated that contaminants should be discussed in terms of MCLG's rather than allowable levels for contaminants in bottled water. These comments maintained that MCLG's are health-based goals for drinking water, unlike EPA's MCL's and FDA's allowable levels that are simply based on MCLG's and that are not health-based standards. Further, several comments advocated giving health effects information for all contaminants that exceed EPA's MCLG's.

In order to respond to this comment, it is important to note that EPA establishes MCLG's and MCL's for contaminants in public drinking water, while FDA establishes quality standards with allowable levels for contaminants and other constituents in bottled water.

To the extent that these comments suggest that it is an appropriate method to discuss contaminants in bottled water as MCLG's rather than as our allowable contaminant levels, we do not agree with these comments. EPA's MCLG's and MCL's are both health-based standards for contaminant levels. Our allowable levels for contaminants and other constituents in bottled water are established under a quality standard (21 CFR part 165.110), but are based on EPA's MCL's and, therefore, are also health-based standards.

We have already stated that, for the purposes of determining the feasibility of appropriate methods of informing customers of the contents of bottled water, we intended for the scope of the information discussed in this study to be analogous to that outlined by EPA for inclusion in a CCR. Public drinking water systems are required, in their CCR's, to provide information regarding the health concerns that resulted in regulation of a contaminant, when that contaminant exceeds a MCL, not a MCLG. The risks from a contaminant that exceeds a MCLG but not a MCL or an allowable level is negligible and, therefore, health effects information may not be appropriate. Because our allowable levels are based on EPA's MCL's, we believe that it would be an appropriate method to base any information regarding health concerns for contaminants in bottled water on our allowable levels. MCLG and MCL are terms defined by EPA for public drinking water and not for bottled water. Therefore, we disagree that it is an appropriate method to discuss contaminants in terms of MCLG's rather than allowable levels.

(Comment 5) Several comments requested that EPA's drinking water hotline be provided to customers or that we establish a bottled water hotline.

We do not believe that it would be appropriate to direct customers to EPA's drinking water hotline for information on bottled water because EPA's hotline only provides information on public drinking water. However, we agree that an information hotline for general information on bottled water would be analogous to CCR-type information available for drinking water. In fact, consumers who have questions about bottled water can contact us on our food information hotline, 1–888–SAFEFOOD (1–888–723–3366), and receive information on bottled water that is similar to the type of information on drinking water provided by EPA on its drinking water hotline.

(Comment 6) Several comments indicated that, in addition to the information contained in a CCR, bottled water information should include a mineral profile, hydrogen-ion concentration (pH) and hardness measurements, and information on the type of treatment the water has received so that immunocompromised individuals can determine whether the water has been treated by one of the methods recommended by the Centers for Disease Control and Prevention for the elimination of *Cryptosporidium*. *Cryptosporidium* is a parasite that has caused serious waterborne illness outbreaks, particularly among immunocompromised individuals, from the consumption of contaminated public drinking water. Comments also suggested that a ''date bottled'' statement, a lot code, an ''expiration date'' and a ''refrigerate after opening'' statement should be provided on the label.

In the draft study, we noted that our intent in the 1997 notice was to solicit information that was analogous to that outlined by EPA for inclusion in a CCR (see above). Although we recognize that the SDWA Amendments provide for States to develop alternative requirements with respect to the form and content of a CCR, it was not our intent to solicit a broad range of information but rather to limit the discussion to information that is analogous to that outlined by EPA for inclusion in a CCR. Therefore, consideration of information that is not within the context of the SDWA Amendments (i.e., analogous to information outlined by EPA for inclusion in a CCR) is beyond the scope of this study and would be considered in any future rulemaking on this subject, if undertaken by us.

C. Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

In the draft study, we evaluated the appropriateness and feasibility of six methods of informing customers of the contents of bottled water. These methods included information on the label, a phone number/address for company contact on the label, a combination of the two previous methods (some information on the label, some available through company contact), a pamphlet at point of purchase, an information package distributed with bulk water deliveries, and the Internet.

(Comment 7) Several comments stated that if it is feasible for public drinking water systems to provide their customers with content information on an annual basis, then it is feasible for bottled water manufacturers to provide their customers with content information on an annual basis, regardless of the method.

We agree that it is feasible for the bottled water industry to provide CCR-type information, updated on a yearly basis, to their customers, as public drinking water systems are required to

provide to their customers. However, certain methods may be more feasible than others for providing such annual updates. Moreover, we note that contaminant information about bottled water that is updated annually may not represent the contents of any one individual bottle of water but may represent the contaminant history for a specific time period.

1. Information on the Label

In the draft study, we stated that placing information on the label is an appropriate method to inform customers about the contents of bottled water. However, we questioned the feasibility of placing all of the information that is analogous to information contained in a CCR on the label of bottled water. We tentatively determined that the amount of information contained in a CCR, as outlined by EPA, is considerable and, if placed on a bottled water label, would result in label clutter.

We stated in the draft study that we also have concerns about the economic feasibility of placing information on a label that has the potential to change on a frequent basis as a result of ongoing monitoring that is required under 21 CFR part 129, ''Processing and Bottling of Bottled Drinking Water.'' Costs associated with labeling changes to accurately report information that changes on a regular basis could be an economic hardship to companies. In addition, frequently changing information may result in a product label that is no longer accurate, due to changing test results, which may misbrand the product under section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343). Therefore, we tentatively determined that it is not feasible to place on a bottled water label all of the information that would be analogous to that contained in a CCR.

(Comment 8) Comments that addressed the issue of whether it is feasible to place all of the bottled water information analogous to that contained in a CCR on a bottled water label, with the exception of the comments in comment 2 of this document, stated that it is not feasible to do so.

We agree with the comments that stated it is not feasible to provide all of the information that is analogous to that contained in a CCR on a bottled water label. Such information would be excessive in limited label space, particularly on the small, single serving bottles. In addition, information that requires frequent changes due to changing test results may result in a product label that is no longer accurate, which may result in a misbranded product. Costs of frequent label changes that are necessary to ensure accurate information on the contents of a bottled water product, due to frequently changing information, may present an economic hardship to companies. Moreover, even annual updates that represent the contaminant history would need information to put the history for all such CCR-type information in context for the customer and would be excessive in limited label space. We believe that other methods discussed below may be more feasible for informing customers about the CCR-type information on bottled water.

2. Information Available by Company Contact

In the draft study, we tentatively determined that a phone number or an address on the label directing customers on how to obtain information from the company is an appropriate and feasible method of providing information to customers. Telephones and mail are available to almost all customers. Information provided in this manner can also be kept current. It is the least costly method to industry of providing information to customers because it does not require frequent label changes. Moreover, the startup costs would only apply to a portion of the industry since many firms already provide information to customers in this manner.

(Comment 9) Most comments received on the draft study stated that making all or some of the CCR-type information on bottled water obtainable via a phone number or an address on the label with directions to customers on how to obtain information from the company is appropriate and feasible. Several comments maintained that the label should provide a toll-free number to call for information, while other comments stated that a toll-free number would be a financial burden for small bottled water manufacturers.

We agree with these comments that it is both appropriate and feasible for water bottlers to provide CCR-type information to customers through a phone number or an address on the label directing customers on how to obtain information from the company. Determining whether the company should provide a toll-free number versus a toll number or an address to customers is beyond the scope of this study.

The comments maintaining that a toll-free number would be an economic burden for small bottled water manufacturers provided no information to support their assertion. In the draft study, we did not find the cost of providing information to customers via a toll-free number to be economically prohibitive and are not persuaded by comments to alter that finding.

3. Information Available by the Combination Approach

In the draft study, we tentatively determined that it would be appropriate to provide information to bottled water customers by placing certain individual pieces of information on the label, while making other CCR-type information available to customers through contact with the company (i.e., a combination approach). We also stated that we believe that this method is feasible as long as the particular information that is placed on the label does not require frequent changes as a result of ongoing monitoring for contaminants.

(Comment 10) A few comments advocated providing lists of contaminants that exceed MCLG's, our allowable level for the contaminant, and health effects for the contaminant on the label or lists of all regulated contaminants detected and their allowable levels on the label, with all other CCR-type information available through company contact. These same comments, that advocated listing contaminants on the label, stated that the number of contaminants that would need to be listed would be minimal; one comment estimated that the number would be less than six, based on anecdotal evidence from public drinking water CCR's. Some comments stated that listing contaminants on the label would not lead to label clutter because the labels could be expanded or an additional label that hangs around the neck of the bottle could be used. Other comments that advocated listing contaminants on the label did not address label space, but stated that it is important that this information be immediately and easily available to the customer.

We do not agree with these comments. Even if the number of contaminants to be included is minimal, when this information is combined with the additional information (e.g., allowable levels, possible sources of the contaminant, and health effects information, if necessary) that would be needed to put the contaminant information in context for the customer, such information could be excessive in limited label space, particularly on the small, single serving bottles. We discourage the use of labels that fold out or hang around the neck of a bottle. These labels can be easily removed or torn apart before purchase or before the product reaches the final consumer, resulting in a product that could be misbranded.

While we agree that the label is an appropriate method for listing certain CCR-type information, as discussed in comment 11 of this document, and provides immediate information to customers, we disagree that such a method is appropriate and feasible for all CCR-type information for the reasons previously stated. In addition, we believe that CCR-type information obtained through other methods, for example through company contact, also is easily available to customers. Comments did not provide information to indicate otherwise.

(Comment 11) Many comments advocated that one or two pieces of information, such as a specific statement of the source of the water and any treatment the water received or levels of specific contaminants (i.e., fluoride, lead, arsenic, mercury, radioactive compounds), be placed on the label, while all other CCR-type information be available by contacting the company.

We agree that placing some pieces of information on the label, while other CCR-type information is available by contacting the company, is an appropriate and feasible method of informing customers of the contents of bottled water. We do not agree that it is feasible to place pieces of information on the label that are not consistent from product to product and may result in excessive information (i.e., contaminant listings that would require considerable additional text to place the information in context for the bottled water customer) in limited label space.

(Comment 12) A few comments also contended that updating contaminant information yearly on a bottled water label would not be burdensome economically to the bottled water industry.

This comment seems to suggest that updating contaminant information yearly on a bottled water label is feasible because it would not create an economic burden to the bottled water industry. Whether such a label change would create an economic burden would likely depend upon the scope and detail of information that would be included as ''contaminant information,'' e.g., whether such information includes a listing of contaminants, allowable contaminant levels, possible sources of contaminants, health effects information, etc. If requiring firms to change labels annually in order to update contaminant information increased the frequency of scheduled label changes, such label changes would result in a greater cost than what would exist in the absence of such a requirement. According to a survey of practices in the bottled drink industry, the average time between typical label changes is over 22 months (Research Triangle Institute, ''Compliance Costs of Food Labeling Regulations,'' January 1991). Requiring firms to update the information on labels every 12 months would increase the frequency of label changes and would therefore impose an additional cost on the industry. Whether such cost would result in an economic burden may depend on how much information needs to be updated.

4. Information in a Pamphlet

In the draft study, we tentatively concluded that providing CCR-type information to customers in a pamphlet that is available at retail may not be the most feasible method when other methods of conveying information are available. Information on bottled water contained in a pamphlet would be subject to the same frequent changes that may be necessary for label information due to changing test results from ongoing monitoring. In addition, there would be practical concerns about assuring that the pamphlets were consistently available at point of purchase.

(Comment 13) Comments did not support placement of a pamphlet containing CCR-type information about bottled water at the point of purchase as an appropriate and feasible method of providing information to customers. One comment stated that retailers carrying several brands of bottled water might be required to keep a virtual library of bottled water pamphlets and the burden of stocking them also would be on the retailer.

We agree with the comments and believe that pamphlets at point of purchase are not a feasible method of providing CCR-type information on bottled water to customers.

5. Distribution of an Information Package With Bulk Water Deliveries

In the draft study, we tentatively determined that it would be appropriate and feasible for bulk water deliverers to include an information package with a bill or deliver it with an invoice. An information package could be prepared in response to any changes in information about the delivered product, rather than printed in advance as labels typically are. The information also could be provided to customers by bulk deliverers only in response to customer request. This would reduce the chance for customers who are not seeking additional information on the contents of bottled water to be confused by information that may not be relevant to them or in which they have no interest.

(Comment 14) Many comments indicated that it would be appropriate and feasible for bulk water deliverers to provide customers with CCR-type information on bottled water on a yearly basis. A few comments noted that the label of bulk water containers should contain the same information as smaller bottles of water and that a package of information delivered with a large container of water should not substitute for the label.

We agree with comments that stated that it is both appropriate and feasible for bulk water deliverers to provide CCR-type information to their customers on a yearly basis. Bulk water deliverers could include this information with a bill or invoice. We also note that the labels of bulk containers of water are required to carry the same information as smaller bottles of water and that information delivered with a large container of water would not substitute for the label that is required on the product itself.

6. Information Available on the Internet

In the draft study, we tentatively determined that it may not be appropriate for the Internet to be the sole source of information on the contents of bottled water for customers, because not all customers have access to it. According to the 1999 Economic Report of the President (Washington, DC, 1999), approximately 70 million Americans (26 percent of the U.S. population) have access to the Internet. It is an appropriate and feasible method of providing information to customers who have access to the Internet; however, it may need to be used in combination with another method to ensure that all bottled water customers have access to CCR-type information.

(Comment 15) Most comments stated that the Internet was not appropriate as the sole source of CCR-type information to bottled water customers and a few noted that small bottled water producers might experience an economic burden if made to create and maintain a website. A few comments indicated that the Internet is an appropriate and feasible method of providing bottled water information to customers. These comments suggested that, if creating and maintaining a website would be burdensome to small bottled water producers, we could defray the costs of their website or provide the information on our website. Another comment indicated that we should maintain a website with CCR-type information on all bottled water producers.

The comments did not dissuade us from our belief that the Internet is not appropriate as the sole source of information on bottled water for customers because all customers do not have access to it. Comments requesting that we establish a website for bottled water information or defray costs to small producers for creating and maintaining a website are beyond the scope of this study.

(Comment 16) One comment stated that we underestimated by 1,000-fold the cost of creating and maintaining a website.

We estimated that it would cost $2,000 to $7,500 per year to create and maintain a website with information on bottled water. We believe our estimate is correct for the cost of a website that provides information only on the contents of bottled water. A website that contains graphics and other information would likely cost more than our estimate. However, we calculated the cost of providing only CCR-type information on bottled water to customers in a simple text format.

III. Our Final Report on the Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

A. Information on the Contents of Bottled Water

In the draft study, we tentatively determined that much of the information contained in a CCR is applicable to bottled water, with the exception of a definition and statement of MCLG's, information on public drinking water systems operating under a variance, and other information that is relevant only to public drinking water systems regulated by EPA, such as information on EPA's drinking water hotline. No substantive comments were received. Therefore, we have concluded that the information contained in a CCR, with the exceptions noted above, is applicable to bottled water.

We intended to limit discussion of information on the contents of bottled water to information that is analogous to that outlined by EPA for inclusion in a CCR. However, we recognize that certain information, such as the type of treatment the bottled water has received, that is not contained in a CCR may be of particular interest to certain customers and, should we engage in rulemaking on this subject in the future, we would consider requiring that manufacturers of bottled water provide this information to customers.

B. Methods We Have Determined Are Appropriate and Feasible for Informing Customers of the Contents of Bottled Water

There are several methods that we have determined are both appropriate and feasible for providing information to customers on the contents of bottled water. In addition, we have determined that it is feasible for bottled water producers to provide CCR-type information on bottled water, updated annually, to customers as public drinking water systems are required to do for their customers.

1. Information by Company Contact

In the draft study, we tentatively determined that a phone number or an address on the label directing customers on how to obtain information from the company is an appropriate and feasible method of providing information to customers. Comments did not provide any information contradicting our tentative determination. Therefore, we have determined that it is both appropriate and feasible to provide CCR-type information to customers through a phone number or an address on the label directing customers on how to obtain information from the company.

2. Information by the Combination Approach

We also believe that the combination approach (i.e., particular pieces of CCR-type information would be placed on the label, and the remainder of the information would be available through contact with the company by phone or mail) is appropriate and feasible. In the draft study, we tentatively determined that this method is appropriate and feasible and has the benefit of delivering certain pieces of information to customers at the point of purchase. The majority of comments agreed with our tentative conclusion.

Therefore, we have determined that the combination approach is an appropriate and feasible method of providing CCR-type information to bottled water customers, provided that the information that appears on the label does not result in excessive information (e.g., contaminant listings that would require considerable additional text to place the information in context for the bottled water customer) in limited label space.

3. Distribution of an Information Package With Bulk Water Deliveries

In the draft study, we tentatively concluded that this is an appropriate and feasible method of informing bulk bottled water customers of the contents of bottled water by distributing an information package with bulk water deliveries. The majority of comments to the draft study agreed with our tentative conclusion.

We have determined that it is both appropriate and feasible for bulk water deliverers to include an information package containing CCR-type information on bottled water with a bill or to deliver the information package with an invoice.

C. Methods We Have Determined Are Not Appropriate and Feasible for Informing Customers of the Contents of Bottled Water

There are several methods that we have determined are not appropriate and feasible for providing information to customers on the contents of bottled water.

1. Information on the Label

In the draft study, we stated that placing information on the label is an appropriate method of conveying information to bottled water customers; however, we questioned the feasibility of placing all CCR-type information, in particular information that might change frequently, on the label of bottled water. Concerns over excessive information in limited label space, potential misbranding and the potential economic burden of frequent label changes led us to tentatively determine that it is not feasible to place all of the information on a bottled water label that would be analogous to information contained in a CCR.

Some comments received on the draft study maintained that customers need CCR-type information in order to be informed and that this information would not crowd the label because the number of contaminants listed would be minimal, even though these comments also advocated information on allowable levels, possible sources of the contaminant, and health effects information to be included on the label. We continue to have concerns about excessive information in limited label space and the cost of frequent label changes. We believe that the amount of information that would need to go on the label to place the contaminant information, as suggested in these comments, in context for the bottled water customer may be considerable and could lead to excessive information in limited label space. Therefore, we have determined that placing all of the information that is analogous to that contained in a CCR on a bottled water label is not an appropriate and feasible method to inform customers of the contents of bottled water.

2. Information in a Pamphlet

In the draft study, we tentatively determined that providing CCR-type information to customers in a pamphlet available at retail may not be the most feasible method of informing customers when other methods are available. We cited concerns over ensuring that the information in the pamphlets is current and that the pamphlets are consistently available at retail. Comments received on the draft study agreed with our assessment. Therefore, we have determined that placing pamphlets containing CCR-type information with bottled water at retail is not a feasible method of informing customers of the contents of bottled water.

3. Information Available on the Internet

In the draft study, we tentatively concluded that the Internet is not appropriate as the sole method of providing information on the contents of bottled water to customers because not all customers may have access to it. Most comments agreed with our tentative conclusion. Therefore, we have determined that the Internet is not appropriate as the sole method of providing information on the contents of bottled water to customers.

Dated: August 21, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–21757 Filed 8–22–00; 3:50 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1149–N]

Medicare Program; September 11 and 12, 2000, Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for September 11, 2000, from 8:30 a.m. until 5 p.m., and for September 12, 2000, from 8:30 a.m. until 1 p.m., e.d.t.

ADDRESSES: The meetings will be held in the Multipurpose Room/Auditorium, 1st Floor, Health Care Financing Administration Building, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Paul Rudolf, Executive Director, Practicing Physicians Advisory Council, Room 435-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, (202) 690–7874. News media representatives should contact the HCFA Press Office, (202) 690–6145. Please refer to the HCFA Advisory Committees Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (http://www.hcfa.gov/fac) for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term. The Council held its first meeting on May 11, 1992.

The current members are: Jerold M. Aronson, Richard Bronfman, Joseph Heyman, Sandral Hullett, Stephen A. Imbeau, Jerilynn S. Kaibel, Angelyn L. Moultrie, Derrick K. Latos, Dale Lervick, Sandra B. Reed, Amilu Rothhammer, Maisie Tam, Victor Vela, Kenneth M. Viste, Jr., and Douglas L. Wood. The Council Chairperson is Derrick L. Latos.

Council members will be updated on the Provider Enrollment Form, Advance Beneficiary Notices (ABN), Physician Regulatory Issues Team (PRIT), OIG Referrals, Physician Involvement in Beneficiary Education Efforts, and Carrier Contractor National Policy Issues.

The agenda will provide for discussion and comment on the following topic:

- Evaluation and Documentation Guidelines.

For additional information and clarification on the aforementioned topics, call the contact person listed above.

Individual physicians or medical organizations that represent physicians that wish to make 5-minute oral presentations on agenda issues should contact the Executive Director by 12 noon, August 29, 2000, to be scheduled. Testimony is limited to listed agenda issues only. The number of oral presentations may be limited by the time available. A written copy of the presenters' oral remarks should be submitted to the Executive Director no later than 12 noon, September 5, 2000, for distribution to Council members for review prior to the meeting. Physicians and organizations not scheduled to speak may also submit written comments to the Executive Director and Council members.

The meeting is open to the public, but attendance is limited to the space available. Individuals requiring sign language interpretation for the hearing impaired or other special accommodation should contact John Lanigan at (202) 690–7418 at least 10 days before the meeting.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a)); 45 C.F.R. Part 11)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 22, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–21787 Filed 8–24–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as