

To: Jackson, Ryan[jackson.ryan@epa.gov]
From: Bloomberg BNA
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EHS Federal Regulatory Alert

October 23, 2017 - Number 203

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Summaries

AIR

Acid Rain Program/Excess Emissions Penalty Adjustment

AIR

Notice of the EPA announces the availability of the annual adjustment factors for excess emissions penalties for failure to comply with certain requirements of the Acid Rain Program. The program limits annual sulfur dioxide and nitrogen oxide emissions of fossil fuel-fired utility units. The excess penalty provisions require units that exceed those limits to pay a penalty based on the number of excess tons emitted times \$2,000, as adjusted by an annual adjustment factor. The annual adjustment factors for compliance years 2017 and 2018 are 1.9330 and 1.9705, respectively. Contact: Robert Miller; EPA, Clean Air Markets Division; 202-343-9077; miller.robertl@epa.gov. Citations: 40 CFR 77.6(b)

82 FR 49020 (10/23/2017)

Regulatory Update

AIR

California SIP/San Joaquin Valley PM-2.5 Nonattainment Area

AIR

Proposed rule of the EPA would determine that the deficiency that formed the basis for the May 12, 2016, (81 FR 29498) disapproval of contingency measures submitted for the San Joaquin Valley nonattainment area for the 1997 fine particulate matter (PM-2.5) NAAQS has been corrected. The rule also would approve revisions to the California SIP that establish standards and other requirements for the control of emissions from new on-road and new and in-use off-road vehicles and engines. If finalized, the rule would permanently stop the sanctions clocks that were triggered by the prior disapproval, including offset sanctions that would apply Dec. 13, 2017, and highway sanctions that would apply June 13, 2018. Comments are due Nov. 22, 2017. Contact: Rory Mays; EPA Region 9; 415-972-3227; mays.rory@epa.gov. Citations: 40 CFR 52

82 FR 48944 (10/23/2017)

Regulatory Update

AIR

New York SIP and FIP/Roseton Generating Station

AIR

Proposed rule of the EPA would approve a revision to the New York SIP and withdraw specified federal implementation plan (FIP) provisions for regional haze. The revision establishes best available retrofit technology (BART) emission limits for sulfur dioxide at the Roseton Generating Station, Units 1 and 2, that are equivalent to emission limits set by the FIP. Those portions of the FIP addressing BART for the Roseton units would be withdrawn. Comments are due Nov. 22, 2017. Contact: Irene Nielson; EPA Region 2, Air Programs Branch; 212-637-3586; nielson.irene@epa.gov. Citations: 40 CFR 52

82 FR 48942 (10/23/2017)

Regulatory Update

ENDANGERED SPECIES

Threatened Status for the Chambered Nautilus

ENDANGERED SPECIES

Proposed rule of the National Marine Fisheries Service would list the chambered nautilus as a threatened species. The proposal is in response to the agency's 12-month finding on a petition from the Center for Biological Diversity. Hearing requests are due Dec. 7, 2017. Comments are due Dec. 22, 2017. Contact: Maggie Miller; NMFS, Office of Protected Resources; 301-427-8403. Citations: 50 CFR 223.102

82 FR 48948 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Alaska/Sand Point City Dock Replacement Project

GENERAL ENVIRONMENT AND SAFETY

Notice of the National Marine Fisheries Service announces the issuance of an incidental harassment authorization to the Alaska Department of Transportation and Public Facilities for authorization to take marine mammals that may be affected by the construction of a new dock in Sand Point, Alaska. The authorization allows take of nine species of marine mammals by levels A and B harassment. The authorization is effective Aug. 1, 2018, and expires July 31, 2019. Contact: Rob Pauline; NMFS, Office of Protected Resources; 301-427-8401; ITP.pauline@noaa.gov

82 FR 48987 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Determination Concerning Safety and Effectiveness/Elavil

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination that Elavil (amitriptyline hydrochloride) oral tablets, 10 milligrams (mg), 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, held by AstraZeneca of Cambridge, U.K., was not withdrawn from sale for reasons of safety or effectiveness. The determination provides that the FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to the drug product and will allow the FDA continue to approve ANDAs that refer to the product if relevant legal and regulatory requirements are met. Contact: Stacy Kane; FDA, Center for Drug Evaluation and Research; 301-796-8363; stacy.kane@fda.hhs.gov

82 FR 49032 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Guidance on Generic Methylphenidate Hydrochloride

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of draft guidance for industry to provide product-specific recommendations on the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for generic methylphenidate hydrochloride oral extended-release tablets. The guidance is issued in response to a petition from KVK-Tech Inc., of Newtown, Pa., manufacturer of the reference listed drug Ritalin-SR, requesting that the FDA not accept for filing any new ANDAs or approve any already received ANDAs for such generic tablets unless certain bioequivalence criteria are met. Comments are due Dec. 22, 2017. Contact: Xiaoqiu Tang; FDA, Center for Drug Evaluation and Research; 301-796-5850

82 FR 49033 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Nevada/Paiute Pipeline 2018 Expansion Project

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces the schedule for environmental review for the 2018 Expansion Project proposed by Paiute Pipeline Co. of Las Vegas. The project involves the installation of 4.61 miles of pipeline and the replacement of 3.85 miles of pipeline in Douglas and Lyon counties and Carson City, Nev. The project will provide incremental firm transportation services of 5,635 dekatherms per day on Paiute's system. The issuance of the environmental assessment is scheduled for Nov. 27, 2017, and the federal authorization decision is due Feb. 25, 2018. Contact: FERC, Office of External Affairs; 866-208-3676; FERCOOnlineSupport@ferc.gov

82 FR 49011 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Ohio/Buckeye Xpress Project

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of FERC to prepare an environmental assessment for the Buckeye Xpress Project in Gallia, Jackson, Lawrence, and Vinton counties in Ohio. The project, proposed by Columbia Gas Transmission LLC, of Houston, involves the installation of 65.7 miles of 36-inch diameter natural gas pipeline and abandonment of 60.8 miles of 20- and 24-inch diameter natural gas pipeline to provide about 275,000 dekatherms per day of additional firm natural gas transportation capacity. The agency's preliminary list of environmental issues includes impacts on water resources and endangered species. Meetings are scheduled for Oct. 24 and 25, 2017, in Ironton and Jackson, Ohio, respectively. Comments are due Nov. 16, 2017. Contact: FERC, Office of External Affairs; 866-208-3676; FERCOOnlineSupport@ferc.gov

82 FR 49012 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Oregon/Jordan Cove Energy and Pacific Connector Gas Pipeline Projects

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces a meeting with representatives of the Confederated Tribes of Grand Ronde to discuss the proposed Jordan Cove LNG Terminal and Pacific Connector Pipeline Projects in Coos, Douglas, Jackson, and Klamath counties in Oregon. The meeting is scheduled for Oct. 24, 2017, via teleconference. Contact: John Peconom; FERC; 202-502-6352; john.peconom@ferc.gov

82 FR 49016 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Oregon/Prospect No. 3 Hydroelectric Project

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC, Office of Energy Projects, announces the availability of a draft environmental assessment for the new license application by PacifiCorp Energy, of Medford, Ore., for the Prospect No. 3 Hydroelectric Project on the South Fork Rogue River in Jackson County, Ore. The existing project, which occupies federal land in the Rogue River-Siskiyou National Forest, includes a concrete diversion dam and spillway, a reservoir, a powerhouse, a transmission line, and a fish passage ladder that produces an average of 35.05 gigawatt-hours annually. The proposed revisions would upgrade certain facilities, increase the project's minimum flow releases and ramping rate limits, and extend the project boundary. The EA concludes that relicensing the project, with appropriate measures, would not constitute a major federal action significantly affecting the quality of the human environment. Comments are due Dec. 1, 2017. Contact: Dianne Rodman; FERC; 202-502-6077

82 FR 49015 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Regulatory Review Period/Inspire Upper Airway Stimulation System

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the Inspire Upper Airway Stimulation System medical device in response to an application submitted by Inspire Medical Systems Inc., of Maple Grove, Minn. The device is indicated for treatment of a subset of patients with moderate to severe obstructive sleep apnea. Comments are due Dec. 22, 2017. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due April 23, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 49029 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Regulatory Review Period/Mitraclip CDS

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the Mitraclip CDS medical device in response to an application submitted by Abbott Vascular Inc., of Santa Clara, Calif., and the Trustees of Columbia University. The device is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation due to primary abnormality of the mitral apparatus in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. Comments are due Dec. 22, 2017. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due April 23, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 49027 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Regulatory Review Period/Obizur

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the human drug product Obizur [antihemophilic factor (recombinant), porcine sequence (rpFVIII)] in response to patent term restoration applications from Emory University, Baxter International Inc., and Baxter Healthcare SA. The product is indicated for the treatment of bleeding episodes in adults with acquired hemophilia A. Comments are due Dec. 22, 2017. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due April 23, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 49031 (10/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

West Virginia/Rover Pipeline Project
GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces the schedule for environmental review for an amended application submitted by Rover Pipeline LLC, of Houston, for the Rover Pipeline Project in Marshall County, W.Va. The project would involve construction and operation of facilities at the previously approved and under construction Majorsville Compressor Station. A third 3,550-horsepower natural gas compressor unit would be installed at the compressor station, and new equipment would be run at the Majorsville Meter Station, which would bring the station to a total of 10,650 horsepower. The proposed facilities also would increase the point capacity of the stations to 400 million cubic feet per day. The issuance of the environmental assessment is scheduled for Nov. 1, 2017, and the federal authorization decision is due Jan. 30, 2018. Contact: FERC, Office of External Affairs; 866-208-3676; FERCONlinesupport@ferc.gov

82 FR 49011 (10/23/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH
Coal Mine Refuse Piles and Impoundment Structures
OCCUPATIONAL SAFETY AND HEALTH

Notice of the Mine Safety and Health Administration announces the submission of a continuing information collection request regarding coal mine operator recordkeeping and reporting requirements for refuse piles and impoundment structures. The collection addresses requirements for operators to submit an annual report and certification on refuse piles and impoundments and to keep records of the results of weekly examination and instrumentation monitoring. Comments are due Nov. 22, 2017. Contact: Sheila McConnell; MSHA, Office of Standards, Regulations and Variances; 202-693-9440; DOL_PRA_PUBLIC@dol.gov. Citations: 30 CFR 77.215, 77.216

82 FR 49043 (10/23/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH
Nationally Recognized Testing Laboratories/TUVRNA
OCCUPATIONAL SAFETY AND HEALTH

Notice of OSHA announces a final decision to grant an application from TUV Rheinland of North America Inc. (TUVRNA), of Newtown, Conn., for expansion and reduction of its scope of recognition as a nationally recognized testing laboratory. The expansion involves the addition of the test standard for electric vehicle charging system equipment to its scope of recognition. The reduction involves the removal of the standard for intrinsically safe apparatus and associated apparatus for use in Class I, II, and III, Division 1, hazardous (classified) locations. The decision is effective Oct. 23, 2017. Contact: Kevin Robinson; OSHA, Directorate of Technical Support and Emergency Management; 202-693-2110; robinson.kevin@dol.gov. Citations: 29 CFR 1910.7

82 FR 49043 (10/23/2017)

Regulatory Update

PESTICIDES

Pesticide Tolerance Petitions

PESTICIDES

Notice of the EPA announces the receipt of initial filings of petitions to establish new and amended tolerances and exemptions for residues of certain pesticides in or on various food commodities. The notice includes 26 filings for new and amended tolerances and tolerance exemptions for inert and noninert ingredients. Comments are due Nov. 22, 2017. Contact: Robert McNally; EPA, Office of Pesticide Programs; 703-305-7090; BPPDFRNotices@epa.gov. Citations: 40 CFR 180

82 FR 49020 (10/23/2017)

Regulatory Update

TOXIC SUBSTANCES

TSCA Premanufacture and Notice of Commencement

TOXIC SUBSTANCES

Notice of the EPA announces the availability of receipt and status information regarding 42 premanufacture notices and 13 notices of commencement to manufacture new chemicals received by the agency from Aug. 1-31, 2017. Comments are due Nov. 22, 2017. Contact: Jim Rahai; EPA, Office of Pollution Prevention and Toxics; 202-564-8593; rahai.jim@epa.gov

82 FR 49016 (10/23/2017)

Regulatory Update

WATER

Alaska/Cruise Vessel Sewage and Graywater Discharge Records

WATER

Notice announces the intention of the U.S. Coast Guard to seek OMB approval for a continuing information collection request regarding sewage and graywater discharge records for certain cruise vessels operating on Alaskan waters. The collection addresses requirements for vessel owners, operators, and masters to sample and test sewage and graywater discharges and related reporting and recordkeeping. Comments are due Dec. 22, 2017. Contact: Anthony Smith; USCG, Office of Information Management; 202-475-3532. Citations: 33 CFR 159, Subpart E

82 FR 49037 (10/23/2017)

Regulatory Update

WATER

Alternative Compliance for International and Inland Navigation Rules

WATER

Notice of the U.S. Coast Guard announces the submission of a continuing information collection request to the OMB regarding alternative compliance for international and inland navigation rules. The collection allows owners, operators, builders, or agents of a unique vessel to present

reasons why the vessel cannot comply with existing international and inland navigation rules and how alternative compliance can be met. Comments are due Nov. 22, 2017. Contact: Anthony Smith; USCG, Office of Information Management; 202-475-3532. Citations: 33 CFR 81 through 89

82 FR 49036 (10/23/2017)

Regulatory Update

WATER

Department of State International Maritime Organization Meeting

WATER

Notice of the State Department announces a meeting to prepare for three sessions of the International Maritime Organization, including the 29th Extraordinary Council Session (CES29) scheduled for Nov. 23-24, 2017; the 30th Assembly (A30) scheduled for Nov. 27-Dec. 6, 2017; and the 119th Council Session scheduled for Dec. 7, 2017. All three sessions will be held in London. The notice includes possible agenda items for the meetings, including CES29 discussions on resource management and prevention of marine pollution by dumping of wastes and other matter and A30 discussions on committee recommendations and reports. The meeting is scheduled for Nov. 14, 2017, in Washington, D.C. Contact: Staci Weist; 202-372-1376; eustacia.y.weist@uscg.mil

82 FR 49074 (10/23/2017)

Regulatory Update

WATER

Safety Approval of Cargo Containers

WATER

Notice announces the intention of the U.S. Coast Guard to seek OMB approval for a continuing information collection request concerning safety approval of cargo containers. The collection addresses reporting and recordkeeping requirements for owners and manufacturers of cargo containers concerning approval and inspection of such containers. Comments are due Dec. 22, 2017. Contact: Anthony Smith; USCG, Office of Information Management; 202-475-3532. Citations: 49 CFR 450, 451, 452, 453

82 FR 49038 (10/23/2017)

Regulatory Update

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