To: Jackson, Ryan[jackson.ryan@epa.gov]
From: Bloomberg BNA
Sent: Wed 8/23/2017 12:29:55 PM
Subject: Aug. 23 -- EHS Federal Regulatory Alert

EHS Federal Regulatory Alert

August 23, 2017 - Number 162

You can create a report customized by topic, jurisdiction, and date range by using the Regulatory Summaries Report Tool. The report can be generated in Excel, Word, or PDF.

Summaries

AIR
Light-Duty Vehicle Greenhouse Gas Emission Standards
AIR

Notice of the EPA announces a hearing on the reconsideration of the EPA's final determination that the light-duty vehicle greenhouse gas emission standards for model years (MYs) 2022-2025 are appropriate and should not be amended, announced in a March 22, 2017, notice (82 FR 14671). The EPA is required to conduct a midterm evaluation and determine by April 1, 2018, whether the MY 2022-2025 standards are appropriate under an Oct. 15, 2012, final rule (77 FR 62623). An Aug. 21, 2017, notice (82 FR 39551) requested comments, data, and information relevant to the reconsideration. Comments were requested on whether standards established for MY 2021 remain appropriate, on the use of alternative methodologies and modeling systems, and on harmonization of the greenhouse gas and the Corporate Average Fuel Economy standards programs. The hearing is scheduled for Sept. 6, 2017, in Washington, D.C. Contact: Christopher Lieske; EPA, Office of Transportation and Air Quality; 734-214-4584; lieske.christopher@epa.gov. Citations: 40 CFR 86; 49 CFR 523, 531, 533, 536, 537

82 FR 39976 (08/23/2017)

Regulatory Update

AIR
Voluntary Criteria for Radon Credentialing Organizations
AIR

Notice announces the intention of the EPA to establish voluntary criteria specifying a standard of competence for organizations that credential radon service providers under the Indoor Radon Abatement Act. The EPA intends to establish an ongoing and open evaluation process of the National Radon Proficiency Program, the National Radon Safety Board, and state-run certification programs. The EPA also intends to require the organizations to meet the specified standards of the International Organization of Standardization and the International Electrotechnical Commission, and to incorporate device requirements. The EPA seeks comments regarding three

separate scenarios, including the agency's development of a basic framework for credentialing organizations, the agency's support for the development of the initial certification scheme, and the agency's support for the development and maintenance of a certification scheme. Comments are due Oct. 23, 2017. Contact: Katrin Kral; EPA, Indoor Environments Division; 202-343-9454; kral.katrin@epa.gov

82 FR 39993 (08/23/2017)

Regulatory Update

FOOD SAFETY

Evaluating the Safety of Veterinary Drug Residues in Human Food

FOOD SAFETY

Notice of the FDA announces the availability of final guidance for industry (#232) on a general approach to establish an acute reference dose in studies to evaluate the safety of residues of veterinary drugs in human food (VICH GL54). The guidance was developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The guidance addresses the nature and types of data that can be useful in determining an acute reference dose for residues of veterinary drugs, the studies that may generate such data, and how the acute reference dose may be calculated based on such data. Comments may be submitted at any time. Contact: Tong Zhou; FDA, Center for Veterinary Medicine; 240-402-0826; Tong.Zhou@fda.hhs.gov

82 FR 40010 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Advancing the Development of Pediatric Therapeutics Workshop

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA, Office of Pediatric Therapeutics, announces a workshop on the application of "big data" to pediatric safety studies. The workshop will address national and international uses of "big data" in health care and the utility of "big data" in the pediatric setting, including specific challenges associated with pediatric data. The workshop is scheduled for Sept. 18-19, 2017, in Silver Spring, Md., and via webcast. Contact: Renan Bonnel; FDA, Office of Pediatric Therapeutics; 301-796-8654; renan.bonnel@fda.hhs.gov

82 FR 40005 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

California/Northern Spotted Owl and California Spotted Owl Incidental Take Permit

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the U.S. Fish and Wildlife Service to prepare an environmental impact statement concerning a habitat conservation plan and proposed incidental take permit requested by Sierra Pacific Industries, of Anderson, Calif. The permit would provide for incidental take of the threatened Northern spotted owl and the California spotted owl, the later of which was

recently petitioned for listing under the Endangered Species Act. Covered activities would include timber harvest and management activities on 1.6 million acres in the Cascade, Klamath, and Sierra Nevada mountains in northern California. Meetings are scheduled for Sept. 13 and 14, 2017, in Redding and Sacramento, respectively, and Sept. 14, 2017, via webinar. Comments are due Sept. 22, 2017. Contact: Kim Turner; USFWS; 916-414-6606; Kim_S_Turner@fws.gov

82 FR 40015 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Drug Supply Chain Security Act/Trading Partners
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the withdrawal of an Aug. 21, 2017, notice (82 FR 39589) regarding the availability of a draft guidance for industry and state and local governments on categorization of entities in the drug supply chain as trading partners under the Drug Supply Chain Security Act. The guidance was published in error and is being removed. Contact: Melissa Mannion; FDA, Center for Drug Evaluation and Research; 301-796-3130; drugtrackandtrace@fda.hhs.gov

82 FR 40011 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
FDA Approved Information Collection Requests
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces OMB approval of 10 information collection requests. The collections address medical device premarket notifications, recordkeeping requirements for institutional review boards, and patent term restoration standards on due diligence petitions for regulatory review period revision. The collections also address the Adverse Event Program for Medical Devices; eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products; and citizen petitions and petitions for stay of agency action subject to Section 505(q) of the Food, Drug, and Cosmetic Act. In addition, the collections address a guidance for industry concerning the use of seriological tests to reduce the risk of transmission of Trypanosoma cruzi infection in whole blood and blood components for transfusion and a guidance for industry on providing information about pediatric uses of medical devices. Finally, the collections address the certification of identity for Freedom of Information Act and Privacy Act requests and the nominations process for FDA advisory committees. Contact: Ila Mizrachi; FDA, Office of Operations; 301-796-7726; PRAStaff@fda.hhs.gov. Citations: 21 CFR 14; 56.115; 60.40; 807, Subpart E; 1271

82 FR 40009 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Medical Devices and Radiological Products/Health Risk Allegations
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the submission of a continuing information collection request to the OMB regarding allegations of actual or potential health risk concerns about a medical device or radiological product or its use. The collection addresses the process for voluntary electronic submission of such allegations to the Center for Devices and Radiological Health. Comments are due Sept. 22, 2017. Contact: Amber Sanford; FDA, Office of Operations; 301-796-8867; PRAStaff@fda.hhs.gov

82 FR 40006 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
North Dakota/Center Mine Coal Lease-by-Application
GENERAL ENVIRONMENT AND SAFETY

Notice of the Bureau of Land Management announces the availability of and a hearing on an environmental assessment for BNI Coal Ltd., of Bismark, N.D., for a proposed lease-by-application of a 160-acre tract of federal coal at the Center Mine in Oliver County, N.D. The lease tract contains 2.43 million tons of in-place coal resources, and the applicant intends to mine approximately 1.69 million tons due to adverse geologic conditions. The agency seeks feedback on the EA, fair market value, and maximum economic recovery of the coal resources located in the proposed tract. The hearing is scheduled for Sept. 12, 2017, in Center, N.D. Comments are due Oct. 12, 2017. Contact: Irma Nansel; BLM, North Dakota Field Office; 406-233-3653; BLM_MT_North_Dakota_BNI_LBA@blm.gov

82 FR 40018 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Oncology Drugs for Companion Animals
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a final guidance for industry (#237) regarding oncology drugs for use in companion animals. The guidance provides recommendations for sponsors of investigational oncology drugs for use in companion animals and specifies the contents of a new animal drug application (NADA) for certain oncology drugs, including the target animal safety, effectiveness, and labeling technical sections of an NADA for oncology drugs administered as single agents. The guidance also includes recommendations on how to address human user safety concerns. Comments may be submitted at any time. Contact: Christopher Loss; FDA, Center for Veterinary Medicine; 240-402-0619; christopher.loss@fda.hhs.gov

82 FR 40008 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Over-the-Counter Drugs/Safety and Effectiveness
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the submission of a revised information collection request to the OMB regarding the evaluation of over-the-counter (OTC) drugs introduced into the U.S. market after OTC drug review began and OTC drug products without any marketing experience in the U.S. under the monograph process. The collection addresses the time and extent application for demonstrating that OTC drug conditions are eligible for inclusion in the monograph system. The collection also addresses safety and effectiveness data submission requirements, sponsor completeness statements, and sponsor withdrawal requests. The revisions incorporate new requirements from a Nov. 23, 2016, final rule (81 FR 84465) regarding content and format of data submissions and informal conference requests. Comments are due Sept. 22, 2017. Contact: Domini Bean; FDA, Office of Operations; 301-796-5733; PRAStaff@fda.hhs.gov. Citations: 21 CFR 330.14

82 FR 40006 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Peripheral and Central Nervous System Drugs Advisory Committee Meeting
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. The agenda includes discussion of new drug application (NDA 200896) submitted by PTC Therapeutics Inc., of South Plainfield, N.J., for ataluren for oral suspension. The product is indicated for the treatment of patients with dystrophinopathy due to a nonsense mutation in the dystrophin gene. The meeting is scheduled for Sept. 28, 2017, in Silver Spring, Md. Comments are due Sept. 27, 2017. Contact: Moon Hee Choi; FDA, Center for Drug Evaluation and Research; 301-796-9001; PCNS@fda.hhs.gov

82 FR 40003 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Texas/South Texas Expansion Project
GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces the schedule of environmental review for the proposed Pomelo Connector Pipeline and South Texas Expansion Project, which involves the construction and operation of facilities in Brazoria, Chambers, Matagorda, Nueces, and Orange counties in Texas. The project, proposed by Pomelo Connector LLC, of Pomelo, Texas, and Texas Eastern Transmission LP, of Houston, includes the modification and operation of pipeline and compression facilities to provide up to 400,000 dekatherms per day of firm transportation service from an interconnection with Texas Eastern at the proposed Pomelo Petronila Compressor Station to an intrastate header system. The issuance of the environmental assessment is scheduled for Sept. 18, 2017, and the 90-day federal authorization decision is due Dec. 17, 2017. Contact: FERC, Office of External Affairs; 866-208-3676; FERCOnlinesupport@ferc.gov

82 FR 39992 (08/23/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Wyoming/Billy Creek Storage Field Abandonment Project
GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of FERC to prepare an environmental assessment for the Billy Creek Storage Field Abandonment Project, in Johnson County, Wyo. The project, proposed by WBI Energy Transmission Inc., of Bismarck, N.D., involves withdrawing an estimated 2.4 billion cubic feet of cushion gas from the Billy Creek Storage Field and then abandoning the storage field and related facilities either in-place or by removal. Comments are due Sept. 18, 2017. Contact: FERC, Office of External Affairs; 866-208-3676; FercOnlineSupport@ferc.gov

82 FR 39989 (08/23/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION
Unified Carrier Registration Plan Board of Directors Meeting
HAZARDOUS MATERIALS TRANSPORTATION

Notice of the Federal Motor Carrier Safety Administration announces a meeting of the Unified Carrier Registration Plan Board of Directors to continue the development and implementation of the unified carrier registration plan and agreement. The meeting is scheduled for Aug. 24, 2017, in Dana Point, Calif., and via teleconference. Contact: Avelino Gutierrez; FMCSA, Unified Carrier Registration Board of Directors; 505-827-4565

82 FR 40058 (08/23/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP
New York/Port Refinery Superfund Site
HAZARDOUS WASTE CLEANUP

Notice of the Justice Department announces a proposed consent decree in United States v. Monroe Iron & Metal Co. (Civil Action No. 17-6217), lodged on Aug. 16, 2017, with the District Court of the Southern District of New York. The consent decree resolves claims under CERCLA for the recovery of response costs incurred at the Port Refinery Superfund Site in Rye Brook, N.Y. The consent decree requires the defendants to pay $151,503 in reimbursement of past response costs at the site. Comments are due Sept. 23, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 40020 (08/23/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH
Chronic Beryllium Disease Prevention Program
OCCUPATIONAL SAFETY AND HEALTH

Notice of the Energy Department announces the submission of a continuing information collection request to the OMB regarding the Chronic Beryllium Disease Prevention Program. The

collection allows the department to reduce the number of workers currently exposed to beryllium in the course of their work at DOE facilities, to minimize the levels and potential exposure, to provide relevant information to employees, to facilitate medical surveillance, and to conduct oversight. Comments are due Sept. 22, 2017. Contact: Bill McArthur; DOE, Office of Health, Safety, and Security; 301-903-9674; bill.mcarthur@hq.doe.gov. Citations: 10 CFR 850

82 FR 39986 (08/23/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH
National Occupational Research Agenda/Manufacturing Sector
OCCUPATIONAL SAFETY AND HEALTH

Notice of the National Institute for Occupational Safety and Health announces the availability of the draft National Occupational Research Agenda for manufacturing. The agenda identifies the most important occupational safety and health research, information, and required actions needed to prevent occupational injuries and illness in the manufacturing sector from 2016 to 2026 and provides a national strategic plan for government, higher education, and industry research and development entities. Comments are due Oct. 23, 2017. Contact: Emily Novicki; NIOSH; 404-498-2581; NORACoordinator@cdc.gov

82 FR 40003 (08/23/2017)

Regulatory Update

PESTICIDES
Pesticide Data Call-in Program
PESTICIDES

Notice announces the intention of the EPA to seek OMB approval for a continuing information collection request regarding the pesticide data call-in program. The collection addresses activities associated with the issuance of data-call-ins under FIFRA Section 3(c)(2)(B) to pesticide registrants identified by the "pesticide and other agricultural chemical manufacturing" code 325320 of the North American Industrial Classification System. Comments are due Oct. 23, 2017. Contact: Cameo Smoot; EPA, Office of Pesticide Programs; 703-305-5454; smoot.cameo@epa.gov

82 FR 39997 (08/23/2017)

Regulatory Update

RADIATION
List of Quantities of Licensed Materials Requiring Labeling/Rulemaking Petition
RADIATION

Notice of the NRC announces the receipt of a petition for rulemaking (PRM-30-66) requesting revisions to add radionuclides and their corresponding activities to the list of quantities of licensed materials requiring labeling. The petitioner, Matthew McKinley on behalf of the Organization of Agreement States, maintains that the list is outdated and does not include conforming updates from the 2005 amendment to the Energy Policy Act that included discrete

naturally occurring and accelerator-produced radioactive materials in the definition of byproduct material. Comments are due Nov. 6, 2017. Contact: Robert MacDougall; NRC, Office of Nuclear Material Safety and Safeguards; 301-415-5175; Robert.MacDougall@nrc.gov. Citations: 10 CFR 30, Appendix B

82 FR 39971 (08/23/2017)

Regulatory Update

TOXIC SUBSTANCES
New York/TSCA Consent Decree
TOXIC SUBSTANCES

Notice of the Justice Department announces a proposed consent decree in United States v. Accolade Construction Group Inc. (Civil Action No. 15 Civ. 5855, JCF), lodged Aug. 17, 2017, in the U.S. District Court for the Southern District of New York. The consent decree resolves claims under TSCA for alleged violations of the lead renovation, repair, and painting regulations under 40 CFR 475, Subpart E, resulting from renovation work in 2013 and 2014 at six residential buildings in New York City. The consent decree requires the settling parties to pay $58,000 in disgorgement, representing profits gained as a result of the alleged conduct. The consent decree also requires the settling parties to propose a compliance plan prior to doing any renovation work, to provide the EPA notice of each proposed renovation project before starting work, to comply with the applicable regulations, and to maintain necessary records. Comments are due Sept. 22, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 40021 (08/23/2017)

Regulatory Update