

FDA also concludes that the special controls guidance document contains information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque"; the notice contains an analysis of the paperwork burden for the guidance.

#### V. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Sinclair Pharmaceuticals, dated January 24, 2005.

#### List of Subjects in 21 CFR Part 872

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

#### PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 872.5580 is added to subpart F to read as follows:

#### § 872.5580 Oral rinse to reduce the adhesion of dental plaque.

(a) *Identification.* The device is assigned the generic name oral rinse to reduce the adhesion of dental plaque and is identified as a device intended to reduce the presence of bacterial plaque on teeth and oral mucosal surfaces by physical means. The device type includes those devices that act by reducing the attachment and inhibiting the growth of bacterial plaque.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque." See § 872.1(e) for the availability of this guidance document.

Dated: September 9, 2005.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### 44 CFR Part 65

[Docket No. FEMA-D-7579]

#### Changes in Flood Elevation Determinations

**AGENCY:** Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Interim rule.

**SUMMARY:** This interim rule lists communities where modification of the Base (1% annual chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

**DATES:** These modified BFEs are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Director reconsider the changes. The modified elevations may be changed during the 90-day period.

**ADDRESSES:** The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646-2903.

**SUPPLEMENTARY INFORMATION:** The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National

Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State or regional entities.

The changes in BFEs are in accordance with 44 CFR 65.4.

*National Environmental Policy Act.* This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

*Regulatory Flexibility Act.* The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

*Regulatory Classification.* This interim rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

*Executive Order 12612, Federalism.* This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

*Executive Order 12778, Civil Justice Reform.* This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

#### List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 65 is amended to read as follows:

**PART 65—[AMENDED]**

Authority: 42 U.S.C. 4001 *et seq.*;  
Reorganization Plan No. 3 of 1978, 3 CFR,  
1978 Comp., p. 329; E.O. 12127, 44 FR 19367,  
3 CFR, 1979 Comp., p. 376.

**§ 65.4 [Amended]**

■ 1. The authority citation for part 65 continues to read as follows:

■ 2. The tables published under the authority of § 65.4 are amended as shown below:

State and County	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Connecticut: Litchfield .....	Town of Harwinton.	September 6, 2005, September 13, 2005, <i>The Register Citizen</i> .	Ms. Marie Knudsen, Town of Harwinton First Selectman, Harwinton Town Hall, 100 Bentley Drive, Harwinton, Connecticut 06791.	Dec. 13, 2005 .....	090147 B
Litchfield .....	Town of Litchfield	September 6, 2005, September 13, 2005, <i>The Register Citizen</i> .	Mr. Leo Paul, Town of Litchfield First Selectman, Town Offices, 74 West Street, P.O. Box 488, Litchfield, Connecticut 06759.	Dec. 13, 2005 .....	090047 B
Litchfield .....	City of Torrington	September 6, 2005, September 13, 2005, <i>The Register Citizen</i> .	The Honorable Owen J. Quinn, Mayor of the City of Torrington, Municipal Building, 140 Main Street, Torrington, Connecticut 06790.	Dec. 13, 2005 .....	095081 B
Pennsylvania: Chester .....	Township of Atglen.	August 11, 2005, August 18, 2005, <i>Daily Local News</i> .	The Honorable Wesley Vincent, Mayor of the Borough of Atglen, P.O. Box 250, Atglen, Pennsylvania 19310.	Nov. 17, 2005 .....	420273 D
Lancaster .....	Township of Sadsbury.	August 11, 2005, August 18, 2005, <i>Parkesburg Post Ledger</i> .	Mr. N. Eugene Lammey, Chairman of the Township of Sadsbury Board of Supervisors, 7182 White Oak Road, Christiana, Pennsylvania 17509.	Nov. 17, 2005 .....	421782 E
Chester .....	Township of West Sadsbury.	August 11, 2005, August 18, 2005, <i>Parkesburg Post Ledger</i> .	Mr. James Landis, Chairman of the Township of West Sadsbury Board of Supervisors, 6400 N. Moscow Road, Parkesburg, Pennsylvania 19365.	Nov. 17, 2005 .....	422281 D

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance")

Dated: September 14, 2005.

**David I. Maurstad,**

*Acting Director, Mitigation Division,  
Emergency Preparedness and Response  
Directorate.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**44 CFR Part 65**

**Changes in Flood Elevation Determinations**

**AGENCY:** Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Final rule.

**SUMMARY:** Modified Base (1% annual chance) Flood Elevations (BFEs) are

finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

**DATES:** The effective dates for these modified BFEs are indicated on the following table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect for each listed community prior to this date.

**ADDRESSES:** The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646-2903.

**SUPPLEMENTARY INFORMATION:** FEMA makes the final determinations listed below of modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that

publication. The Mitigation Division Director of the Emergency Preparedness and Response Directorate has resolved any appeals resulting from this notification.

The modified BFEs are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection.

The modifications are made pursuant to Section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).