

the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

## XI. Proposed Effective Date

FDA is proposing that any final order based on this proposal become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

## XII. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

### 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, it is proposed that 21 CFR part 872 be 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 872.3640 is amended by revising paragraphs (a) and (b)(2) to read as follows:

### § 872.3640 Endosseous dental implant.

(a) *Identification.* An endosseous dental implant is a prescription device made of a material such as titanium or titanium alloy that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

(b) \* \* \*

(2) Class II (special controls). The device is classified as class II if it is a

blade-form endosseous dental implant. The special controls for this device are:

(i) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use;

(ii) Mechanical performance (fatigue) testing under simulated physiological conditions to demonstrate maximum load (endurance limit) when the device is subjected to compressive and shear loads;

(iii) Corrosion testing under simulated physiological conditions to demonstrate corrosion potential of each metal or alloy, couple potential for an assembled dissimilar metal implant system, and corrosion rate for an assembled dissimilar metal implant system;

(iv) The device must be demonstrated to be biocompatible;

(v) Sterility testing must demonstrate the sterility of the device;

(vi) Performance testing to evaluate the compatibility of the device in a magnetic resonance (MR) environment;

(vii) Labeling must include a clear description of the technological features, how the device should be used in patients, detailed surgical protocol and restoration procedures, and relevant precautions and warnings based on the clinical use of the device;

(viii) Patient labeling must contain a description of how the devices works, how the device is placed, how the patient needs to care for the implant, possible adverse events and how to report any complications; and

(ix) Documented clinical experience must demonstrate safe and effective use and capture any adverse events observed during clinical use.

Dated: January 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00388 Filed 1–11–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

[Docket Number USCG–2012–1082]

RIN 1625–AA00

### Safety Zone, Atlantic Intracoastal Waterway; Wrightsville Beach, NC

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of Proposed Rulemaking.

**SUMMARY:** The Coast Guard proposes to extend the temporary safety zone

established on the waters of the Atlantic Intracoastal Waterway at Wrightsville Beach, North Carolina. The safety zone is necessary to provide for the safety of mariners on navigable waters during maintenance on the US 74/76 Bascule Bridge crossing the Atlantic Intracoastal Waterway, mile 283.1, at Wrightsville Beach, North Carolina. The safety zone extension will temporarily restrict vessel movement within the designated area starting on May 1, 2013 through July 27, 2013.

**DATES:** Comments and related material must be received by the Coast Guard on or before February 13, 2013.

**ADDRESSES:** You may submit comments identified by docket number using any one of the following methods:

(1) *Federal eRulemaking Portal:*

<http://www.regulations.gov>.

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this proposed rule, call or email CWO4 Joseph M. Edge, U.S. Coast Guard Sector North Carolina; telephone 252–247–4525, email [Joseph.M.Edge@uscg.mil](mailto:Joseph.M.Edge@uscg.mil). If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

## SUPPLEMENTARY INFORMATION:

### Table of Acronyms

DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking

### A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

### 1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at <http://www.regulations.gov>, or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, type the docket number (USCG-2012-1082) in the "SEARCH" box and click "SEARCH." Click on "Submit a Comment" on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

### 2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number (USCG-2012-1082) in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

### 3. Privacy Act

Anyone can search the electronic form of comments received into any of

our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

### 4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

### B. Regulatory History and Information

The Coast Guard is proposing to extend a safety zone originally established by a final rule published July 17, 2002, entitled "Safety Zones: Atlantic Intracoastal Waterway; Wrightsville Beach, NC" (77 FR 41911, docket number USCG-2012-0368).

### C. Basis and Purpose

North Carolina Department of Transportation has awarded a contract to American Bridge Company of Coraopolis, PA to perform bridge maintenance on the U.S. 74/76 Bascule Bridge crossing the Atlantic Intracoastal Waterway, mile 283.1, at Wrightsville Beach, North Carolina. The contract provides for cleaning, painting, steel repair, and grid floor replacement to commence on September 1, 2012. The original completion date was May 1, 2013, however, the contractor was granted an extension on the completion date by North Carolina Department of Transportation to July 27, 2013.

The contractor will utilize a 40 foot deck barge with a 40 foot beam as a work platform and for equipment staging. This safety zone will provide a safety buffer to transiting vessels as bridge repairs present potential hazards to mariners and property due to reduction horizontal clearance.

### D. Discussion of Proposed Rule

The proposed temporary safety zone would encompass the waters directly under the U.S. 74/76 Bascule Bridge crossing the Atlantic Intracoastal Waterway, mile 283.1, at Wrightsville Beach, North Carolina (34°13'07" N, 077°48'46" W). All vessels transiting the this section of the waterway requiring a horizontal clearance of greater than 50 feet would be required to make a one hour advanced notification to the U.S. 74/76 Bascule Bridge tender while the

safety zone is in effect. The initial safety zone, which began on 8 a.m. September 1, 2012, is scheduled to be in effect through 8 p.m. May 1, 2013. The proposed extension would be in effect from 8 p.m. May 1, 2013, through 8 p.m. July 27, 2013.

### E. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes or executive orders.

#### 1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. This rule does not restrict traffic from transiting through the noted portion of the Atlantic Intracoastal Waterway; it only imposes a one hour notification to ensure the waterway is clear of impediment to allow passage to vessels requiring a horizontal clearance of greater than 50 feet.

#### 2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which may be small entities: the owners or operators of commercial tug and barge companies, recreational and commercial fishing vessels intending to transit the specified portion of Atlantic Intracoastal Waterway from 8 p.m. May 1, 2013 through 8 p.m. July 27, 2013.

This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons. Although the safety zone will apply to the entire width of this section of the Atlantic Intracoastal Waterway, vessel traffic will be able to request passage by providing a one hour advanced notification. Before the effective period, the Coast Guard will issue maritime advisories widely available to the users of the waterway. If you think that your business,

organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

### 3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

### 4. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

### 5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

### 6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the “For Further Information Contact” section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

### 7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this

proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### 8. Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

### 9. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

### 10. Protection of Children From Environmental Health Risks

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

### 11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

### 12. Energy Effects

This proposed rule is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

### 13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

### 14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969

(NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves the establishment of a temporary safety zone. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

**Authority:** 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–1082 to read as follows:

### § 165.T05–1082 Safety Zone; Atlantic Intracoastal Waterway, Wrightsville Beach, NC.

(a) *Regulated area.* The following area is a safety zone: This zone includes the waters directly under and 100 yards either side of the U.S. 74/76 Bascule Bridge crossing the Atlantic Intracoastal Waterway, mile 283.1, at Wrightsville Beach, North Carolina (34°13'07" N/ 077°48'46" W).

(b) *Regulations.* The general safety zone regulations found in 33 CFR 165.23 apply to the safety zone created by this temporary section, § 165.T05–1082. In addition the following regulations apply:

(1) All vessels and persons are prohibited from entering this zone, except as authorized by the Coast Guard Captain of the Port North Carolina.

(2) All vessels requiring greater than 50 feet horizontal clearance to safely transit through the U.S. 74/76 Bascule Bridge crossing the Atlantic Intracoastal Waterway, mile 283.1, at Wrightsville

Beach, North Carolina must contact the bridge tender on VHF-FM marine band radio channels 13 and 16 one hour in advance of intended transit.

(3) Persons or vessels requiring entry into or passage within the zone must request authorization from the Captain of the Port North Carolina or his designated representative by telephone at (910) 343-3882 or on VHF-FM marine band radio channel 16.

(4) All Coast Guard assets enforcing this safety zone can be contacted on VHF-FM marine band radio channels 13 and 16.

(5) The operator of any vessel within or in the immediate vicinity of this safety zone shall: (i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign, and

(ii) Proceed as directed by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign.

(c) *Definitions.* (1) Captain of the Port North Carolina means the Commander, Coast Guard Sector North Carolina or any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(2) Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port North Carolina to assist in enforcing the safety zone described in paragraph (a) of this section.

(d) *Enforcement.* The U.S. Coast Guard may be assisted by Federal, State and local agencies in the patrol and enforcement of the zone. (e) Enforcement period. This section will be enforced from 8 p.m. May 1, 2013 through 8 p.m. July 27, 2013 unless cancelled earlier by the Captain of the Port.

Dated: December 21, 2012.

**A. Popiel,**

*Captain, U.S. Coast Guard, Captain of the Port Sector North Carolina.*

[FR Doc. 2013-00513 Filed 1-11-13; 8:45 am]

**BILLING CODE 9110-04-P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 20

[WT Docket No. 10-254; DA 13-6]

### Comment Deadline Extended for Updated Information and Comment on Review of Hearing Aid Compatibility Regulations

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** In this document, the Wireless Telecommunications Bureau (Bureau) extends the time within which to file comments on the Public Notice seeking updated information and comment on review of hearing aid compatibility regulations.

**DATES:** Comments are due on or before January 22, 2013.

**ADDRESSES:** You may submit comments, identified by WT Docket No. 10-254, by any of the following methods:

- *Federal Communications Commission's Web Site:* <http://fjallfoss.fcc.gov/ecfs2/>. Follow the instructions for submitting comments.
- *Mail.*
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: [FCC504@fcc.gov](mailto:FCC504@fcc.gov) or phone: 202-418-0530 or TTY: 202-418-0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Flynn, Spectrum & Competition Policy Division, Wireless Telecommunications Bureau, (202) 418-0612 or by email [Jennifer.Flynn@fcc.gov](mailto:Jennifer.Flynn@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Order in WT Docket No. 10-254, DA 13-6, released January 3, 2013. The full text of the Order is available for public inspection and copying during business hours in the FCC's Reference Information Center, Portals II, 445 12th Street SW., Room CY-A257, Washington, DC 20554. Copies may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc. (BCPI), 445 12th Street SW., Room CY-B402, Washington, DC 20554, 202-488-5300 or 800-378-3160 (voice), 202-488-5562 (TTY), 202-488-5563 (fax), or you may contact BCPI at its Web site: <http://www.BCPIWEB.com>.

When ordering documents from BCPI, please provide the appropriate FCC document number, for example, DA 13-6. The *Comment Deadline Extended for Updated Information and Comment Sought on Review of Hearing Aid Compatibility Regulations Public Notice* is available on the Internet at the Commission's Web site at <http://www.fcc.gov/document/hearing-aid-compatibility-review-additional-comments-sought> and related documents are also available by using the search function for WT Docket No. 10-254 on the Commission's Electronic Comment Filing System (ECFS) Web page at <http://apps.fcc.gov/ecfs/>. To request information in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the FCC's Consumer and Governmental Affairs Bureau at 202-418-0530 (voice) or 202-418-0432 (TTY).

### Summary

1. On November 27, 2012, the Wireless Telecommunications Bureau released a Public Notice in which it granted, on its own motion, an extension of time to file comments in its ongoing review of the wireless hearing aid compatibility rules (77 FR 72294, December 5, 2012). That Public Notice set the deadline for filing comments on January 7, 2013.

2. On December 31, 2012, the law firm of Blooston, Mordkofsky, Dickens, Duffy & Prendergast, LLP (BloostonLaw) filed a request to extend the comment deadline until January 22, 2013. BloostonLaw states that the extension will alleviate the "conflicting time demands" on counsel who must both file comments in this proceeding and prepare Form 655 reports that are due from service providers on January 15, 2013. BloostonLaw further states that the January 7th comment deadline will deprive the Commission and the public of the benefit of comments based on experiences encountered during the Form 655 reporting window.

3. The Commission does not routinely grant extensions of time, 47 CFR 1.46(a). However, given the proximity of the filing deadline to the end of the Form 655 filing window, the Wireless Telecommunications Bureau finds that an extension of time for filing comments is warranted.

### Procedural Matters

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may