(B) A grain grader licensed under State law and employed by a warehouse operator who has a commodity storage agreement with the Commodity Credit Corporation; or

(C) A grain grader not licensed under State law, but who is employed by a warehouse operator who has a commodity storage agreement with the Commodity Credit Corporation and is in compliance with State law regarding warehouses; and

(iv) With regard to substances or conditions injurious to human or animal health, the samples are analyzed by a laboratory approved by us.

(4) Small grain production that is eligible for quality adjustment, as specified in sections 11(d)(2) and (3), will be reduced by the quality adjustment factor contained in the Special Provisions.

* * * * *

12. Late Planting

A late planting period is applicable to small grains, except to any barley or wheat acreage covered under the terms of the Wheat or Barley Winter Coverage Endorsement. Barley or wheat covered under the terms of the Winter Coverage Endorsement must be planted on or prior to the applicable final planting date specified in the Special Provisions. In counties having one fall final planting date for acreage covered under the Wheat or Barley Winter Coverage Endorsement and another fall final planting date for acreage not covered under the endorsement, the fall late planting period will begin after the final planting date for acreage not covered under the endorsement.

* * * * *

■ 3. Amend the crop insurance endorsement contained in § 457.102 as follows:

■ a. Revise the section title; and

■ b. Revise the endorsement, all to read as follows:

§ 457.102 Wheat or barley winter coverage endorsement.

United States Department of Agriculture

Federal Crop Insurance Corporation

Wheat or Barley Winter Coverage Endorsement

(This is a continuous endorsement)

1. In return for payment of the additional premium designated in the actuarial documents, this endorsement is attached to and made part of the Small Grains Crop Provisions subject to the terms and conditions described herein.

2. This endorsement is available only in counties for which the Special Provisions for the insured crop designate both a fall final planting date and a spring final planting date, and for which the actuarial documents provide a premium rate for this coverage.

3. You must have a Small Grains Crop Insurance Policy in force and elect to insure barley or wheat under that policy.

4. You must select this coverage, by crop, on your application for insurance. Failure to do so means you have rejected this coverage for both wheat and barley and this endorsement is void.

5. In addition to the requirements of section 34(b) of the Basic Provisions and section 2 of the Small Grains Crop Provisions, optional units may be established for barley if each optional unit contains only initially planted winter barley or only initially planted spring barley.

6. If you elect this endorsement for winter barley, the contract change, cancellation, and termination dates applicable to wheat in the county will be applicable to all your spring and winter barley.

7. Coverage under this endorsement begins on the later of the date we accept your application for coverage or on the fall final planting date designated in the Special Provisions. Coverage ends on the spring final planting date designated in the Special Provisions.

8. The provisions of section 14 of the Basic Provisions are amended to require that all notices of damage be provided to us by the spring final planting date designated in the Special Provisions.

9. All eligible acreage of each crop covered under this endorsement must be insured.

10. The amount of any indemnity paid under the terms of this endorsement will be subject to any reduction specified in the Basic Provisions for multiple crop benefits in the same crop year.

11. Whenever any winter wheat or barley is damaged during the insurance period and at least 20 acres or 20 percent of the insured planted acreage in the unit, whichever is less, does not have an adequate stand to produce at least 90 percent of the production guarantee for the acreage, you may, at your option, take one of the following actions:

(a) Continue to care for the damaged crop. By doing so, coverage will continue under the terms of the Basic Provisions, the Small Grains Crop Insurance Provisions and this endorsement.

(b) Replant the acreage to an appropriate variety of the insured crop, if it is practical, and receive a replanting payment in accordance with the terms of section 9 (Replanting Payments) of the Small Grains Crop Insurance Provisions. By doing so, coverage will continue under the terms of the Basic Provisions, the Small Grains Crop Insurance Provisions and this endorsement, and the production guarantee for winter wheat or barley will remain in effect.

(c) Destroy the remaining crop on such acreage. By doing so, you agree to accept an appraised amount of production determined in accordance with section 11(c)(1) of the Small Grains Crop Insurance Provisions to count against the unit production guarantee. This amount will be considered production to count in determining any final indemnity on the unit and will be used to settle your claim as described in section 11 (Settlement of Claim) of the Small Grains Crop Insurance Provisions. You may use such acreage for any purpose, including planting and separately insuring any other crop if such insurance is available. If you elect to plant and elect to insure a spring type of the same crop (you must elect whether or not you want insurance on the spring type of the same crop at the time we release the winter type acreage), you must pay additional premium for the insurance. Such acreage will be insured in accordance with the policy provisions that are applicable to acreage that is initially planted to a spring type of the insured crop, and you must:

(1) Plant the spring type in a manner which results in a clear and discernable break in the planting pattern at the boundary between it and any remaining acreage of the winter type; and

(2) Store or market the production in a manner which permits us to verify the amount of spring type production separately from any winter type production. In the event you are unable to provide records of production that are acceptable to us, the spring type acreage will be considered to be a part of the original winter type unit.

Signed in Washington, DC, on June 3, 2003.

Ross J. Davidson, Jr.,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 03–14413 Filed 6–4–03; 2:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. 03N–0068]

Beverages: Bottled Water; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 8, 2003, for the direct final rule that appeared in the **Federal Register** of March 3, 2003 (68 FR 9873). The direct final rule amends the bottled water quality standards regulations by establishing an allowable level for uranium. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: December 8, 2003.

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1640.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 3, 2003 (68 FR 9873), FDA published a direct final rule that amends the bottled water quality standards regulations (21 CFR part 165) by establishing an allowable level for uranium. Interested persons were given until May 2, 2003, to

comment on the direct final rule. FDA stated that the effective date of the direct final rule would be December 8, 2003, and, if the agency received no significant adverse comments, it would publish a notice of confirmation of the effective date no later than June 11, 2003. FDA received no significant adverse comments within the comment period. Therefore, FDA is confirming that the effective date of the direct final rule is December 8, 2003. As noted in the direct final rule, FDA is publishing this confirmation document 180 days before the effective date to permit affected firms adequate time to take appropriate steps to bring their bottled water products into compliance with the quality standard imposed by the new rule.

Dated: June 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14477 Filed 6–6–03; 8:45 am]

BILLING CODE 4164–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 350, and 369

[Docket No. 78N–0064]

RIN 0910–AA01

Antiperspirant Drug Products For Over-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) antiperspirant drug products are generally recognized as safe and effective and not misbranded as part of FDA's ongoing review of OTC drug products. FDA is issuing this final rule after considering public comments on its proposed regulation, issued as a tentative final monograph (TFM), and all new data and information on antiperspirant drug products that have come to the agency's attention.

DATES: *Effective Date*: This rule is effective December 9, 2004.

Compliance Dates: The compliance date for products with annual sales less than $25,000 is June 9, 2005. The compliance date for all other products is December 9, 2004.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

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I. Background

In the **Federal Register** of October 10, 1978 (43 FR 46694), FDA published an advance notice of proposed rulemaking to establish a monograph for OTC antiperspirant drug products, together with the recommendations of the Advisory Review Panel on OTC Antiperspirant Drug Products (the Panel), which evaluated the data on these products. The agency's proposed regulation (TFM) for OTC antiperspirant drug products was published in the **Federal Register** of August 20, 1982 (47 FR 36492).

In the **Federal Register** of November 7, 1990 (55 FR 46914), the agency issued a final rule establishing that certain active ingredients in OTC drug products are not generally recognized as safe and effective and are misbranded. These ingredients included seven antiperspirant ingredients, which are included in § 310.545(a)(4) (21 CFR 310.545(a)(4)). In this rulemaking, the agency is adding one additional ingredient to this section. (See section III.1 of this document.)

In the **Federal Register** of March 23, 1993 (58 FR 15452), the agency requested public comment on two citizen petitions, and a response to one of the petitions, related to the safety of aluminum compounds in OTC antiperspirant drug products. This final monograph completes the TFM and provides the substantive response to the citizen petitions.

Twenty-four months after the date of publication in the **Federal Register**, for products with annual sales less than $25,000, and 18 months after the date of publication in the **Federal Register**, for all other products, no OTC drug product that is subject to this final rule and that contains a nonmonograph condition may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved new drug application (NDA) or abbreviated new drug application. Further, any OTC drug product subject to this final monograph that is repackaged or relabeled after the compliance dates of the final rule must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily as soon as possible.

In response to the TFM on OTC antiperspirant drug products and the request for comment on the citizen petitions, the agency received 20 comments. One manufacturer requested an oral hearing before the Commissioner of Food and Drugs on six different issues. Copies of the information considered by the Panel, the comments, and the hearing request are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. ''OTC Volumes'' cited in this document refer to information on public display.

The agency received some ''feedback'' communications under the OTC drug review procedures (see the **Federal Registers** of September 29, 1981 (46 FR 47740) and April 1, 1983 (48 FR 14050)). The agency has included these communications in the administrative record and addressed them in this document.

The safety issues raised by the citizen petitions are discussed in section II.F of this document. The agency believes it has adequately responded to the six issues related to the hearing request; therefore, a hearing is not necessary.

II. The Agency's Conclusions on the Comments

A. General Comments on OTC Antiperspirant Drug Products

(Comment 1) One comment requested that FDA reconsider its position that OTC drug monographs are substantive, as opposed to interpretive, regulations.

The agency addressed this issue and reaffirms its conclusions as stated in