depository institution shall be deemed to be a deposit by a trustee of trust funds of which the noteholders or bondholders are pro rata beneficiaries, and the beneficial interest of each noteholder or bondholder in the deposit shall be separately insured up to $100,000.

(d) *Definition of ''political subdivision''.* The term ''political subdivision'' includes drainage, irrigation, navigation, improvement, levee, sanitary, school or power districts, and bridge or port authorities and other special districts created by state statute or compacts between the states. It also includes any subdivision of a public unit mentioned in paragraphs (a)(2), (a)(3) and (a)(4) of this section or any principal department of such public unit:

(1) The creation of which subdivision or department has been expressly authorized by the law of such public unit;

(2) To which some functions of government have been delegated by such law; and

(3) Which is empowered to exercise exclusive control over funds for its exclusive use.

§ 330.16 Effective dates.

(a) *Prior effective dates.* Former §§ 330.1(j), 330.10(a), 330.12(c), 330.12(d)(3) and 330.13 (see 12 CFR part 330, as revised January 1, 1998) became effective on December 19, 1993.

(b) *Time deposits.* Except with respect to the provisions in former § 330.12 (a) and (b) (see 12 CFR part 330, as revised January 1, l998) and current § 330.14(a) and (b), any time deposits made before December 19, 1991 that do not mature until after December 19, 1993, shall be subject to the rules as they existed on the date the deposits were made. Any time deposits made after December 19, 1991 but before December 19, 1993, shall be subject to the rules as they existed on the date the deposits were made. Any rollover or renewal of such time deposits prior to December 19, 1993 shall subject those deposits to the rules in effect on the date of such rollover or renewal. With respect to time deposits which mature only after a prescribed notice period, the provisions of this part shall be effective on the earliest possible maturity date after June 24, 1993 assuming (solely for purposes of this section) that notice had been given on that date.

By order of the Board of Directors.

Dated at Washington, D.C., this 28th day of April, 1998.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 98–11987 Filed 5–8–98; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. 98N–0294]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to lift the stay of the effective date for the allowable levels in the bottled water quality standard for nine chemical contaminants, i.e., antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8–TCDD (dioxin), that was imposed in a final rule published on March 26, 1996. By lifting the stay of the effective date, bottled water manufacturers will be required to monitor source waters and finished bottled water products at least once a year for these nine chemical contaminants under the current good manufacturing practice (CGMP) regulations for bottled water. FDA is required to issue monitoring requirements for the nine chemical contaminants under the Safe Drinking Water Act Amendments of 1996 (SDWA Amendments). FDA is using direct final rulemaking for this action because the agency expects that there will be no significant adverse comment on the rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under FDA'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 comments and withdraws this direct final rule. The companion proposed rule and direct final rule are substantively identical.

DATES: The regulation is effective November 9, 1998. Submit written comments by July 27, 1998. If no timely significant adverse comments are received, the agency will publish a notice in the **Federal Register** no later than August 6, 1998, confirming the effective date of the direct final rule. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule no later than August 6, 1998.

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

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

SUPPLEMENTARY INFORMATION:

I. Background

Before the enactment of the SDWA Amendments on August 6, 1996, section 410 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349) required that, whenever the Environmental Protection Agency (EPA) prescribed interim or revised National Primary Drinking Water Regulations (NPDWR's) under section 1412 of the Public Health Service Act (SDWA) (42 U.S.C. 300f through 300j–9)), FDA consult with EPA and either amend its regulations for bottled drinking water in § 165.110 (21 CFR 165.110) or publish in the **Federal Register** its reasons for not making such amendments.

In accordance with section 410 of the act, FDA published in the **Federal Register** of March 26, 1996 (61 FR 13258), a final rule (hereinafter ''the March 1996 final rule'') that amended the quality standard for bottled water by establishing or revising the allowable levels for 5 inorganic chemicals (IOC's) and 17 synthetic organic chemicals (SOC's), including 3 synthetic volatile organic chemicals (VOC's), 9 pesticide chemicals, and 5 nonpesticide chemicals. This action was in response to EPA's issuance of NPDWR's consisting of maximum contaminant levels (MCL's) for the same 5 IOC's and 17 SOC's in public drinking water (see 57 FR 31776, July 17, 1992).

However, in the March 1996 final rule, FDA stayed the effective date for the allowable levels for the five IOC's (antimony, beryllium, cyanide, nickel, and thallium) and four of the SOC's (diquat, endothall, glyphosate, and dioxin). This action was in response to bottled water industry comments (responding to the August 4, 1993, proposal (58 FR 41612)) which asserted that additional monitoring for these nine chemicals required under the bottled water CGMP regulations would pose an undue economic burden on bottlers. If the agency had not stayed the effective date for the allowable levels,

the bottled water CGMP regulations under part 129 (21 CFR part 129) would have been in effect for these nine chemical contaminants. The bottled water CGMP regulations require a minimum yearly monitoring of source water and finished bottled water products for chemical contaminants for which allowable levels have been established in the bottled water quality standard. The comments requested that FDA adopt reduced frequency monitoring requirements for chemical contaminants that are not likely to be present in the source water for bottling or in the finished bottled water products. The comments submitted data that supported the request that FDA reconsider the current monitoring frequency requirements for chemical contaminants in the bottled water CGMP regulations.

Based on the information submitted by the comments, FDA stated in the March 1996 final rule (61 FR 13258 at 13261) that the matter of reduced frequency of monitoring (less frequently than once per year) requirements for chemical contaminants that are not likely to be found in bottled water merited consideration by the agency. FDA also stated, however, that any revision of the monitoring requirements for chemical contaminants in bottled water would require an amendment of the bottled water CGMP regulations (part 129). FDA stated that it intended to initiate, considering its resources and competing priorities, a separate rulemaking to address the issue of circumstances in which reduced frequency of monitoring requirements for chemical contaminants in bottled water products may be appropriate.

Therefore, FDA stayed the effective date for the nine chemical contaminants pending completion of a rulemaking to address the issue of reduced frequency monitoring for chemical contaminants in bottled water. Although the effect of the stay does not require bottled water manufacturers to monitor source waters and finished bottled water products annually for the nine chemical contaminants, FDA advised water bottlers to ensure, through appropriate manufacturing techniques and sufficient quality control procedures, that their bottled water products are safe with respect to levels of these nine chemical contaminants.

II. Direct Final Rulemaking

FDA has determined that the subjects of this rulemaking are suitable for a direct final rule. The actions taken should be noncontroversial and the agency does not anticipate receiving any significant adverse comments.

FDA is lifting the stay for the nine chemical contaminants for which the agency stayed the effective date in the March 1996 final rule. By lifting the stay, the bottled water CGMP requirements for annual testing for the nine chemical contaminants will become effective. This action will meet the statutory mandate provided in the SDWA Amendments that requires the agency to issue monitoring requirements for the nine chemical contaminants by August 6, 1998.

If FDA does not receive significant adverse comment on or before July 27, 1998, the agency will publish a notice in the **Federal Register** no later than August 6, 1998, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective 180 days after publication of the confirmation notice in the **Federal Register**.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. A comment recommending a rule change in addition to the rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule no later than August 6, 1998.

The companion proposed rule, which is substantively identical to the direct final rule, provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider such comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. Action to Lift the Stay

Subsequent to the March 1996 final rule, on August 6, 1996, the SDWA Amendments were enacted. Section 305 of the SDWA Amendments requires that, for contaminants covered by a standard of quality regulation issued by FDA before the enactment of the SDWA Amendments for which an effective date had not been established, FDA issue monitoring requirements for such contaminants (e.g., the nine chemical contaminants: Antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and dioxin) not later than 2 years after the date of enactment of the SDWA Amendments. Under this mandate, FDA is required to issue monitoring requirements for the nine chemical contaminants for which it stayed the effective date in the March 1996 final rule by August 6, 1998, with an effective date of February 6, 1999. If FDA does not meet this statutory time period, the NPDWR's for the nine chemical contaminants become applicable to bottled water.

For the reasons set forth in this document, FDA is lifting the stay of the effective date for the allowable levels for the nine chemical contaminants (antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and dioxin). First, the agency's CGMP regulations for bottled water, which require that source waters and finished bottled water products be tested for these nine contaminants at least once a year, are protective of the public health. The agency considers at least annual testing, as set forth in its CGMP regulations in part 129 to be of sufficient frequency, absent circumstances that may warrant more frequent testing, to ensure that bottled water has been prepared, packed or held under sanitary conditions. Second, Congress mandated, under the SDWA Amendments, that the agency issue monitoring requirements for the nine chemical contaminants by August 6, 1998. The agency's action to lift the stay is consistent with this mandate. By lifting the stay of the effective date for the allowable levels for

the nine chemical contaminants in the bottled water quality standard, bottled water manufacturers will be required to monitor source waters and finished bottled water products at least once a year for these nine chemical contaminants under the CGMP provisions in part 129. Third, in the March 1996 final rule, FDA stated that it intended to initiate rulemaking to address the issue of whether there are circumstances in which reduced frequency of monitoring for contaminants is appropriate. However, such rulemaking would require consideration of all chemical contaminants, not just the nine chemical contaminants that are the subject of the stay. FDA is only addressing, in this rulemaking, the frequency of monitoring for the nine chemical contaminants that are the subject of the stay. FDA may consider, in a future rulemaking, the issue of reduced frequency of monitoring in the context of all chemical contaminants in bottled water subject to the bottled water CGMP regulations (part 129). Therefore, the agency is, at this time, electing to lift the stay of the effective date for the allowable levels in the bottled water quality standard for the nine chemical contaminants, i.e., antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and dioxin, and thereby require annual testing for these nine contaminants, consistent with the CGMP requirements for bottled water.

IV. Environmental Impact

The agency has determined under 21 CFR 25.32(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the impacts of this direct final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that this direct final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, it has been determined that this direct final rule is not a major rule for the purpose of Congressional review. For the purpose of Congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

B. Final Regulatory Flexibility Analysis

FDA has examined the impact of the rule as required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the RFA requires agencies to analyze options that would minimize the economic impact of that rule on small entities. The agency acknowledges that the direct final rule may have a significant economic impact on a substantial number of small entities. The agency is not, in this analysis, addressing comments received in response to an initial regulatory flexibility analysis. The nature of the direct final rule provides for a companion proposed rule published at the same time as the direct final rule. An initial regulatory flexibility analysis is contained in the companion proposed rule. The agency is publishing the direct final rule because the agency does not anticipate any significant adverse comment. Should the agency receive any significant adverse comment in response to the direct final rule, the agency will withdraw the direct final rule and use the companion proposed rule in developing a final rule.

1. Objectives

The RFA requires a succinct statement of the purpose and objectives of any rule that may have a significant economic impact on a substantial number of small entities. The agency is taking this action to lift the stay for nine chemical contaminants under a Congressional mandate, under the SDWA Amendments, that FDA issue monitoring requirements for these nine chemical contaminants in bottled water. Lifting the stay of the effective date for the allowable levels in the bottled water quality standard for the nine chemical contaminants (antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and dioxin) protects the public health. By lifting the stay, bottled water manufacturers will be required to monitor source waters and finished bottled water products at least once a year for the nine chemical contaminants under the bottled water CGMP regulations in part 129. The agency considers at least annual testing, as set forth in its CGMP regulations, to be of sufficient frequency, absent circumstances that may warrant more frequent testing, to ensure that bottled water has been prepared, packed, or held under sanitary conditions.

2. Description of Small Business and the Number of Small Businesses Affected

The RFA requires a description of small businesses used in the analysis and an estimate of the number of small businesses affected, if such estimate is available. Table 1 of this document describes small businesses affected and estimates the number of small businesses affected by the rule. The agency combined the Small Business Administration (SBA) definition of a small business as an upper bound of the total number in the analysis with data from Duns Market Identifiers (DMI) on the number of plants using SIC 2086. FDA has used the International Bottled Water Association (IBWA) estimate as a lower bound of the number of small entities in the industry. According to DMI, there are a total of 1,567 establishments in the industry group of which 66 percent of the entities (1,028 firms) have fewer than 500 employees. According to IBWA, there are approximately 560 member firms, of which 50 percent or 280 firms have annual sales below $1 million.

TABLE 1.—APPROXIMATE NUMBER OF SMALL ENTITIES COVERED BY THIS RULE

Type of Establishment	Standard Industry Classification Codes	Classification of Small Entities	Percentage of Category Defined as Small by SBA	No. of Small Establishments Covered by the Rule
IBWA	NA	Annual Sales below $1million	50%	280

TABLE 1.—APPROXIMATE NUMBER OF SMALL ENTITIES COVERED BY THIS RULE—Continued

Type of Establishment	Standard Industry Classification Codes	Classification of Small Entities	Percentage of Category Defined as Small by SBA	No. of Small Establishments Covered by the Rule
DMI	2,086	Less than 500 employees	66%	1,028

3. Description of the Economic Impact on Small Entities

a. *Estimated costs for testing source waters.* The estimated costs for testing source waters are the estimated total additional costs the small entity would incur to monitor source waters for the nine chemical contaminants annually. Table 2 of this document summarizes the expected additional costs. As discussed in the March 1996 final rule (61 FR 13258 at 13263), additional cost per sample is estimated to be $1,290, and an estimated 50 percent of source waters are from municipal sources that do not require testing.

TABLE 2.—ESTIMATED SUBTOTAL COSTS FOR TESTING SOURCE WATERS

No. of Small Establishments Covered by the Rule	Cost per Sample	Percent Water from Nonmunicipal Sources	Subtotal Annual Cost
Lower Bound–280	$1,290	50%	$180,600
Upper Bound–1028	$1,290	50%	$663,060

b. *Estimated costs for testing finished bottled water products.* The estimated costs for testing are the estimated total additional costs the small entity would incur to monitor finished bottled water products for the nine chemical contaminants annually. Table 3 of this document summarizes the expected costs. As discussed in the March 1996 final rule (61 FR 13258 at 13263), additional cost per sample is estimated to be $1,290.

TABLE 3.—ESTIMATED SUBTOTAL COSTS FOR TESTING FINISHED BOTTLED WATER PRODUCTS

No. of Small Establishments Covered by the Rule	Cost per Sample	Average Number of Products	Subtotal Annual Cost
Lower Bound–280	$1,290	2	$722,400
Upper Bound–1028	$1,290	2	$2,652,240

c. *Estimated total costs for testing source waters and finished bottled water products.* The estimated total testing costs are the sum of estimated costs to monitor source waters and finished bottled water products. The agency estimates that the lower bound cost is $900,000 and the upper bound cost is $3 million. Table 4 of this document summarizes the expected additional costs.

TABLE 4.—ESTIMATED TOTAL COSTS

No. of Small Establishments Covered by the Rule	Subtotal Costs for Testing Source Waters	Subtotal Costs for Testing Finished Bottled Water Products	Total Testing Costs[1]
Lower Bound–280	$180,600	$722,400	$900,000
Upper Bound–1028	$660,060	$2,652,240	$3,000,000

[1]Total Testing Costs are rounded to the nearest significant digit.

d. *Professional skills required for compliance.* The RFA requires a description of the professional skills necessary for the preparation of a report or record. This rule does not require professional skills for the preparation of a report or record. Any sampling of source water or finished bottled water product for analysis of chemical contaminants can be carried out by trained plant personnel who can ship such samples to a testing laboratory for analysis. Other trained skills would also include recording and maintaining the test result records at the plant for a minimum of 2 years.

e. *Recordkeeping requirements.* The RFA requires a description of the recordkeeping requirements of the rule. Table 5 of this document shows the provisions for making and maintaining records by small businesses, the number of small businesses affected, the annual frequency of making each record, the amount of time needed for making each record, and the total number of hours for each provision in the first year and then in subsequent years.

TABLE 5.—SMALL BUSINESS RECORDKEEPING REQUIREMENTS

Provision	No. of Small Entities Keeping Records	Annual Frequency	Hours per Record per Small Entity	Total Hours, First Year	Total Hours, Subsequent Years
Monitoring SOP	280	1	10	2,800	2,800
Monitoring SOP	1,028	1	10	10,280	10,280
Validation	280	1	5	1,400	1,400
Validation	1028	1	5	5,140	5,140
Record Maintenance	280	1	5	1,400	1,400
Record Maintenance	1,028	1	5	5,140	5,140
Totals-Lower Bound	280	1	20	5,600	5,600
Totals-Upper Bound	1,028	1	20	20,560	20,560

4. Minimizing the Burden to Small Entities

The RFA requires an evaluation of any regulatory alternatives that would minimize the costs to small entities. There are four alternatives that the agency has considered to provide regulatory relief for small entities. First, FDA considered the option of not lifting the stay of the effective date for the allowable levels in the bottled water quality standard for the nine chemical contaminants. Second, FDA considered the option of exempting small entities from the requirements of this rule. Third, FDA considered lengthening the compliance period for small entities. Fourth, FDA considered reducing the testing frequency.

a. *Not lifting the stay*. By convention, the option of taking no action is the baseline in comparison with the evaluation of the other options. Taking no action in this case means not lifting the stay of the effective date for the allowable levels in the bottled water quality standard for the nine chemical contaminants. By not lifting the stay, FDA would not meet the statutory mandate provided in the SDWA Amendments that requires the agency to issue monitoring requirements for the nine chemical contaminants by August 6, 1998. If FDA does not issue monitoring requirements by August 6, 1998, the NPDWR's for public drinking water for these nine contaminants would be considered to be the standard of quality regulations for bottled water under § 165.110. Under the NPDWR's, EPA's base monitoring requirements for ground water testing are once every 3 years for testing inorganic chemicals (e.g., antimony, beryllium, cyanide, nickel, and thallium), and four successive quarters every 3 years for ground water testing for synthetic organic chemicals (e.g., diquat, endothall, glyphosate, and dioxin). Under part 129, FDA requires at least annual testing for both the inorganic and synthetic organic chemicals. Therefore, the frequency of testing requirements under EPA's NPDWR's for public drinking water and FDA's frequency of testing requirements for bottled water differ.

Moreover, the regulatory scheme under EPA regulations for public drinking water contemplates State coordination, including the use of State-issued waivers in certain situations. EPA regulations address treated ground and surface water testing, whereas FDA regulations address source water (which in most cases involves testing of untreated ground water) and finished bottled water product testing. Source water testing provides a preliminary review of the safety and quality of the water source that a water bottler intends to manufacture into a bottled water product. FDA considers source water testing to be as important as finished bottled water product testing because the safety and quality of the source water, determined by source water testing, will affect the treatment necessary to produce a finished bottled water product that complies with the bottled water quality standard. However, if EPA's regulatory scheme for public drinking water would need to be considered for the nine chemical contaminants that are the subject of this rule for bottled water, it is unclear whether only finished bottled water product testing for these nine chemical contaminants, without source water testing, would be applicable.

Furthermore, EPA's monitoring requirements are designed to address water that is provided to customers through municipal water distribution systems while FDA's requirements address water that is produced to be sold to consumers in discrete units. Some differences between these two sets of monitoring requirements exist (e.g., criteria for determining when a system (or bottler) is not in compliance), because they address two fundamentally different production circumstances. FDA believes that its regulations for bottled water, which are designed to ensure that bottled water is prepared, packed, or held under sanitary conditions, should apply to the testing for these nine chemical contaminants in bottled water rather than having such contaminants subject to a regulatory scheme established for public drinking water.

Furthermore, the extent to which FDA would consider certain aspects of EPA's regulatory scheme for public drinking water as ''monitoring requirements'' is not clear. FDA has not had to apply EPA's regulations for public drinking water to bottled water under the bottled water quality standard regulations. Therefore, if FDA did not lift the stay and issue monitoring requirements under the agency's CGMP requirements in part 129 for these nine chemical contaminants, the application of section 410(b)(4)(A) of the act would create uncertainty for industry and regulators. The practical effect of the application of section 410(b)(4)(A) of the act may be additional burdens on small businesses if such businesses must adhere to two regulatory schemes for testing of their bottled water products rather than one comprehensive scheme for all bottled water testing. As stated earlier, FDA's CGMP requirements are protective of the public health and the application of these CGMP requirements to all bottled water would not result in uncertainty to industry and regulators. As discussed below in section V.B.3.d of this document, FDA believes that retaining the applicability of its CGMP requirements to all bottled water, with further evaluation of reduced frequency of testing in the context of all chemical contaminants in a future rulemaking, would be less confusing to small entities. Therefore, FDA believes that lifting the stay would be beneficial to the public.

b. *Exempt small entities*. One alternative for alleviating the burden for small entities would be to exempt them from the testing requirements of this rule. Although, this option would eliminate the cost of testing on small firms, it may also result in a decrease in the potential public health benefits of the rule. Small entities comprise a large part of the affected industry and

exempting them would affect the testing requirements for a large segment of the bottled water products on the market. Such products would not be subject to a certain frequency of testing that provides adequate assurance that such products manufactured by small businesses are as protective of the public health as those that have undergone the testing requirements for these nine contaminants under part 129. Therefore, exempting small businesses would reduce the potential public health benefits of lifting the stay.

c. *Extend compliance period.* FDA considered an extended compliance period. Lengthening the compliance period would provide regulatory relief to small entities because it would reduce the present value of the costs of testing. However, as stated in section V.B.4.b of this document, because small entities comprise a large part of the affected industry, longer compliance periods would delay any potential public health benefits of the rule. For example, if a small business had an excess level of one of the nine chemical contaminants in its bottled water product, it would not be aware of the potential public health problem as a result of the specific contaminant because the small business would not be testing during the longer compliance period. Therefore, the agency has concluded that lifting the stay is more protective of the public health.

d. *Reduced testing frequency.* Another alternative for alleviating the burden for small entities would be to reduce the testing frequency for certain chemical contaminants, including the nine chemical contaminants that are the subject of this rule. The agency believes that, in considering the issue of reduced frequency of testing, it needs to do so in the context of all chemical contaminants, not just the nine that are the subject of this rule. Reduced frequency of testing may include an entirely different scheme that may include waivers for certain chemical contaminants. The contemplation of such a scheme is better addressed in a context that includes consideration of all chemical contaminants, rather than considering and implementing a different regulatory scheme for only the nine chemical contaminants. Moreover, Congress mandated that the agency issue monitoring requirements for these nine chemical contaminants by August 6, 1998. Because the scope of this rule is limited to these nine chemical contaminants, and the agency does not have sufficient time to enlarge the scope of this rulemaking to the issue of reduced frequency of testing for all chemical contaminants, the agency is not pursuing this alternative in this rulemaking. However, the agency plans to consider the issue of reduced frequency of monitoring for all chemical contaminants in bottled water in a future rule.

5. Summary

FDA has examined the impact of the direct final rule on small businesses in accordance with RFA. This analysis, together with the preamble, constitutes RFA.

C. Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of this direct final rule under the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). This rule does not require a written statement under section 202(a) of the UMRA because it does not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by State, local, and tribal governments in the aggregate, or by the private sector, in any one year.

VI. Paperwork Reduction Act of 1995

FDA concludes that this direct final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Comments

Interested persons may, on or before July 27, 1998, submit to the Dockets Management Branch (address above) written comments regarding this direct final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Effective Date

The agency intends to make the direct final rule effective 180 days after the publication of the confirmation notice in the **Federal Register**. The agency is providing a 180 day effective date to permit affected firms adequate time to take appropriate steps to bring their product into compliance with the standard imposed by the new rule.

List of Subjects in 21 CFR Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 165 is amended as follows:

PART 165—BEVERAGES

1. The authority citation for 21 CFR part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

§ 165.110 [Amended]

2. Section 165.110 *Bottled water* is amended in the table in paragraph (b)(4)(iii)(A) by removing the superscript ''1'' after the entries for ''Antimony,'' ''Beryllium,'' ''Cyanide,'' ''Nickel,'' and ''Thallium,'' and by removing the footnote to the table; in the table in paragraph (b)(4)(iii)(C) by removing the superscript ''1'' after the entries for ''Diquat,'' ''Endothall,'' ''Glyphosate,'' and ''2,3,7,8–TCDD (Dioxin),'' and by removing the footnote to the table; and by removing the note that follows paragraph (b)(4)(iii)(G)(*3*)(*iv*).

Dated: May 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12381 Filed 5–6–98; 3:57 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Expedited Revocation Procedure for Parole Violators

AGENCY: Parole Commission, Justice.

ACTION: Final rule.

SUMMARY: The U.S. Parole Commission is adding to its regulations a provision whereby certain parolees who have been arrested and charged with violations of parole (or who are serving new sentences for crimes committed while on parole) may consent to revocation of parole upon the acceptance of a sanction within the applicable guideline range. The purpose of this procedure is to avoid the need for holding parole violators in local jails for revocation hearings, and to save the Parole Commission the time and expense of conducting hearings when an appropriate sanction can be imposed with the consent of the offender.

DATES: Effective June 10, 1998.

FOR FURTHER INFORMATION CONTACT: Pamela A. Posch, Office of General