

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

June 15, 2017 - Number 114

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Summaries

AIR

California SIP/Placer County APCD

AIR

Proposed rule of the EPA amends regulations under 40 CFR 52 to approve revisions to the Placer County Air Pollution Control District (APCD) portion of the California SIP. The revisions concern the district's demonstration regarding reasonably available control technology (RACT) requirements for the 1997 and 2008 eight-hour ozone NAAQS and negative declarations for the polyester resin control techniques guidelines for the 2008 eight-hour ozone standard. Comments are due July 17, 2017. Contact: Nicole Law; EPA Region 9; 415-947-4126; law.nicole@epa.gov

82 FR 27456 (06/15/2017)

Regulatory Update

AIR

California SIP/South Coast Air Quality Management District

AIR

Proposed rule of the EPA amends regulations under 40 CFR 52 to approve revisions to the South Coast Air Quality Management District portion of the California SIP. The revisions concern the district's demonstration of reasonably available control technology requirements for the 2008 eight-hour ozone NAAQS in the South Coast Air Basin and Coachella Valley ozone nonattainment areas under the nitrogen oxides Regional Clean Air Incentives Market (RECLAIM) program. The revisions supplement a prior RACT submission and include additional emissions analysis, two negative declarations, and certain conditions from permits for two specific stationary sources located in Coachella Valley. The EPA also is withdrawing a Nov. 3, 2016, proposed rule (81 FR 76547) that would have partially approved and partially disapproved the RACT SIP demonstration. The proposed approval is based on a draft version of the RACT supplement that was submitted by the California Air Resources Board, and final approval will not be granted until the supplement is adopted and submitted to the EPA. Comments are due July 17, 2017. Contact: Stanley Tong; EPA Region 9; 415-947-4122; tong.stanley@epa.gov

82 FR 27451 (06/15/2017)

Regulatory Update

AIR

Tennessee SIP/Visibility Transport Infrastructure Requirements

AIR

Final rule of the EPA adopts regulations under 40 CFR 52.2219 to conditionally approve portions of revisions to the Tennessee SIP. The revisions address the visibility transport (prong 4) infrastructure requirements for the 2010 one-hour nitrogen dioxide, the 2010 one-hour sulfur dioxide, and the 2012 annual fine particulate matter NAAQS. The rule is effective July 17, 2017. Contact: Sean Lakeman; EPA Region 4, Air, Pesticides and Toxics Management Division; 404-562-9043; lakeman.sean@epa.gov

82 FR 27428 (06/15/2017)

Regulatory Update

ENDANGERED SPECIES

California/Monterey Bay Marine Mammals Incidental Take

ENDANGERED SPECIES

Final rule of the National Oceanic and Atmospheric Administration, National Marine Fisheries Service, amends regulations under 50 CFR 217.11 through 217.18 to allow for issuance of letters of authorization for the take of marine mammals incidental to commercial fireworks displays permitted by the Monterey Bay National Marine Sanctuary in California. The rule authorizes take of small numbers of California sea lions and harbor seals by Level B harassment in the Cambria, Half Moon Bay, Monterey Peninsula, and Santa Cruz/Soquel regions from 2017 through 2022. The rule extends current incidental take authorizations under a May 29, 2012, final rule (77 FR 31537) from June 28, 2017, through July 3, 2022. The rule is effective July 4, 2017. Contact: Laura McCue; NMFS, Office of Protected Resources; 301-427-8401

82 FR 27434 (06/15/2017)

Regulatory Update

FOOD SAFETY

Animal Generic Drug User Fee Act Cover Sheet

FOOD SAFETY

Notice of the Food and Drug Administration announces the submission of a continuing information collection request to the OMB regarding the Animal Generic Drug User Fee Act cover sheet (FDA Form 3728). The collection addresses fees for certain types of abbreviated applications for generic new animal drugs, annual fees for certain generic new animal drug products, and annual fees for certain sponsors of abbreviated applications for new animal drugs and/or investigational submissions for generic new animal drugs. The collection also provides information to determine whether a fee is required for an application, to determine the amount of the fee required, and to account for and track user fees. Comments are due July 17, 2017. Contact: Ila Mizrahi; FDA, Office of Operations; 301-796-7726; PRASStaff@fda.hhs.gov

82 FR 27512 (06/15/2017)

Regulatory Update

FOOD SAFETY

Food Labeling

FOOD SAFETY

Notice of the Food and Drug Administration announces the submission of a continuing information collection request to the OMB concerning food labeling requirements and exemptions from such requirements for small businesses (21 CFR 101, 102, 104, and 105). The collection addresses requirements for food producers to disclose specific information on the label of a product, to retain records concerning the basis for the information contained in the label, and to submit food labeling petitions to the FDA. The collection also addresses small business exemption claims (FDA 3570), requirements for restaurants to provide nutrition information upon request, requirements concerning certain nutrient claims, and requirements for dietary supplements. Comments are due July 17, 2017. Contact: Ila Mizrachi; FDA, Office of Operations; 301-796-7726

82 FR 27504 (06/15/2017)

Regulatory Update

FOOD SAFETY

Human Food and Cosmetics Manufactured with Cattle Material

FOOD SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding human food and cosmetics manufactured from, processed with, or containing material from cattle. The collection addresses the recordkeeping and reporting requirements for manufacturers, processors, and importers of FDA regulated human food, dietary supplements, and cosmetics to ensure such products do not contain prohibited cattle materials, including specified risk materials, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, and mechanically separated beef (21 CFR 189.5 and 700.27). Comments are due Aug. 14, 2017. Contact: Ila Mizrachi; FDA, Office of Operations; 301-796-7726

82 FR 27501 (06/15/2017)

Regulatory Update

FOOD SAFETY

Infant Formula Recall Requirements

FOOD SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request concerning infant formula recall requirements (21 CFR 107). The collection addresses reporting and recordkeeping requirements that allow the agency to monitor the effectiveness and speed of recalls in order to protect babies from products that may be unsafe because of contamination, nutritional inadequacy, misbranding, or other

adulteration. Comments are due Aug. 14, 2017. Contact: Ila Mizrachi; FDA, Office of Operations; 301-796-7726; PRAStaff@fda.hhs.gov

82 FR 27509 (06/15/2017)

Regulatory Update

FOOD SAFETY

Temporary Market Permits/Experimental Packs of Food

FOOD SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding temporary market permits to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions or standards of identity (21 CFR 130.17). The collection addresses agency monitoring of the manufacture, labeling, and distribution of experimental packs of food to be used to support petitions to establish or revise applicable definitions or standards of identity. The collection also addresses requirements for firms to submit certain information to obtain an extension of a temporary marketing permit. Comments are due Aug. 14, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794; PRAStaff@fda.hhs.gov

82 FR 27489 (06/15/2017)

Regulatory Update

FOOD SAFETY

U.S. Milk Product Manufacturers and Processors with Interest in Exporting

FOOD SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request concerning lists of U.S. milk product manufacturers and processors with interest in exporting. The collection addresses the voluntary submission of information for and maintenance of a list of manufacturers and processors with an interest in exporting their products that are subject to FDA jurisdiction and are not the subject of a pending enforcement action. The notice specifies that the list currently provides the information for use by Chile, China, and the European Union member countries. Comments are due Aug. 14, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794

82 FR 27485 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Alaska/Marine Mammals Incidental Take

GENERAL ENVIRONMENT AND SAFETY

Notice of the National Oceanic and Atmospheric Administration, National Marine Fisheries Service, announces the issuance of a letter of authorization to Alaska Aerospace Corp. for the take of marine mammals incidental to space vehicle and missile launch operations at the Pacific Spaceport Complex Alaska on Kodiak Island, Alaska. The letter allows the incidental take of

harbor seals during the same type and amount of activities as specified in a March 24, 2017, final rule (82 FR 14996). The authorization is effective May 11, 2017, through April 25, 2022. Contact: Stephanie Egger; NMFS, Office of Protected Resources; 301-427-8401

82 FR 27472 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

California/Shasta Dam Fish Passage Evaluation

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Department of Interior, Bureau of Reclamation, to prepare an environmental impact statement for the Shasta Dam Fish Passage Evaluation. The project includes a pilot program concerning the near-term reintroduction of federally listed endangered winter-run and potentially spring-run Chinook salmon into historical habitat on the Shasta Lake and the Sacramento and McCloud rivers in Shasta and Siskiyou counties in California. The pilot program will implement the near-term actions identified in the National Marine Fisheries Service's 2009 biological opinion and conference opinion on the long-term operation of the Central Valley Project and the State Water Project reasonable and prudent alternative. Meetings are scheduled for June 27 and 28, 2017, in Sacramento and Lakehead, respectively. Comments are due July 21, 2017. Contact: Carolyn Bragg; Bureau of Reclamation; 916-414-2433; cbragg@usbr.gov

82 FR 27522 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Drug Regulatory Review Period/Natpara

GENERAL ENVIRONMENT AND SAFETY

Notice of the Food and Drug Administration announces a determination of the regulatory review period for the human biological product Natpara (parathyroid hormone (recombinant human)) in response to an application submitted by NPS Pharmaceuticals Inc., of Bedminster, N.J. The notice specifies that the product is an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. Comments are due Aug. 14, 2017. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due Dec. 12, 2017. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 27496 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

FDA Consumer Advisory Committees and Panels Nominations

GENERAL ENVIRONMENT AND SAFETY

Notice of the Food and Drug Administration announces a request for nominations for voting and nonvoting consumer representatives on numerous advisory committees and panels. The agency also seeks to identify consumer organizations interested in participating in the selection of

advisory committee or panel members. Nominations and notifications are due July 17, 2017. Contact: Kimberly Hamilton; FDA, Advisory Committee Oversight and Management Staff; 301-796-8220; kimberly.hamilton@fda.hhs.gov

82 FR 27497 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

FDA Qualitative Feedback on Agency Service Delivery

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding generic clearance for the collection of qualitative feedback on agency service delivery. The collection concerns feedback from customers and stakeholders about perceptions, experiences, expectations, early warning of issues with services, and potential changes to improve the delivery of products or services. Comments are due Aug. 14, 2017. Contact: Amber Sanford; FDA, Office of Operations; 301-796-8867; PRASStaff@fda.hhs.gov

82 FR 27508 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Food Labeling State Petitions for Exemption From Preemption

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request concerning state petitions for exemption from federal preemption of state food labeling and standard-of-identity requirements (21 CFR 100.1). The collection addresses agency's process for determining whether a state food labeling or standard-of-identity requirement satisfies statutory criteria for granting an exemption. Comments are due Aug. 14, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794; PRASStaff@fda.hhs.gov

82 FR 27491 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Human Drug Compounding Outsourcing Facility Registration

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding industry guidance on fees for human drug compounding outsourcing facilities. The collection, as described in the guidance, addresses required fees that entities seeking to register as outsourcing facilities must pay, required fee adjustments, the submission of payment to the FDA, the consequences for failure to pay fees, the way an outsourcing facility may qualify as a small business to obtain a reduction in fees, and the process for facility reconsideration requests. Comments are due Aug. 14, 2017. Contact: Domini

Bean; FDA, Office of Operations; 301-796-5733; PRAStaff@fda.hhs.gov

82 FR 27493 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Modified Risk Tobacco Product Applications/Marlboro Heatsticks

GENERAL ENVIRONMENT AND SAFETY

Notice of the Food and Drug Administration announces the availability of modified risk tobacco product applications for the IQOS system with Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks, and Marlboro Fresh Menthol Heatsticks submitted by Philip Morris Products SA, of Neuchâtel, Switzerland. The notice requests comments on the label, labeling, and advertising accompanying the application. Comments are due Dec. 12, 2017. Contact: Paul Hart; FDA, Center for Tobacco Products; 877-287-1373; AskCTP@fda.hhs.gov

82 FR 27487 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Oregon/Jordan Cove LNG Terminal and Pacific Connector Pipeline Projects

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Federal Energy Regulatory Commission to prepare an environmental impact statement for the proposed Jordan Cove LNG Terminal and Pacific Connector Pipeline Projects located in Coos, Douglas, Jackson, and Klamath counties in Oregon. The projects, proposed by Jordan Cove Energy Project LP, a subsidiary of Veresen Inc., of Calgary, and Pacific Connector Gas Pipeline LP, of Roseburg, Ore., include the construction and operation of a liquefied natural gas export terminal on the North Spit of Coos Bay designed to liquefy about 1.04 billion cubic feet per day of LNG for export to markets across the Pacific Rim. The projects also include the construction and operation of a 235-mile-long, 36-inch diameter interstate natural gas transmission pipeline capable of transporting about 1.2 billion cubic feet per day of natural gas, and associated aboveground facilities. The notice specifies that although no formal application has been filed with FERC, the agency has begun initial review of the project under the pre-filing process. The agency previously denied the project application in a March 11, 2016, order. The notice also specifies preliminary environmental issues identified by FERC and cooperating agencies, including impacts on endangered species and aquatic resources. Meetings are scheduled for June 27, 28, and 29, 2017, in Coos Bay, Roseburg, and Klamath Falls, Ore., respectively. Comments are due July 10, 2017. Contact: FERC, Office of External Affairs; 866-208-3676; FercOnlineSupport@ferc.gov

82 FR 27473 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Regulated Drug Products/Social and Behavioral Research

GENERAL ENVIRONMENT AND SAFETY

Notice of the Food and Drug Administration announces the submission of a new information collection request to the OMB regarding data to support the agency's social and behavioral research. The collection includes individual and focus group interviews and surveys to test communications and social and behavioral methods about regulated drug products. Comments are due July 17, 2017. Contact: Domini Bean; FDA, Office of Operations; 301-796-5733; PRASStaff@fda.hhs.gov

82 FR 27492 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Texas/Border Crossing Project

GENERAL ENVIRONMENT AND SAFETY

Notice of the Federal Energy Regulatory Commission announces the availability of the schedule of environmental review for the Border Crossing Project, proposed by Valley Crossing Pipeline LLC, of Houston. The project involves the siting, construction, and operation of 1,000 feet of natural gas pipeline that extends into the Gulf of Mexico in Texas state waters to the international boundary between the U.S. and Mexico. The issuance of the environmental assessment is scheduled for June 30, 2017, and the 90-day federal authorization decision is due Sept. 28, 2017. Contact: FERC, Office of External Affairs; 866-208-3676; FERCOnlinesupport@ferc.gov

82 FR 27477 (06/15/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Utah/Uinta-Wasatch-Cache National Forest EIS

GENERAL ENVIRONMENT AND SAFETY

Notice of the U.S. Forest Service announces the cancellation of a notice of intent to prepare an environmental impact statement for a special use application for authorization to construct and maintain a crude oil pipeline from the Uinta Basin to Salt Lake City, including 14 miles of land located in the Uinta-Wasatch-Cache National Forest, in Utah (79 FR 4657; 01/29/2014). The application was submitted by Uinta Express Pipeline Co., a subsidiary of Tesoro Refining and Marketing Co., of San Antonio, Texas. The notice specifies that the project has been cancelled. Contact: Peter Gomben; USFS, Uinta-Wasatch-Cache National Forest; 801-999-2182; pgomben@fs.fed.us

82 FR 27462 (06/15/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP

Florida/Cape Canaveral Air Force Station

HAZARDOUS WASTE CLEANUP

Notice of the Department of Justice announces a proposed consent decree in *United States v. Johnson Controls Inc.* (Civil Action No.6:17-cv-01028-RBD-DCI), lodged on June 7, 2017, with the U.S. District Court for the Middle District of Florida. The consent decree resolves claims under

CERCLA regarding the alleged release of hazardous substances at certain Installation Restoration Program (IRP) sites at the Cape Canaveral Air Force Station in Brevard County, Fla. The consent decree requires Johnson Controls Inc., IAP World Services Inc., and IAP Worldwide Services Inc. to pay \$3.3 million to reimburse recovery costs incurred by the U.S. at the sites. In addition, the decree contains an agreement that the U.S. will not sue the defendant at certain Cape Canaveral IRP sites. Comments are due July 17, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 27526 (06/15/2017)

Regulatory Update

OIL AND GAS INDUSTRY

Onshore Oil and Gas Leases/Venting and Flaring of Waste Gases

OIL AND GAS INDUSTRY

Notice the Department of the Interior, Bureau of Land Management, announces the postponement of compliance dates for a Nov. 18, 2016, final rule (81 FR 83008) that amended regulations under 43 CFR 3103.3-1, 3160.0-5c, and 3162.3-1 and adopted regulations under 43 CFR 3178.1 through 3179.401 to set forth requirements to reduce waste of natural gas from venting, flaring and leaks during oil and natural gas production activities on onshore federal and Indian leases. The rule updated and revised requirements for flaring, venting, and royalty-free use of gas (NTL-4A). The current action postpones compliance dates that have not yet passed for provisions requiring operators to capture a certain percentage of gas they produce; to measure flared volumes; to upgrade or replace pneumatic equipment; to capture or combust storage tank vapors; and to implement leak detection and repair programs. The action is effective June 15, 2017. Contact: Timothy Spisak; BLM; 202-912-7311

82 FR 27430 (06/15/2017)

Regulatory Update

OIL AND GAS INDUSTRY

PHMSA Voluntary Information-Sharing System Working Group Meeting

OIL AND GAS INDUSTRY

Notice of the Pipeline and Hazardous Materials Safety Administration announces a meeting of the Voluntary Information-Sharing System Working Group. The agenda includes discussions regarding the development of a voluntary information sharing system, including mandate requirements, integrity management requirements, data types and tools, repair methods, geographic information system pipeline data and operator implementation, lessons learned, existing information-sharing and safety management systems, and administrative matters. The meeting is scheduled for June 29-30, 2017, in Arlington, Va. Comments are requested, but a due date is not specified. Contact: Cheryl Whetsel; PHMSA; 202-366-4431; cheryl.whetsel@dot.gov

82 FR 27544 (06/15/2017)

Regulatory Update

RADIATION

Storage of Spent Nuclear Fuel, Radioactive Waste

RADIATION

Notice announces the intention of the Nuclear Regulatory Commission to seek OMB approval for a continuing information collection request concerning licensing requirements for storage of spent nuclear fuel, high-level radioactive waste, and reactor-related greater than Class C waste (10 CFR 72). The collection addresses applications for new licenses, certificates of compliance, amendments, and applications for renewal of licenses to receive, transfer, and possess spent fuel and other radioactive materials associated with spent fuel storage in an independent storage of spent nuclear fuel or a monitored retrievable storage facility. Comments are due Aug. 14, 2017. Contact: David Cullison; NRC; 301-415-2084; INFOCOLLECTS.Resource@NRC.GOV

82 FR 27536 (06/15/2017)

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RADIATION

Technical Electronic Product Radiation Safety Standards Committee

RADIATION

Notice of the Food and Drug Administration announces a request for nominations to fill vacancies on the Technical Electronic Product Radiation Safety Standards Committee. The committee provides advice to the commissioner on the technical feasibility, reasonableness, and practicality of performance standards for electronic products to control such product's emission of radiation. Nominations and participant requests are due Aug. 14, 2017. Contact: Shanika Craig; FDA, Center for Devices and Radiological Health; 301-796-6639; Shanika.Craig@fda.hhs.gov

82 FR 27504 (06/15/2017)

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