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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. 98N–0294]

Beverages: Bottled Water; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend 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). This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments by July 27, 1998. See section VIII. of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments on the companion proposed rule 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

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The companion proposed rule and the direct final rule are substantively identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. FDA is publishing the direct final rule because the agency anticipates that it will receive no significant adverse comment. A detailed discussion of this rule is set forth in section II of the direct final rule. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation notice no later than August 6, 1998. FDA intends the direct final rule to become effective 180 days after publication of the confirmation notice. If FDA receives significant adverse comment, the agency will withdraw the direct final rule. FDA will proceed to respond to all of the comments received regarding the rule, and, if appropriate, the rule will be finalized under this companion proposed rule using notice-and-comment procedure. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule.

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 (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 21 CFR part 129 (part 129) would have been in effect for these nine chemical contaminants. The bottle 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 in 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. Additional Information

For additional information see the corresponding direct final rule published elsewhere in this issue of the **Federal Register**. All persons who wish to submit comments should review the detailed rationale for these amendments set out in the preamble discussion of the direct final rule.

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. 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.

III. Proposal to Lift the Stay

Subsequent to the March 1996 final rule, on August 6, 1996, the SDWA Amendments was 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.

FDA is proposing to lift 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) for the following reasons: 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, FDA, in the March 1996 final rule, 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 in 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 proposed rule under Executive Order 12866. Executive Order 12866 directs agencies to assess the 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 effects; 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 proposed rule is not a significant regulatory action as defined by Executive Order 12866. In addition, it has been determined that this proposed 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. Initial 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 proposed rule may have a significant economic impact on a

substantial number of small entities. If the agency receives any significant adverse comments to the direct final rule, the agency will withdraw the direct final rule and proceed with the rulemaking based on this proposed rule. In the context of the rulemaking based on this proposed rule, the agency will consider comments to the initial regulatory flexibility analysis.

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 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 $1 million	50%	280
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 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-1,028	$1,290	50%	$663,060

b. *Estimated costs for testing finished bottle 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 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 BOTTLE 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-1,028	$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 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-1,028	$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 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	1,028	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's 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's 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, in lieu of 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, and 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 in option d of this section 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 option b of section V.B.4.c 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 the 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 proposed rule on small businesses in accordance with the RFA. This analysis, together with the preamble, constitutes the RFA.

C. Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of this proposed 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 1 year.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this companion proposed 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 proposal. 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 any final rule based on this proposal effective 180 days following the date of publication of the final rule in the **Federal Register**. The agency is providing this time period 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.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 165 be 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. 98–12382 Filed 5–6–98; 3:57 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. 98N–0249]

Ear, Nose, and Throat Devices; Classification of the Nasal Dilator, the Intranasal Splint, and the Bone Particle Collector

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the nasal dilator, intranasal splint, and the bone particle collector into class I and exempt these devices from premarket notification procedures. FDA is also publishing the recommendations of the Ear, Nose, and Throat Devices Panel (the panel) regarding the classification of the devices. After considering public comments on the proposed classifications, FDA will publish a final regulation classifying the devices. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments by August 10, 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: Harry R. Sauberman, Center for Devices and Radiological Health (HFZ–420), Food and Drug Administration, 9200 Corporate Blvd, Rockville, MD 20850, 301– 594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

The act, as amended by the 1976 amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and FDAMA (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval). Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments) are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee), (2) published the panel's recommendations for comment, along with a proposed regulation classifying the device, and (3) published a final regulation classifying the device. A device that is first offered in commercial distribution after May 28, 1976, and which FDA determines to be substantially equivalent to a device classified under this scheme, is classified into the same class as the device to which it is substantially equivalent. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A device that was not in commercial distribution prior to May 28, 1976, and that has not been found by FDA to be substantially equivalent to a legally marketed predicate device, is classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process.

In the **Federal Register** of November 6, 1986 (51 FR 40378), FDA published a final rule classifying ear, nose and throat devices. At that time, FDA was not aware that the nasal dilator, the intranasal splint, and the bone particle collector were preamendments devices and inadvertently omitted classifying them.

II. Device Descriptions

FDA is proposing the following device descriptions based on the panel's recommendations (Ref. 1) and the agency's review:

(1) The nasal dilator is a device intended to provide temporary relief from breathing difficulties resulting from structural abnormalities in the nose. The external nasal dilator is described as a device constructed from layers of fabric material with a flat plastic spring inserted between the layers, with a skin adhesive applied to adhere to the skin of the nose. The device is placed externally on the lower third of the nose. The external nasal dilator acts with a pulling force to open the nares and the nasal valves thereby decreasing nasal airway resistance and increasing nasal air flow. The internal nasal dilator is constructed from metal or plastic and is placed inside the nostrils. It acts by pushing the nostrils open or by gently pressing on the columella, thereby decreasing nasal airway resistance and increasing nasal airflow;

(2) The intranasal splint is a device intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity. The intranasal splint is constructed from plastic, silicone, or absorbent material and is placed in the nasal cavity after surgery or trauma; and

(3) The bone particle collector is a filtering device intended to be inserted into the suction tube line during the early stages of otologic surgery to collect bone particles for future use.

III. Recommendations of the Panel

In a public meeting held on October 25, 1990, the panel made classification recommendations for the nasal dilator, the intranasal splint, and the bone particle collector. The panel recommended that the devices be classified in class I (general controls). No recommendation was made to exempt these devices.

IV. Summary of the Reasons for the Recommendations

The panel concluded that the safety and effectiveness of the nasal dilator, intranasal splint, and bone particle collector can be reasonably assured by general controls. Specifically, the panel believed that the safety and effectiveness of the nasal dilator,