amount of the bond prescribed under paragraph (b) of this section.

PART 113—CUSTOMS BONDS

1. The authority citation for Part 113 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1623, 1624.

* * * * *

§ 113.62 [Amended]

2. In § 113.62, paragraph (l)(1) is amended by removing the words ''conditions (a), (g), or (i)'' and adding, in their place, the words ''conditions in paragraphs (a), (g), (i), or (k) of this section'' and by adding the words ''or prohibited'' after the word ''restricted''.

§ 113.63 [Amended]

3. In § 113.63, paragraph (h)(1) is amended by adding the words ''or prohibited'' after the word ''restricted''.

§ 113.64 [Amended]

4. In § 113.64, the second sentence of paragraph (b) is amended by adding the words ''or prohibited'' after the word ''restricted''.

§ 113.67 [Amended]

5. In § 113.67, paragraphs (a)(2)(i) and (b)(2)(i) are amended by adding the words ''or prohibited'' after the word ''restricted''.

§ 113.73 [Amended]

6. In § 113.73, the second sentence of paragraph (a)(2) is amended by adding the words ''or prohibited'' after the word ''restricted''.

PART 141—ENTRY OF MERCHANDISE

1. The authority citation for Part 141 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

* * * * *

Section 141.113 also issued under 19 U.S.C. 1499, 1623.

§ 141.113 [Amended]

2. In § 141.113, the first sentence of paragraph (h) is amended by adding the words ''or prohibited'' after the word ''restricted''.

Raymond W. Kelly,

Commissioner of Customs.

Approved: March 8, 2001.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 01–7659 Filed 3–27–01; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR PART 24

[T.D. 01–25]

RIN 1515–AC82

Amended Procedure for Refunds of Harbor Maintenance Fees Paid on Exports of Merchandise

AGENCY: Customs Service, Department of the Treasury.

ACTION: Interim regulation.

SUMMARY: This document amends the Customs Regulations to provide a new procedure for requesting refunds of export harbor maintenance fees collected by Customs since 1987. The United States Supreme Court held these fees to be unconstitutional in 1998. Customs has received numerous requests for refunds from exporters who paid these export fees. The new procedure will simplify the refund process by relieving exporters from documentary requirements in most cases. This amendment is being made on an interim basis in order to expedite the process for exporters entitled to refunds of fees held unconstitutional and no longer required under the Customs Regulations.

DATES: The interim regulation is effective on March 28, 2001. Written comments must be received on or before April 27, 2001.

ADDRESSES: Written comments may be submitted to and inspected at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Ave., NW., 3rd Floor, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Deborah Thompson, Accounts Receivable Branch, Accounting Services Division, (317) 298–1200 (ext. 4003).

SUPPLEMENTARY INFORMATION:

Background

The Harbor Maintenance Fee (HMF) was created by the Water Resources Development Act of 1986 (Pub. L. 99–622; codified at 26 U.S.C. 4461 *et seq.*) (the Act) and is implemented by § 24.24 of the Customs Regulations (19 CFR 24.24). Imposition of the HMF is intended to require those who benefit from the maintenance of U.S. ports and harbors to share in the cost of that maintenance. Pursuant to the Act and as implemented by the regulations, the HMF became effective on April 1, 1987.

The HMF has been assessed on port use associated with imports, exports, foreign trade zone admissions, passengers, and movements of cargo between domestic ports. Currently, the fee is assessed based on 0.125 percent of the value of commercial cargo loaded or unloaded at certain identified ports or, in the case of passengers, on the value of the actual charge paid for the transportation. In 1998, the U.S. Supreme Court held the fee unconstitutional as applied to exports (*United States Shoe Corporation* v. *United States,* 118 S. Ct. 1290, No. 97–372 (March 31, 1998)). Subsequently, by a notice published in the **Federal Register** (63 FR 24209) on May 1, 1998, Customs announced that, as of April 25, 1998, the HMF for cargo loaded on board a vessel for export will no longer be collected. On July 31, 1998, Customs published in the **Federal Register** (63 FR 40822) an amendment to § 24.24 of the Customs Regulations, removing the requirement that exporters loading cargo at ports subject to the HMF are liable for payment of the fee. Thus, currently, application of the HMF continues but only for imports, domestic shipments, foreign trade zone admissions, and passengers.

On August 28, 1998, the U.S. Court of International Trade (CIT) ordered an immediate refund of undisputed export fee payments to exporters who had filed complaints with the court seeking recovery of these payments (*United States Shoe Corp.* v. *United States,* No. 94–11–00668, slip op. 98–126 (C.I.T. Aug. 28, 1998)). The order applied to payments received by Customs within two years of an exporter's filing of a complaint with the court. The order required these exporters to file a claim with Customs (attaching a copy of the filed complaint) and required that Customs would: (1) Conduct an initial search of its database for all export fee payments subject to refund (made during the prescribed two-year period) that were received from the exporter; (2) notify the exporter of that amount; and (3) unless disputed by the exporter, submit a stipulated judgment to the court for the court to enter judgment and order Customs to issue refunds to the exporter in the determined amount. Again, this court-ordered procedure applied only to exporters who filed a complaint with the court. Accordingly, Customs issued refunds only to exporters who received judgments from the court. All refund claims made under the court-ordered procedure have been processed.

Subsequently, on February 28, 2000, the U.S. Court of Appeals for the Federal Circuit, noting that the Customs Regulations do not impose a time limit on requests for refunds of the HMF (see current 19 CFR 24.24(e)(4)), held that

there is no limitation on the period within which a refund request may be filed pursuant to Customs Regulations (*Swisher International, Inc.* v. *United States,* 205 F. 3d 1358 (No. 99–1277 C.A.F.C. February 28, 2000), cert. denied). This ruling allowed exporters who received refunds under the procedure imposed by the court to file administrative requests (processed according to the Customs Regulations without filing a complaint in the court) for additional export fee refunds going back to July of 1987. Those exporters who never filed a complaint under the court procedure were also free to file administratively for export fee refunds.

Current Administrative Procedure for Refund of Export Harbor Maintenance Fees

The administrative procedure for requesting refunds of export fee (and other HMF) payments is provided for under § 24.24(e)(4) of the Customs Regulations (19 CFR 24.24(e)(4)). Under the regulation, exporters are required to file with Customs a request for a refund on a Harbor Maintenance Fee Amended Quarterly Summary Report (Customs Form (CF) 350), accompanied by copies of any relevant Harbor Maintenance Fee Quarterly Summary Reports (CF 349) representing proof of payment of the export fee. Prior to May of 1991, when the Customs Regulations were amended to require submission of the CF 349 with payment of the fee, the regulations required submission of an Export Vessel Movement Summary Sheet (EVM Summary Sheet) or, where Automated Summary Monthly Shipper's Export Declarations were filed, a letter (SED letter) containing the exporter's identity, its employer identification number (EIN), the applicable Census Bureau reporting symbol, and the quarter for which the payment was being made. Many exporters, not having copies of these payment forms, have filed requests for documentation under the Freedom of Information Act (FOIA). Most of these FOIA requests have not yet been processed by Customs, as the volume of requests has had the effect of straining resources.

Amended Administrative Procedure for Refund of Export Harbor Maintenance Fees

To proceed with the issuance of export fee refunds, and to simplify the process and improve its effectiveness, this document amends the Customs Regulations to provide a new procedure for exporters requesting a refund of export fees.

The procedure set forth in the amended regulation is designed to allow a refund request without submission of documentary proof of payment in most cases. Because Customs possesses copies of original payment forms (CF 349s, EVM Summary Sheets, or SED letters) from July 1, 1990, through the date collection of the export fee ceased in 1998, submission of supporting documentation will not be required to obtain refunds of export fee payments made on or after July 1, 1990. However, Customs does not possess these documents for export fee payments made prior to that date. Accordingly, for refund requests relating to export fee payments made prior to July 1, 1990, the exporter must submit proof of payment with the letter of request, that is, relevant copies of EVM Summary Sheets or SED letters provided for under the then current regulations.

In making this amendment to the regulations, Customs recommends that exporters who have filed FOIA requests for copies of payment forms withdraw those requests. In most cases, payment forms sought through a FOIA request seeking documents pertaining to payments made on or after July 1, 1990, are not necessary to obtain a refund. In addition, because Customs does not possess payment forms relating to export fees paid prior to July 1, 1990, a FOIA request relative to payments made during this period would be fruitless. If the FOIA requests are withdrawn, Customs will be able to more effectively expend its time and resources on the refunding of export fees owed rather than on the processing of numerous FOIA requests. For the same reasons, Customs recommends that exporters seeking a refund of export harbor maintenance fees who have not filed FOIA requests refrain from doing so.

On December 15, 2000, Customs published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (65 FR 78430) that proposed, in the future, in the interest of administrative efficiency, that persons requesting refunds of harbor maintenance fees paid on a quarterly schedule have one year from the date of payment to file for refunds. This would apply to quarterly payments relating to domestic shipments, imported merchandise admitted into a foreign trade zone, passengers, and, though no longer collected, quarterly payments made on export fees. The one-year time limitation was proposed to commence on the date the quarterly fee was paid to Customs, except for fees paid on the unloading of imported merchandise admitted into a foreign trade zone and subsequently withdrawn from the zone for any purpose specified in 19 U.S.C. 1309. For these latter fees, the one-year time limitation was proposed to commence on the date merchandise was withdrawn from the foreign trade zone. If this amendment proposing a time limitation on filing refund requests is adopted as a final rule, refund requests for export fee payments (and for any other quarterly harbor maintenance fee payment older than one year) will be required to be received on or before the effective date of that final rule document, which will be 30 days from the date of its publication in the **Federal Register**.

Already-filed export fee refund requests. An exporter who has already filed a request for a refund of export fees need not file again. Customs will treat the already filed request as one made under the amended procedure set forth in this document. Customs will process these requests in the order received, so that these filers will not be disadvantaged.

Requesting and processing refunds under the amended regulation. The procedure for exporters requesting and Customs processing export fee refunds as set forth in the amended regulation includes the following steps and features:

1. The exporter requests a refund by filing a letter with Customs requesting a refund of export fee payments collected from that exporter (or collected from a freight forwarder or other agent who paid the fee on the exporter's behalf) by Customs. For payments made prior to July 1, 1990, the letter must identify specific payments claimed and be accompanied by supporting documentation for each payment (a copy of the then required EVM Summary Sheet or its alternative document, an SED letter). For payments made on or after July 1, 1990, the letter must specify the quarters for which a refund is sought and include the following information: the exporter's name, address, and EIN; if payments of the fee were made by a freight forwarder or other agent on the exporter's behalf, the name and EIN of the freight forwarder or other agent; and the name, telephone number, and facsimile number of a contact person to answer questions. Supporting documentation need not be submitted for payments made during this period.

2. If the NPRM of December 15, 2000, is adopted as a final rule, the request for export fee refunds must be received by Customs by the effective date of that final rule document, 30 days after the date of its publication in the **Federal Register**. Requests for refunds filed after that date relative to quarterly harbor maintenance fee payments that are more

than a year old will be rejected as untimely.

3. Upon receipt of a timely filed letter of request for a refund, Customs, for payments made prior to July 1, 1990, will evaluate the documentation submitted and issue a refund if warranted. If the request lacks documentation or the documentation is insufficient, the request will be rejected, in which case the exporter will be given an additional 120 days to submit documentation/additional documentation for Customs consideration and final decision. (For purposes of filing a protest under 19 U.S.C. 1514 (within 90 days of a covered Customs decision), Customs initial decision will be final for exporters not filing documentation during the 120-day period.)

4. For payments made on or after July 1, 1990, Customs will perform a search of its records to locate export fee payment information relative to the exporter filing the refund request (and any freight forwarder or other agent named by the exporter as having made payments on the exporter's behalf) and the quarters identified in the letter of request. Customs will then issue a report to the exporter or its agent containing the results of the search. The report is entitled the ''Harbor Maintenance Tax Payment Report and Certification'' (the Report/Certification).

5. If the exporter agrees with the payment information in the Report/Certification, the exporter must sign the Report/Certification and return it to Customs with a letter providing an address for receipt of the refund. The Report/Certification must be signed by an officer of the company duly authorized to bind the company, or an agent (such as a broker or freight forwarder) authorized to sign a document of this kind under a properly executed power of attorney or a letter signed by the exporter. Upon receipt of the signed Report/Certification, Customs will issue the refund. If the exporter disagrees with any payment listed on the Report/Certification, or with the omission from the list of a payment it believes was made, the exporter must submit supplementary documentation (a copy of a relevant CF 349, EVM Summary Sheet, or SED letter) as proof of payment. Customs will conduct a second review and notify the exporter (or its agent) of the results. Depending on the results of the review, Customs will either confirm the disputed payment and issue a revised Report/Certification or notify the exporter that the disputed payment cannot be confirmed. In the latter instance, the Report/Certification will not be revised. To obtain the refund, the exporter must sign and return the (initial or revised) Report/Certification to Customs for its issuance of the refund.

6. The exporter's signature on the Report/Certification (or revised Report/Certification) signifies the exporter's concurrence with Customs determination of the full amount owed and constitutes the exporter's agreement that payment by Customs of the determined amount is in full accord and satisfaction of export fee claims against the Government. By its certification, the exporter will also release, waive, and abandon all claims against the Government, its officers, agents, and assigns for costs, attorney fees, expenses, compensatory damages, and exemplary damages arising out of all HMF export payments other than any payments Customs has already processed under the court-ordered procedure (for which release, etc., were already agreed to).

7. Upon receipt of a signed Report/Certification, the Government releases, waives, and abandons all claims other than fraud that it may have against the exporter or its officers, agents, or employees arising out of all HMF export payments other than those already processed under the court-ordered procedure (for which release, etc., were already agreed to).

8. As litigation concerning payment of interest on refunds continues, the exporter's claim to interest is not released, waived, or abandoned. However, as of the date of publication of this document, interest is not applicable to these refunds.

Customs emphasizes that the procedure for refunds set forth in § 24.24(e)(4)(ii) of the amended regulation applies only to payments of export fees that were held unconstitutional by the U.S. Supreme Court. The procedure for refund requests for any other harbor maintenance fees remains unchanged and is provided for in § 24.24(e)(4)(i) of the amended regulation.

Comments

Before adopting the interim regulation as a final rule, consideration will be given to any written comments timely submitted to Customs including comments on the clarity of the interim regulation and how it may be made easier to understand. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4 of the Treasury Department Regulations (31 CFR 1.4), and § 103.11(b) of the Customs Regulations (19 CFR 103.11(b)) on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC.

Inapplicability of Notice and Delayed Effective Date Provisions

Pursuant to the provisions of 5 U.S.C. 553(b)(B), Customs has determined that notice and public procedures for this regulation are unnecessary. The regulatory change in this document relieves certain exporters filing for refunds of export harbor maintenance fees from the restriction of having to file documentation representing proof of payment before receiving a refund. For the same reason, pursuant to 5 U.S.C. 553(d)(1) and (3), Customs is dispensing with a delayed effective date. However, before adopting final regulations, consideration will be given to all written comments timely submitted.

Executive Order 12866

This document does not meet the criteria for a ''significant regulatory action'' as specified in E.O. 12866.

Paperwork Reduction Act

The collection of information contained in the interim regulation has previously been reviewed and approved by the Office of Management and Budget (OMB) under OMB control number 1515–0158. Additional information requested in the interim regulation relates to usual and customary business information/records. This rule does not propose any substantive changes to the existing approved information collection.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this interim regulation, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Drafting Information

The principal author of this document was Bill Conrad, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices contributed in its development.

List of Subjects in 19 CFR Part 24

Accounting, Claims, Customs duties and inspection, Fees, Financial and accounting procedures, Imports, Taxes, User fees.

Amendments to the Regulations

For the reasons stated in the preamble, part 24 of the Customs

Regulations (19 CFR parts 24) is amended as follows:

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

1. The authority citation for part 24 continues to read in part as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58a–58c, 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1505, 1624; 26 U.S.C. 4461, 4462; 31 U.S.C. 9701.

* * * * *

2. Section 24.24 is amended by revising paragraph (e)(4) to read as follows:

§ 24.24 Harbor maintenance fee.

* * * * *

(e) *Collections*— * * *

(4) *Refund and supplemental payment.*—(i) *For fees paid on other than export movements.* If a refund is requested or a supplemental payment is made relative to quarterly fee payments previously made regarding the loading or unloading of domestic cargo, the unloading of cargo destined for admission into a foreign trade zone, or the boarding or disembarking of passengers, the refund request or supplemental payment must be accompanied by a Harbor Maintenance Fee Amended Quarterly Summary Report, Customs Form 350, along with a copy of the Harbor Maintenance Fee Quarterly Summary Report, Customs Form 349, for the quarter(s) covering the refund requested or the supplemental payment being made. A supplemental payment should be mailed to: U.S. Customs Service, PO Box 70915, Chicago, Illinois 60673–0915. A refund request should be mailed to: U.S. Customs Service, HMT Refunds, 6026 Lakeside Blvd., Indianapolis, IN, 26278. A request for a refund must specify the grounds for the refund. Refunds of fees regarding the unloading of imported cargo (except that admitted into a foreign trade zone) must be sought in accordance with the procedure for seeking a refund of ordinary duties.

(ii) *For fees paid on export movements.* Customs will process refund requests relative to fee payments previously made regarding the loading of cargo for export as follows:

(A) For export fee payments made prior to July 1, 1990, the exporter (the name that appears on the SED or equivalent documentation authorized under 15 CFR 30.39(b)) or its agent must submit a letter of request for a refund to the U.S. Customs Service, HMT Refunds, 6026 Lakeside Blvd., Indianapolis, IN, 26278, specifying the grounds for the refund and identifying the specific payments made. The letter must be accompanied by proof of payment then required under the regulations relative to each payment claimed, a copy of the Export Vessel Movement Summary Sheet or, where an Automated Summary Monthly Shipper's Export Declaration was filed, a letter containing the exporter's identification, its employer identification number (EIN), the Census Bureau reporting symbol, and the quarter for which the payment was made. Upon receiving a letter of request for a refund, Customs will evaluate the supporting documentation submitted and issue the refund to the exporter or its agent if warranted. Interest is not applicable to these refunds. If the request lacks documentation or the documentation submitted is insufficient, the exporter's refund request will be denied, in which case the exporter will have an additional 120 days to submit documentation or additional documentation. If the documentation submitted is insufficient, Customs will deny the request.

(B) For export fee payments made on or after July 1, 1990, the exporter or its agent must submit a letter of request for a refund (to the address set forth in paragraph (e)(4)(ii)(A) of this section) specifying the grounds for the refund, identifying the quarters for which a refund is sought, and containing the following additional information: the exporter's name, address, and employer identification number (EIN); the name and EIN of any freight forwarder or other agent that made export fee payments on the exporter's behalf; and a name, telephone number, and facsimile number of a contact person. If a refund request is filed by a freight forwarder or other agent on the exporter's behalf, the request must include a properly executed power of attorney and/or a letter signed by the exporter authorizing the representation. Refund requests for payments made on or after July 1, 1990, need not be accompanied by supporting documentation. Upon receipt of the letter of request, Customs will search its records for export fee payments made by or on behalf of the requesting exporter during the quarters identified in the letter of request. Customs will then mail to the exporter or its agent a ''Harbor Maintenance Fee Payment Report and Certification'' (Report/Certification) containing the results of the search and a statement of the amount of refunds owed to the exporter, if any. If the exporter agrees with the information in the Report/Certification, the exporter must sign the Report/Certification and submit it to Customs with a letter containing an address for mailing the refund. The Report/Certification must be signed by an officer of the company duly authorized to bind the company, or an agent (such as a broker or freight forwarder) authorized to sign the document under a properly executed power of attorney or a letter signed by an authorized officer of the company. Upon receipt of the signed Report/Certification, Customs will issue the refund. If the exporter disagrees with the information in the Report/Certification, the exporter must submit a letter explaining its claim along with proof of payment, either a copy of a Harbor Maintenance Fee Quarterly Summary Report, Customs Form 349, for the quarter(s) covering the refund requested or, if applicable, a copy of an Export Vessel Movement Summary Sheet or, where an Automated Summary Monthly Shipper's Export Declaration was filed, a letter containing the exporter's identification, its employer identification number (EIN), the Census Bureau reporting symbol, and the quarter for which the payment was made. Upon receiving the letter and documentation, Customs will conduct a second review and will either confirm the exporter's claim and mail a revised Report/Certification to the exporter or its agent, or notify the exporter or its agent that confirmation cannot be made. In the latter instance, the Report/Certification will not be revised. Upon receipt of a properly signed Report/Certification (initial or revised), Customs will issue the refund. Interest is not applicable to these refunds. The signed Report/Certification received by Customs constitutes the exporter's agreement that Customs payment of the refund amount determined to be owed in the Report/Certification is in full accord and satisfaction of all export fee refund claims. The signed Report/Certification also represents the exporter's release, waiver, and abandonment of all claims against the Government, its officers, agents, and assigns for costs, attorney fees, expenses, compensatory damages, and exemplary damages. Upon receipt of the signed Report/Certification, Customs releases, waives, and abandons all claims other than fraud against the exporter, its officers, agents, or employees arising out of all export fee payments.

* * * * *

Dated: March 6, 2001.

Charles W. Winwood,

Acting Commissioner of Customs.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 01–7603 Filed 3–27–01; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 129 and 165

[Docket No. 01N–0126]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its bottled water quality standard regulations by establishing allowable levels for three residual disinfectants (chloramine, chlorine, and chlorine dioxide) and three types of disinfection byproducts (DBP's) (bromate, chlorite, and haloacetic acids (HAA5)). FDA also is revising the existing allowable level for the DBP total trihalomethanes (TTHM). Finally, FDA is revising, for the three residual disinfectants and four types of DBP's only, the monitoring requirement for source water found in the current good manufacturing practice (CGMP) regulations for bottled water. As a consequence of FDA's amending the quality standard for these residual disinfectants and DBP's, bottled water manufacturers are required to monitor their finished bottled water products for these disinfectants and DBP's at least once each year under the CGMP regulations for bottled water. Bottled water manufacturers also are required to monitor for these contaminants at least once each year in their source water, unless the bottlers meet the criteria for source water monitoring exemptions under the CGMP regulations. This direct final rule will ensure that the minimum quality of bottled water, as affected by the previously mentioned disinfectants and DBP's, remains comparable with the quality of public drinking water that meets the Environmental Protection Agency's (EPA's) standards. FDA is issuing a direct final rule for this action because the agency expects that there will be no significant adverse comment on this rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under the agency's usual procedure for notice-and-comment rulemaking to provide a procedural framework to finalize the rule in the event the agency receives significant adverse comment and withdraws this direct final rule. The companion proposed rule and direct final rule are substantively identical.

DATES: This rule is effective January 1, 2002. Submit written comments by June 11, 2001. If FDA receives no significant adverse comments during the specified comment period, the agency will publish a document in the **Federal Register** no later than July 5, 2001, confirming the effective date of the direct final rule. If the agency receives any significant adverse comment during the comment period, FDA intends to withdraw this direct final rule by publication in the **Federal Register** no later than July 5, 2001. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR 51 of certain publications in § 165.110(b)(4)(iii)(I) as of January 1, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–358–3568.

SUPPLEMENTARY INFORMATION:

I. Background

On December 16, 1998, EPA published the Stage 1 Disinfection Byproducts Rule (Stage I DBPR) (63 FR 69390) to address potential public health effects from the presence of disinfectants and DBP's in drinking water. This rulemaking finalized a proposed rule that EPA published in the **Federal Register** on July 29, 1994 (59 FR 38668).

Disinfectants are chemicals, such as chlorine and ozone, that are added to drinking water to control microbial contamination. Both bottlers and public water systems may use disinfectants. Public water systems typically add disinfectants to drinking water at levels sufficient to maintain a disinfectant residual throughout the distribution system (i.e., the system of pipes that takes water from water treatment plants to customers). DBP's are chemicals that result from the unintentional interaction of the disinfectants with inorganic or organic compounds present in the water supply. Examples of DBP's include chloroform (a byproduct of treatment with chlorine) and bromate (a byproduct of ozonation). Both disinfectants and DBP's can have adverse health effects (59 FR 38668 at 38679–38710).

National primary drinking water regulations (NPDWR's) are issued by EPA to protect the public health from the adverse effects of contaminants in drinking water. NPDWR's specify maximum contaminant levels (MCL's) or treatment techniques for drinking water contaminants. In addition, at the same time that it issues NPDWR's, EPA publishes maximum contaminant level goals (MCLG's), which are not regulatory requirements but rather are nonenforceable health goals that are based solely on considerations of protecting the public from adverse health effects of drinking water contamination. In its proposed rule on disinfectants and DBP's (59 FR 38668), EPA also introduced the concept of maximum residual disinfectant levels (MRDL's) and maximum residual disinfectant level goals (MRDLG's). MRDL's and MRDLG's are comparable to MCL's and MCLG's, in that they set contaminant levels and health goals, respectively. EPA used the terms MRDL and MRDLG for disinfectants, rather than using the terms MCL and MCLG, to reflect the fact that disinfectants have beneficial properties (63 FR 69390 at 69398; 59 FR 38668 at 38672, 38679).

In the Stage I DBPR (63 FR 69390), EPA issued NPDWR's consisting of MCL's for the DBP's bromate, chlorite, HAA5, and TTHM. EPA also published MRDL's for the chlorine-based disinfectants chlorine, chloramine, and chlorine dioxide. Finally, EPA published MCLG's and MRDLG's for these contaminants, as well as approved methods of testing for these contaminants.

Under section 410 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349), not later than 180 days before the effective date of an NPDWR issued by EPA for a contaminant under section 1412 of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300g-l),[1] FDA is required to issue a standard of quality regulation for that 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

[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 act. The compliance date was set at December 16, 2001, in the Stage I DBPR (63 FR 69390) and updated in a subsequent rule to January 1, 2002 (65 FR 20303, April 14, 2000).