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From: Bloomberg BNA
Sent: Tue 9/19/2017 11:50:46 AM
Subject: Sep. 19 -- EHS Federal Regulatory Alert



EHS Federal Regulatory Alert

September 19, 2017 - Number 180

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Summaries

AIR

Maine SIP/Regional Haze

AIR

Final rule of the EPA approves a revision to the Maine SIP for regional haze. The revision includes a five-year progress report toward reasonable progress goals (RPGs) for regional haze and a determination of adequacy of the existing regional haze SIP. The progress report specifies that the state has implemented the necessary measures and that visibility in federal Class I areas affected by the state's emissions is improving and meets the applicable RPGs for 2018. The rule is effective Oct. 19, 2017. Contact: Anne McWilliams; EPA Region 1, Air Quality Unit; 617-918-1697; mcwilliams.anne@epa.gov. Citations: 40 CFR 52.1020

82 FR 43699 (09/19/2017)

Regulatory Update

AIR

Primary NAAQS for SOx/Draft External Review Documents

AIR

Notice of the EPA announces the availability of two external review draft documents concerning risk and exposure assessment for the review of the primary NAAQS for sulfur oxides (SOx) and the policy assessment for the review of the primary SOx NAAQS. The draft documents address quantitative exposure and risk analyses for the NAAQS review and, when finalized, the policy assessment is intended to connect currently available scientific information and the judgments required of the administrator in determining whether to retain or revise the existing primary SOx NAAQS. The agency will announce a meeting at a later date. Comments are due Oct. 18, 2017. Contact: Nicole Hagan; EPA, Office of Air Quality Planning and Standards; 919-541-3153; hagan.nicole@epa.gov

82 FR 43756 (09/19/2017)

Regulatory Update

ENDANGERED SPECIES

Maui Dolphin, South Island Hector's Dolphin Listing

ENDANGERED SPECIES

Final rule of the National Marine Fisheries Service lists the Maui dolphin as endangered and the South Island Hector's dolphin as threatened. The subspecies are endemic to New Zealand and do not occur within areas under U.S. jurisdiction, and therefore NMFS does not intend to propose any critical habitat designations. The rule is issued in response to a petition from WildEarth Guardians. The rule is effective Oct. 19, 2017. Contact: Lisa Manning; NMFS, Office of Protected Resources; 301-427-8466; lisa.manning@noaa.gov. Citations: 50 CFR 223.102, 224.101

82 FR 43701 (09/19/2017)

Regulatory Update

FOOD SAFETY

Listing of Manufacturers/Processors for Food Exports to China

FOOD SAFETY

Notice announces the intention of the FDA to seek OMB approval for a continuing information collection request regarding lists maintained by the agency identifying U.S. manufacturers/processors interested in exporting milk and milk products, seafood, infant formula, formula for young children, or other products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) to China. The collection addresses requirements in FDA guidance for manufacturers/processors to provide evidence of third-party certification of compliance with applicable Chinese standards to be placed on the lists and to update information biennially to remain on the lists. Comments are due Nov. 20, 2017. Contact: Domini Bean; FDA, Office of Operations; 301-796-5733; PRAStaff@fda.hhs.gov

82 FR 43761 (09/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Cigarette Graphic Health Warnings

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the submission of a new information collection request to the OMB regarding warning statements for cigarette graphic health warnings. The collection concerns a study of consumer responses to potential textual warnings statements intended to promote greater public understanding of the negative health consequences of cigarette smoking. The study is being conducted due to a 2012 appeals court ruling that a June 22, 2011, final rule (76 FR 36628) requiring nine specified images to accompany textual warning statements for cigarettes violated the First Amendment. Comments are due Oct. 19, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794; PRAStaff@fda.hhs.gov. Citations: 21 CFR 1141

82 FR 43764 (09/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Generic Drug Policy

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces an extension of the comment period relating to a July 18, 2017, meeting (82 FR 28493; 06/22/2017) regarding implementation of the Hatch-Waxman Amendments and the appropriate balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs. The FDA seeks information regarding how the existing legal and regulatory framework and available incentives and marketplace practices impact consumer access to generic drugs. The previous notice listed several detailed questions on which the FDA would like specific input, including the impact of the Hatch-Waxman amendments on exclusivity periods, patents and patent listing procedures, innovator drug product labeling, post-approval changes to innovator drug products, and other regulatory processes such as the citizen petition process. Comments now are due Nov. 17, 2017. Contact: Philip Bonforte; FDA, Center for Drug Evaluation and Research; 240-402-6980; GenericDrugPolicy@fda.hhs.gov

82 FR 43767 (09/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Michigan, Wisconsin/Menominee and Park Mill Hydroelectric Project

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC, Office of Energy Projects, announces the availability of an environmental assessment for the Menominee and Park Mill Hydroelectric Project on the Menominee River in Menominee County, Mich., and Marinette County, Wis. The project, proposed by North East Wisconsin Hydro LLC, of Neshkoro, Wis., consists of two developments with a total installed capacity of 4.348-megawatts. The EA concludes that issuing a new license for the project, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment. Comments are due Oct. 30, 2017. Contact: Chelsea Hudock; FERC; 202-502-8448; chelsea.hudock@ferc.gov

82 FR 43754 (09/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Registration of Tobacco Establishments, Product Listing

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a revised guidance for industry regarding registration and product listing for owners and operators of domestic tobacco product establishments. The guidance is intended to assist persons making establishment registration and product listing submissions to the FDA. The revisions specify a compliance policy for certain product listing labeling submissions. The revisions also update the compliance date concerning newly deemed products to specify that the agency does not intend to enforce such requirements if submissions are received by Sept. 30, 2017. Comments may be submitted at any time. Contact: Matthew Brenner; FDA, Center for Tobacco Products; 877-287-1373;

CTPRegulations@fda.hhs.gov

82 FR 43768 (09/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Tobacco Flavor Developer and Manufacturer Site Tours

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA, Center for Tobacco Products, announces an invitation for participation in its voluntary Flavor Developer and Manufacturer Site Tours Program. The program will provide agency staff an opportunity to visit companies that develop and/or manufacture flavors that are sold to tobacco product manufacturers to gain a better understanding of the development, testing, and production of flavors and flavor mixtures. A May 10, 2016, final rule (81 FR 28974) provided that all products that meet the statutory definition of "tobacco product," including components and parts, are subject to tobacco product manufacturing, distribution, and marketing regulations under the Federal Food, Drug, and Cosmetic Act. Company requests for participation in the program are due Nov. 20, 2017. Contact: Karla Price; FDA, Center for Tobacco Products; 877-287-1373; AskCTP@fda.hhs.gov

82 FR 43770 (09/19/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION

Chemical Transportation Advisory Committee Meeting

HAZARDOUS MATERIALS TRANSPORTATION

Notice of the U.S. Coast Guard announces additional information concerning Oct. 3-5, 2017, meetings of the Chemical Transportation Advisory Committee and its subcommittees to discuss issues related to the marine transportation of hazardous materials (82 FR 41279; 08/30/2017). The meeting will address safety standards for the design of vessels carrying natural gas or using natural gas as fuel, marine vapor control system regulations implementation and guidance, hazardous substance response plans for tank vessels and facilities, and international maritime organization activities. The meeting also will address regulatory reform of Coast Guard regulations per executive orders 13771 (82 FR 9339; 02/03/2017) and 13783 (82 FR 16093; 03/31/2017). The notice announces a teleconference participation option for the full committee meeting scheduled for Oct. 5, 2017. Contact: Jake Lobb; USCG; 202-372-1428; jake.r.lobb@uscg.mil

82 FR 43778 (09/19/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION

Motor Carrier Safety Medical Review Board

HAZARDOUS MATERIALS TRANSPORTATION

Notice of the Federal Motor Carrier Safety Administration announces a meeting of the Medical Review Board. The meeting agenda includes revisions to the handbook for medical examiners on

the National Registry of Certified Medical Examiners for use in evaluating interstate commercial motor vehicle drivers for a medical qualification determination. The meeting also includes review of the current advisory and exemption program criteria concerning individuals taking anti-seizure medication and identification of factors for consideration for potential regulatory actions to eliminate the need for granting exemptions. The meeting is scheduled Sept. 26-27, 2017, in Arlington, Va. Comments are due Sept. 20, 2017. Contact: Shannon Watson; FMCSA; 202-366-5221; mrb@dot.gov

82 FR 43809 (09/19/2017)

Regulatory Update

RADIATION

Georgia/Robins Air Force Base Decommissioning Plan

RADIATION

Notice of the NRC announces the availability of an environmental assessment and finding of no significant impact regarding an application from the Department of the Air Force for an amendment to its materials license (No. 42-23539-01AF) that authorizes the possession, storage, and use of radioactive materials around the U.S. The applicant seeks approval of a proposed decommissioning plan for Building 181 at Robins Air Force Base in Warner Robins, Ga., that would involve the cleanup of residual depleted uranium inside and underneath the building and partial demolition of the building. Contact: Vivian Campbell; NRC Region IV Office; 817-200-1455; Vivian.Campbell@nrc.gov

82 FR 43794 (09/19/2017)

Regulatory Update

RADIATION

NRC Fitness-for-Duty Programs

RADIATION

Notice of the NRC announces the submission of a continuing information collection request to the OMB regarding nuclear power fitness-for-duty programs. The collection addresses forms used by nuclear power plant licensees, strategic special nuclear material licensees, and other affected entities to report compliance with fitness-for-duty requirements related to drug and alcohol testing and fatigue reporting (NRC Forms 890, 891, and 892). Comments are due Oct. 19, 2017. Contact: David Cullison; NRC, Office of the Chief Information Officer; 301-415-2084; INFOCOLLECTS.Resource@nrc.gov. Citations: 10 CFR 26

82 FR 43797 (09/19/2017)

Regulatory Update

TOXIC SUBSTANCES

Federal Explosives Licensing Center/Notification of Change of Address

TOXIC SUBSTANCES

Notice of the Bureau of Alcohol, Tobacco, Firearms, and Explosives announces the submission of a continuing information collection request to the OMB concerning notification requirements

for explosives permit and license holders of a change of mailing or premise address. The collection addresses requirements for notification of the chief of the Federal Explosives Licensing Center of a business or operations address change. Comments are due Oct. 19, 2017. Contact: Shawn Stevens; ATF, Federal Explosives Licensing Center; 304-616-4421; Shawn.Stevens@atf.gov. Citations: 27 CFR 555.54

82 FR 43791 (09/19/2017)

Regulatory Update

WATER

Advanced Notice of Vessel Arrival

WATER

Notice of the U.S. Coast Guard announces the submission of a continuing information collection request to the OMB concerning the requirement for prearrival messages from any vessel entering a port or place in the U.S. The collection facilitates the control of vessel traffic, development of contingency plans, and enforcement of agency regulations. Comments are due Oct. 19, 2017. Contact: Anthony Smith; USCG, Office of Information Management; 202-475-3532. Citations: 33 CFR 146; 160, Subpart C

82 FR 43779 (09/19/2017)

Regulatory Update

WATER

Waiver of Compliance with Navigation Laws/Hurricanes Harvey and Irma

WATER

Notice of the Department of Homeland Security, Office of the Secretary, announces the extension and modification of a Sept. 14, 2017, waiver (82 FR 43248) of provisions of the Jones Act through Sept. 22, 2017. The act requires certain vessels providing transportation of merchandise by water, or by water and land between points in the U.S., to have a coastwise endorsement or the vessel to have been built in and documented under U.S. laws and to be wholly owned by U.S. citizens. The waiver was provided due to severe disruptions in both the midstream and downstream sectors of the Gulf Coast oil supply system due to Hurricane Harvey and the potential imminent shortage of energy supply in areas affected by Hurricane Irma. The waiver is intended to facilitate movement of refined petroleum products, including gasoline, diesel, and jet fuel, to be shipped from Alabama, Arkansas, Delaware, Louisiana, Maryland, Mississippi, New Mexico, New Jersey, New York, Pennsylvania, and Texas to Florida, Georgia, North Carolina, Puerto Rico, South Carolina, Virginia, and West Virginia. The modification extends the waiver to several additional states. The extension is effective Sept. 12, 2017. Contact: DHS; 202-282-8010

82 FR 43782 (09/19/2017)

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