its CMA expenses. Submission of this form is thus required by section 412(a)(4) of the Immigration and Nationality Act, which provides that ''no grant or contract may be awarded under this section unless an appropriate proposal and application * * * are submitted to, and approved by, the appropriate administering official.''

Respondents: State, Local, or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1	48	1	.5	24
Estimated Total Annual Burden Hours				24

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: June 28, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–16751 Filed 7–3–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0280]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it does not need to issue a standard of quality regulation for bottled water in response to the Environmental Protection Agency's (EPA's) issuance of National Primary Drinking Water Regulations (NPDWRs) for the control of *Cryptosporidium* contamination in surface water sources for public drinking water, to protect the public health. This action is in accordance with the Federal Food, Drug, and Cosmetic Act (the FFDCA), which requires that, whenever EPA issues NPDWRs for a contaminant in public drinking water, FDA must issue a standard of quality regulation for the same contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water used for bottled drinking water.

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–358–3571.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 16, 1998 (63 FR 69478), EPA published the Interim Enhanced Surface Water Treatment Rule (IESWTR) that established NPDWRs consisting of treatment technique requirements for reduction of *Cryptosporidium* in surface water and in ground water under the direct influence of surface water that public water systems serving 10,000 people or more use as their source water. This rulemaking finalized a proposed rule that EPA published in the **Federal Register** on July 29, 1994 (59 FR 38832).

Cryptosporidium is a gastrointestinal illness caused by ingestion of *Cryptosporidium* oocysts. The mode of transmission for *Cryptosporidium* is through the fecal-oral route and occurs by ingestion of infective oocysts from contaminated water or food, or by direct or indirect contact with infected persons or animals. While cryptosporidiosis generally is considered a self-limiting disease, it can be chronic and life threatening in immunocompromised individuals. Recently, a waterborne outbreak of *Cryptosporidium* was documented in association with public drinking water (Ref. 1).

Under the Safe Drinking Water Act (SDWA), as amended in 1996, EPA issues NPDWRs to protect the public health from the adverse effects of contaminants in public drinking water. NPDWRs specify maximum contaminant levels (MCLs) or treatment techniques for public drinking water contaminants. At the same time that it issues NPDWRs, EPA publishes maximum contaminant level goals (MCLGs), which are not regulatory requirements, but rather nonenforceable health goals that are based solely on considerations of protecting the public from adverse health effects of public drinking water contamination.

Under section 410(b)(1) of the FFDCA (21 U.S.C. 349(b)(1)), not later than 180 days before the effective date of a NPDWR issued by EPA for a contaminant under section 1412 of the SDWA (42 U.S.C. 300g-l)[1], FDA is required to issue a standard of quality regulation for the contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems, but not in water used for bottled drinking water. The effective date for any such standard of quality regulation is to be the same as the effective date of the NPDWR. In addition, section 410(b)(2) of the FFDCA provides that a quality standard regulation issued by FDA shall include monitoring requirements that the agency determines to be appropriate for bottled water. Further, section 410(b)(3) of the FFDCA requires a quality standard regulation for a contaminant in bottled water to be no less stringent than EPA's MCL and no less protective of the public

[1]FDA considers EPA's compliance date for subpart H public water systems (systems using surface water or ground water under the direct influence of surface water) that serve a population of 10,000 or more to be the effective date for purposes of section 410 of the FFDCA. The compliance date was set at December 16, 2001, in the IESWTR (63 FR 69478, December 16, 1998) and revised in a subsequent rule to January 1, 2002 (65 FR 20304, April 14, 2000).

health than EPA's treatment technique requirements for the same contaminant.

II. EPA Standards

The SDWA, as amended in 1996, requires EPA to publish an NPDWR that specifies either an MCL or treatment technique requirement for contaminants that may have an adverse effect on the health of persons, are known to occur or have a substantial likelihood of occurring in public water systems with a frequency and at levels of public health concern, and for which regulation presents a meaningful opportunity for health risk reduction for persons served by public water systems (section 1412(b)(1)(A) of the SDWA). The SDWA (section 300g-l(a)(3)) also requires that EPA issue MCLGs at the time that it issues NPDWRs. MCLGs are nonenforceable health goals based solely on considerations of protecting the public from the adverse health effects of contaminants, and are not based on other considerations, such as potential cost of regulating contaminants and potential technical difficulties of achieving the health goals. EPA sets MCLs, the enforceable contaminant levels, as close as feasible to the nonenforceable MCLGs. When it is not economically or technologically feasible to set MCLs, EPA establishes treatment technique requirements that can reduce the levels of such contaminants to protect the public health (section 1412(b)(1)(A) of the SDWA).

In the **Federal Register** of December 16, 1998 (63 FR 69478), EPA published the IESWTR establishing treatment technique requirements for public water systems that use surface water or ground water under the direct influence of surface water and serve at least 10,000 people. The primary purpose of the IESWTR is to improve control of microbial pathogens in public drinking water, particularly for the protozoan *Cryptosporidium*. Key provisions established in the IESWTR include (63 FR 69478 at 69483):

(a) An MCLG of zero for the protozoan genus *Cryptosporidium*.

(b) A 2-log (99 percent) removal of *Cryptosporidium* in public water systems that use surface water or ground water under the direct influence of surface water, serve 10,000 or more people, and are required to filter their source water under the Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989).

(c) Strengthened turbidity performance requirements for the combined filter effluent. The turbidity of a system's combined filtered water at each plant must be below levels established by EPA for public water systems when the plant uses surface water or ground water under the direct influence of surface water, serves 10,000 or more people, and is required to filter its source water under the SWTR.

(d) New requirements for individual filters. The turbidity for each individual filter effluent at each plant must be monitored continuously and be below levels established by EPA for public water systems when the plant uses surface water or ground water under the direct influence of surface water, serves 10,000 or more people, and is required to filter its source water under the SWTR.

III. FDA Standards

A. The Agency's Approach to Bottled Water Quality Standards Established Under Section 410 of the FFDCA

Under section 401 of the FFDCA (21 U.S.C. 341), FDA may issue a regulation establishing a standard of quality for a food under its common or usual name when the Secretary of Health and Human Services determines that such action will promote honesty and fair dealing in the interest of consumers. On November 26, 1973 (38 FR 32558), FDA established a quality standard for bottled water set forth in § 165.110 (21 CFR 165.110).

Producers of bottled water are responsible for ensuring, through appropriate manufacturing techniques and sufficient quality control procedures, that all bottled water products introduced or delivered for introduction into interstate commerce comply with the quality standard (§ 165.110(b)). Bottled water that is of a quality below the prescribed standard is required by§ 165.110(c) to be labeled with a statement of substandard quality. Moreover, any bottled water containing a substance at a level that causes the food to be adulterated under section 402(a)(1) of the FFDCA (21 U.S.C. 342(a)(1)) is subject to regulatory action, even if the bottled water bears a label statement of substandard quality.

FDA traditionally has fulfilled its obligation under section 410 of the FFDCA to respond to EPA's issuance of NPDWRs by amending the quality standard regulations for bottled water to maintain compatibility with EPA's public drinking water regulations. In general, FDA believes that, with few exceptions, EPA standards for contaminants in public drinking water are appropriate as allowable levels for contaminants in the quality standard for bottled water when bottled water may be expected to contain the same contaminants.

FDA generally has not duplicated the efforts of EPA in judging the adequacy of MCLs or treatment techniques in NPDWRs for contaminants when determining their applicability to bottled water in order to protect the public health. FDA believes that it would be redundant for FDA to reevaluate the public drinking water standards prescribed by EPA. Further, because bottled water increasingly is used in some households as a replacement for tap water, consumption patterns considered by EPA for tap water can be used as an estimate for the maximum expected consumption of bottled water by some individuals. Therefore, in cases where bottled water is subject to the same contaminants as tap water, FDA believes it should establish standard of quality regulations for bottled water that are no less stringent and no less protective of the public health, respectively, than EPA's MCLs and treatment technique requirements.

B. The EPA's IESWTR and Bottled Water

FDA has evaluated the treatment technique requirements for the reduction of *Cryptosporidium* in public drinking water established in EPA's IESWTR and finds that a standard of quality regulation for bottled water to reduce *Cryptosporidium* is not necessary to protect the public health.

According to industry information (Ref. 2), approximately 75 percent of bottled water sold in the United States originates from ground water (e.g., artesian well water, spring water, mineral water). Under the standard of identity regulations for bottled water (§ 165.110(a)), FDA has defined ground water as''* * * water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure * * *. Ground water must not be under the direct influence of surface water as defined in 40 CFR 141.2.'' (See 21 CFR 165.110(a)(2)(ii).) In an EPA **Federal Register** proposal (65 FR 30194, May 10, 2000) to require a targeted risk-based regulatory strategy for all ground water systems to reduce public health risk associated with waterborne pathogens (Ground Water Rule), EPA stated that, when *Cryptosporidium* occurs in ground water systems, it occurs in ground water under the direct influence of surface water (65 FR 30194 at 30204). In light of this, ground water, as defined in § 165.110(a)(2)(ii), used for bottled water is not expected to contain the contaminant*Cryptosporidium* because, by definition, it cannot be under the direct influence of surface water. Therefore, FDA concludes that

EPA's IESWTR establishing treatment technique requirements for *Cryptosporidium* in ground water under the influence of surface water does not apply to ground water used for the production of bottled water.

In addition, according to industry information (Ref. 2), the remaining 25 percent of bottled water sold in the United States is derived from public water systems. Public water systems serving at least 10,000 people or more, using surface water or ground water under the direct influence of surface water, must comply with EPA's IESWTR. In the **Federal Register** of April 10, 2000 (65 FR 19046), EPA published a proposed rule (Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule (LT1FBR)) to establish NPDWRs consisting of treatment technique requirements for reduction of *Cryptosporidium* in surface water and in ground water under the direct influence of surface water that public water systems serving less than 10,000 people use as their source water. Therefore, public water systems serving less than 10,000 people using surface water or ground water under the direct influence of surface water, will be subject to any EPA final rule on LT1FBR. Thus, under the EPA's IESWTR and LT1FBR if finalized as proposed, all water obtained from public water systems used for bottled water would be treated previously by public water systems to reduce the contaminant *Cryptosporidium*.

FDA concludes that because surface water and ground water under the direct influence of surface water would be subject to EPA's treatment technique requirements to reduce *Cryptosporidium*, a standard of quality regulation for bottled water derived from public water systems is not necessary to protect the public health. The contaminant may be contained in public water systems, which would be treated to reduce *Cryptosporidium* before such water would be used for bottled water. Further, because bottled water sources other than public drinking water are from ground water, which by definition (§ 165.110(a)(2)(ii)) must not be ground water under the direct influence of surface water, *Cryptosporidium* would not be expected to be present. Thus, FDA also concludes that a standard of quality regulation for bottled water derived from ground water is not necessary to protect the public health because *Cryptosporidium* would not be in ground water used for bottled water.

IV. References

The following references are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. MacKenzie, W. R., N. J. Hoxie, M. E. Proctor, M. S. Gradus, K. A. Blair, D. E. Peterson, J. J. Kazmierczak, D. G. Addiss, K. R. Fox, J. B. Rose, and J. P. Davis, ''A Massive Outbreak in Milwaukee of Cryptosporidium Infection Transmitted Through the Public Water Supply,'' *New England Journal of Medicine* 331:161–167 (1994).

2. Yablonski, C., International Bottled Water Association, letter to Henry Kim, March 23, 2001.

Dated: June 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–16910 Filed 7–2–01; 4:22 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–724]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare/Medicaid Psychiatric Hospital Survey Data and Supporting Regulations Contained in 42 CFR 482.60, 482.61 and 482.62; *Form No.:* HCFA–724 (OMB# 0938–0378); *Use:* The information collected on this form will assist HCFA in maintaining an accurate data base on providers participating in the Medicare psychiatric hospital program; *Frequency:* Annually; *Affected Public:* Federal government, Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; *Number of Respondents:* 250; *Total Annual Responses:* 250; *Total Annual Hours:* 125.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer:OMB Human Resources and Housing Branch,Attention: Wendy Taylor,New Executive Office Building, Room 10235,Washington, DC 20503.

Dated: May 22, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services,Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–16819 Filed 7–3–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–417]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The