

SUPPLEMENTARY INFORMATION: FDA is amending our regulations in 21 CFR part 860 that set forth procedures for mailing reclassification petitions (§ 860.123 (21 CFR 860.123)) to revise the mailing address for CDRH. The current mailing address in the regulation for CDRH is as follows: Center for Devices and Radiological Health, Regulations Staff, 10903 New Hampshire Ave., Bldg. 66, Rm. 4438, Silver Spring, MD 20993-0002. The room number, 4438, has been changed; the new room number is G609. The mailing address is revised as follows: Center for Devices and Radiological Health, Regulations Staff, Document Mail Center-WO66-G609, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

Sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(e) and (f); 360d(b); 360e(b), and 360j(l)), provide for the reclassification of a device and prescribe procedures to petition for reclassification. FDA provides procedures for the content and form of reclassification petitions submitted pursuant to § 860.123(b)(1) for devices regulated by CDRH. The address for submitting a reclassification petition for devices regulated by CDRH in § 860.123(b)(1) is amended to reflect the new room number. The addresses remain the same for the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research.

List of Subjects in 21 CFR Part 860

Administrative practice and procedure, 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 860 is amended as follows:

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

■ 1. The authority citation for part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

■ 2. Revise § 860.123(b)(1) to read as follows:

§ 860.123 Reclassification petition: Content and form.

* * * * *

(b) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Regulations Staff,

Document Mail Center-WO66-G609, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002; for devices regulated by the Center for Biologics Evaluation and Research, addressed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002; for devices regulated by the Center for Drug Evaluation and Research, addressed to the Food and Drug Administration, Center for Drug Evaluation and Research, Central Document Control Room, 5901-B Ammendale Rd., Beltsville, MD 20705-1266, as applicable.

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Dated: August 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-17564 Filed 8-18-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2017-0699]

RIN 1625-AA00

Safety Zone: PG&E Evolution, King Salmon, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of Humboldt Bay in King Salmon, CA in support of the Pacific Gas and Electric Evolution that will be effective on August 2, 2017 and on August 30, 2017. This safety zone is established to ensure the safety of workers, mariners, and other vessels transiting the area from the dangers associated with this evolution. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or their designated representative. **DATES:** This rule is effective without actual notice from August 21, 2017 until August 30, 2017. For the purposes of enforcement, actual notice will be used from August 2, 2017, until August 21, 2017.

This rule is being enforced from 8 a.m. to 4 p.m. on August 2, 2017 and from 8 a.m. to 4 p.m. on August 30, 2017.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG-2017-0699. To view these documents go to <http://www.regulations.gov>, type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Marcia Medina, U.S. Coast Guard Sector San Francisco; telephone (415) 399-7443 or email at D11-PF-MarineEvents@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

APA Administrative Procedures Act
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NAD North American Datum of 1983
NPRM Notice of Proposed Rulemaking
PG&E Pacific Gas & Electric
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Due to the date of the event, notice and comment procedures would be impracticable in this instance.

For similar reasons as those stated above, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Legal Authority and Need for Rule

The legal basis for the proposed rule is 33 U.S.C 1231; 50 U.S.C. 191; 33 CFR 1.05-1, 6.04-1, 6.04-6, 160.5; Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish safety zones.

The Pacific Gas and Electric Company will sponsor the Pacific Gas and Electric Evolution on August 2, 2017 and on August 30, 2017, in the navigable waters of Humboldt Bay in King Salmon, CA. The evolution is necessary to complete an inspection and for re-licensing purposes. The evolution is scheduled to take place on August 2, 2017 and on

August 30, 2017. The Coast Guard believes that a safety zone is necessary to provide for the safety of workers, mariners, and other vessels transiting the area due to the danger posed by the inspection of the dynamic fuel storage installation. This restricted area will apply to all vessels transiting the specified area.

IV. Discussion of the Rule

For the reasons stated above, the Coast Guard is establishing a safety zone for the duration of the event. Upon commencement of the evolution, the safety zone will encompass the navigable waters of Humboldt Bay within a 300 meter radius of position: 40°44'31" N., 124°12'39" W. (NAD83). The safety zone is issued to establish a temporary restricted area on the waters surrounding the evolution. The Coast Guard or a designated representative will enforce a safety zone in navigable waters of Humboldt Bay within a 300 meter radius of position: 40°44'31" N., 124°12'39" W. (NAD83) during the evolution. The evolution is necessary to complete an inspection and for relicensing purposes is scheduled to take place on August 2, 2017 and on August 30, 2017. At the conclusion of the evolution the safety zone shall terminate.

The effect of the temporary safety zone will be to restrict navigation in the vicinity of the evolution. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the restricted area. These regulations are needed to keep mariners and vessels away from the immediate vicinity of the evolution to ensure the safety of workers, mariners, and other vessels transiting the area.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not

been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because it is outside of the Fields Landing Channel and the public will be notified via a Broadcast Notice to Mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which may be small entities: Owners and operators of waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities and sightseeing, if these facilities or vessels are in the vicinity of the safety zone at times when this zone is being enforced. This rule will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) This rule will encompass only a small portion of the waterway for a limited period of time, (ii) vessel traffic can transit safely around the safety zone, and (iii) the maritime public will be advised in advance of this safety zone via Broadcast Notice to Mariners.

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 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** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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 rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. 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 rule will not result in such an expenditure,

we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have determined 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 rule involves a safety zone of limited size and duration. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2-1 of the Commandant Instruction. A Record of Environmental Consideration is available in the docket for this rulemaking. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. 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.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 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; 50 U.S.C. 191; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11-867 to read as follows:

§ 165.T11-867 Safety Zone; PG&E Evolution, King Salmon, CA.

(a) *Location.* This temporary safety zone is established for the navigable waters of Humboldt Bay in King Salmon, California as depicted in National Oceanic and Atmospheric Administration (NOAA) Chart 18622. The safety zone will encompass the

navigable waters of Humboldt Bay within a 300 meter radius of position: 40°44'31" N., 124°12'39" W. (NAD83).

(b) *Enforcement period.* The zone described in paragraph (a) of this section will be enforced from 8 a.m. until 4 p.m. on August 2, 2017 and from 8 a.m. until 4 p.m. on August 30, 2017. The Captain of the Port San Francisco (COTP) will notify the maritime community of periods during which this zone will be enforced via Broadcast Notice to Mariners in accordance with 33 CFR 165.7.

(c) *Definitions.* As used in this section, "designated representative" means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer on a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the COTP in the enforcement of the safety zone.

(d) *Regulations.* (1) Under the general regulations in 33 CFR part 165, subpart C, entry into, transiting or anchoring within this safety zone is prohibited unless authorized by the COTP or a designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or a designated representative. Persons and vessels may request permission to enter the safety zone through the 24-hour Command Center at telephone (415) 399-3547 or on VHF channel 16.

Dated: August 1, 2017.

Anthony J. Ceraolo,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2017-0387; FRL-9966-34-Region 4]

Air Plan Approval; SC: Miscellaneous Revisions to Multiple Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve changes to the South Carolina State Implementation Plan (SIP) to revise several miscellaneous rules, covering definitions, source tests, credible evidence, open burning, air pollution episodes, and fugitive particulate matter. EPA is approving portions of SIP revisions submitted by the State of South Carolina, through the South Carolina Department of Health and Environmental Control (SC DHEC) on the following dates: July 18, 2011, June 17, 2013, April 10, 2014, August 8, 2014, January 20, 2016, and July 27, 2016. These actions are being taken pursuant to the Clean Air Act.

DATES: This direct final rule is effective October 20, 2017 without further notice, unless EPA receives adverse comment by September 20, 2017. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2017-0387 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

D. Brad Akers, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Mr. Akers can be reached via telephone at (404) 562-9089 or via electronic mail at akers.brad@epa.gov.

SUPPLEMENTARY INFORMATION: