

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL ND E5 Lisbon, ND [New]

Lisbon Municipal Airport, ND
(Lat. 46°26'49" N., long. 097°43'42" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Lisbon Municipal Airport.

Issued in Fort Worth, TX, on May 9, 2016.

Robert W. Beck

Manager, Operations Support Group, ATO Central Service Center.

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DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****15 CFR Part 922**

[Docket Number [160413330-6330-01]]

RIN 0648-BF99

Delay of Discharge Requirements for U.S. Coast Guard Activities in Greater Farallones and Cordell Bank National Marine Sanctuaries

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Final rule; delay of effectiveness for discharge requirements with regard to U.S. Coast Guard activities.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) expanded the boundaries of Gulf of the Farallones National Marine Sanctuary (now renamed Greater Farallones National Marine Sanctuary or GFNMS) and Cordell Bank National Marine Sanctuary (CBNMS) to an area north and west of their previous boundaries with a final rule published on March 12, 2015. The final rule entered into effect on June 9, 2015. At that time, NOAA postponed the effectiveness of the discharge requirements in both sanctuaries' regulations in the areas added to GFNMS and CBNMS boundaries in 2015 with regard to U.S. Coast Guard activities for 6 months.

This notice extends the postponement of the discharge requirements for these activities for another 6 months to provide adequate time for completion of an environmental assessment, and subsequent rulemaking, as appropriate.

DATES: The effectiveness for the discharge requirements in both CBNMS and GFNMS expansion areas with regard to U.S. Coast Guard activities is December 9, 2016.

ADDRESSES: Copies of the FEIS, final management plans, and the final rule published on March 12, 2015, can be viewed or downloaded at http://farallones.noaa.gov/manage/expansion_cbgf.html.

FOR FURTHER INFORMATION CONTACT: Maria Brown, Greater Farallones National Marine Sanctuary Superintendent, at Maria.Brown@noaa.gov or 415-561-6622.

SUPPLEMENTARY INFORMATION:**I. Background**

On March 12, 2015, NOAA expanded the boundaries of Gulf of the Farallones National Marine Sanctuary (now renamed Greater Farallones National Marine Sanctuary or GFNMS) and Cordell Bank National Marine Sanctuary (CBNMS) to an area north and west of their previous boundaries with a final rule (80 FR 13078). The final rule entered into effect on June 9, 2015 (80 FR 34047). To ensure that the March 12, 2015, rule does not undermine USCG's ability to perform its duties, at that time, NOAA postponed the effectiveness of the discharge requirements in both sanctuaries' regulations with regard to U.S. Coast Guard (USCG) activities for 6 months. An additional six month postponement of the effectiveness of the discharge requirements was published in the **Federal Register** on December 1, 2015 (80 FR 74985), to provide adequate time for completion of an environmental assessment and to determine NOAA's next steps. Without further NOAA action, the discharge regulations would become effective with regard to USCG activities June 9, 2016. However, NOAA needs more time to assess USCG activities, conduct public scoping, and develop alternatives for an environmental assessment developed pursuant to the requirements of the National Environmental Policy Act. Therefore, this notice postpones the effectiveness of the discharge requirements in the expansion areas of both sanctuaries with regard to USCG activities for another 6 months, until December 9, 2016. During this time, NOAA will consider how to address USCG's concerns and will consider, among other things, whether to exempt

certain USCG activities in sanctuary regulations. The public, other federal agencies, and interested stakeholders will be given an opportunity to comment on various alternatives that are being considered. This will include the opportunity to review any proposed rule and related environmental analysis. In the course of the rule making to expand GFNMS and CBNMS, NOAA learned from USCG that the discharge regulations had the potential to impair the operations of USCG vessels and air craft conducting law enforcement and on-water training exercises in GFNMS and CBNMS. The USCG supports national marine sanctuary management by providing routine surveillance and dedicated law enforcement of the National Marine Sanctuaries Act and sanctuary regulations.

II. Classification**A. National Environmental Policy Act**

NOAA previously conducted an environmental analysis under the National Environmental Policy Act (NEPA) as part of the rulemaking process leading to the expansion of CBNMS and GFNMS, which addressed regulations regarding the discharge of any matter or material in the sanctuaries. The environmental impacts of the decision to postpone effectiveness reflect a continuation of the environmental baseline and the no action alternative presented in that analysis. Should NOAA decide to amend the regulations governing discharges for USGS activities in CBNMS and GFNMS, any additional environmental analysis required under NEPA would be prepared and released for public comment.

B. Executive Order 12866: Regulatory Impact

This action has been determined to be not significant for purposes of the meaning of Executive Order 12866.

C. Administrative Procedure Act

The Assistant Administrator of National Ocean Service (NOS) finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive the notice and comment requirements of the Administrative Procedure Act (APA) because this action is administrative in nature. This action postpones the effectiveness of the discharge requirements in the regulations for CBNMS and GFNMS in the areas added to the sanctuaries' boundaries in 2015 (subject to notice and comment review) with regard to U.S. Coast Guard activities for 6 months to provide adequate time for public scoping,

completion of an environmental assessment, and subsequent rulemaking, as appropriate. Should NOAA decide to amend the regulations governing discharges in CBNMS and GFNMS, it would publish a proposed rule followed by an appropriate public comment period as required by the APA. The substance of the underlying regulations remains unchanged. Therefore, providing notice and opportunity for public comment under the Administrative Procedure Act would serve no useful purpose. The delay in effectiveness provided by this action will also enable NOAA to fully implement its statutory responsibilities under the NMSA to protect resources of a national marine sanctuary. For the reasons above, the Assistant Administrator also finds good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness and make this action effective immediately upon publication.

Authority: 16 U.S.C. 1431 *et seq.*

Dated: May 24, 2016.

Christopher C. Cartwright,

Acting, Deputy Assistant Administrator for Ocean Services and Coastal Management.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA-2016-N-1268]

Medical Devices; Ophthalmic Devices; Classification of the Diurnal Pattern Recorder System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the diurnal pattern recorder system into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the diurnal pattern recorder system's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective May 31, 2016. The classification was applicable on March 4, 2016.

FOR FURTHER INFORMATION CONTACT: Alexander Beylin, Center for Devices

and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2404, Silver Spring, MD 20993-0002, 301-796-6463.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the

device submitted is not of "low-moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On April 28, 2014, Sensimed AG submitted a request for classification of the SENSIMED Triggerfish® device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 4, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 886.1925.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a diurnal pattern recorder system will need to comply with the special controls named in this final order.

The device is assigned the generic name diurnal pattern recorder system, and it is identified as a nonimplantable, prescription device incorporating a telemetric sensor to detect changes in ocular dimension for monitoring diurnal patterns of intraocular pressure (IOP) fluctuations.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks in Table 1: