To: Jackson, Ryan[jackson.ryan@epa.gov]
From: Bloomberg BNA
Sent: Mon 8/7/2017 11:29:04 AM
Subject: Aug. 07 -- EHS Federal Regulatory Alert

EHS Federal Regulatory Alert

August 07, 2017 - Number 150

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Summaries

AIR
Air Emission Sources/Test Methods, Performance Specifications and Testing
AIR

Final rule of the EPA removes obsolete provisions concerning Performance Specification 2 for sulfur dioxide and nitrogen oxides in continuous emission monitoring systems and stationary sources. The provisions are no longer necessary due to an Aug. 30, 2016, final rule (81 FR 59800) that revised test methods, performance specifications, and testing standards for various air emission sources. The rule is effective Aug. 7, 2017. Contact: Lula Melton; EPA, Office of Air Quality Planning and Standards; 919-541-2910; melton.lula@epa.gov. Citations: 40 CFR 60, Appendix B

82 FR 36688 (08/07/2017)

Regulatory Update

AIR
Kentucky SIP/Regional Haze Progress Report
AIR

Proposed rule of the EPA would approve a revision to the Kentucky SIP regarding the state's regional haze progress report. Under the rule, the agency would approve the state's determination that the regional haze plan is adequate to meet the reasonable progress goals for the first implementation period through 2018 and does not currently require substantive revisions. Comments are due Sept. 6, 2017. Contact: Michele Notarianni; EPA Region 4, Air Planning and Implementation Branch; 404-562-9031; notarianni.michele@epa.gov. Citations: 40 CFR 51.308, 40 CFR 52

82 FR 36707 (08/07/2017)

Regulatory Update

AIR

NESHAP for Off-Site Waste and Recovery Operations

AIR

Proposed rule of the EPA would revise the NESHAP for off-site waste and recovery operations (OSWRO). The revision would remove additional monitoring requirements for equipment leaks from pressure relief devices on containers. The revision is in response to a May 16, 2016, petition (81 FR 30182) for reconsideration of a final rule (80 FR 14247; 03/18/2015) that revised the NESHAP for OSWRO based on the results of a residual risk and technology review. The agency is seeking comments concerning whether to impose frequent inspections for filled or partially filled OSWRO containers that remain on-site longer than 60 days, whether additional inspection requirements should apply to all containers or only to larger containers, and whether the agency should incorporate inspection requirements under 40 CFR 264 and 265, Subparts BB and CC for RCRA-permitted and interim status facilities. If requested by Aug. 14, 2017, a hearing will be held Aug. 22, 2017, in Washington, D.C. Comments are due Sept. 21, 2017. Contact: Angie Carey; EPA, Office of Air Quality Planning and Standards; 919- 541-2187; carey.angela@epa.gov. Citations: 40 CFR 63.691

82 FR 36713 (08/07/2017)

Regulatory Update

AIR

Test Procedure for Dedicated-Purpose Pool Pumps

AIR

Final rule of the Energy Department, Office of Energy Efficiency and Renewable Energy, establishes a test procedure for dedicated-purpose pool pumps applicable to self-priming and nonself-priming pool filter pumps, waterfall pumps, and pressure cleaner booster pumps. The rule also adds definitions, specifies a new weighted energy factor (WEF) metric to characterize energy performance, and includes a test method to determine the self-priming capability of pool filter pumps. In addition, the rule incorporates by reference the Hydraulic Institute's Standard 40.6-2014, Methods for Rotodynamic Pump Efficiency Testing; UL's Standard 1081-2014, Standard for Swimming Pool Pumps, Filters, and Chlorinators; Canadian Standards Association's Standard C747-2009, Energy Efficiency Test Methods for Small Motors; IEEE's Standard 113-1985, Test Procedures for Direct-Current Machines; IEEE's Standard 114-2010, Standard Test Procedure for Single-Phase Induction Motors; and NSF International's Standard 50-2015, Equipment for Swimming Pools, Spas, Hot Tubs, and Other Recreational Water Facilities. The test procedure does not apply to integral cartridge-filter pool pumps, integral sand-filter pool pumps, storable electric spa pumps, or rigid electric spa pumps, and the scope of energy conservation standards applicable to dedicated-purpose pool pumps will be established in a separate action. Compliance with the final rule will be mandatory for representations of WEF and other metrics addressed by the adopted test procedures made on or after Feb. 3, 2018. The rule is effective Sept. 6, 2017. Contact: Ashley Armstrong; EPA, Office of Energy Efficiency and Renewable Energy; 202-586-6590; Ashley.Armstrong@ee.doe.gov. Citations: 10 CFR 429.4, 429.59, 429.110, 429.134, 431.462, 431.463, 431.464, 431.466, 10 CFR 431, Subpart Y, Appendix A

82 FR 36858 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Assurance Cases for Infusion Pump Manufacturers

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the withdrawal of a March 15, 2017, notice (82 FR 13817) regarding the intention to seek OMB approval for a continuing information collection request regarding safety assurance cases for infusion pump devices. The collection would have addressed requirements for infusion pump manufacturers to describe how and why their device meets FDA safety standards. The agency is withdrawing the notice because the information collected for safety assurance cases is already included in another collection. The withdrawal is effective Aug. 7, 2017. Contact: Amber Sanford; FDA, Office of Operations; 301-796-8867; PRAStaff@fda.hhs.gov. Citations: 21 CFR 880.5725

82 FR 36792 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Cooperative Manufacturing Arrangements for Licensed Biologics

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the FDA to seek OMB approval for a continuing information collection request regarding a guidance for industry concerning cooperative manufacturing arrangements for biological products subject to licensure under Section 351 of the Public Health Service Act. The guidance addresses various types of manufacturing arrangements and describes certain reporting and recordkeeping responsibilities associated with the arrangements, including standard operating procedures and the notification of all important proposed changes to production and facilities, of the results of tests and investigations regarding or possibly impacting the product, and of when products are manufactured in a contract facility. Comments are due Oct. 6, 2017. Contact: Domini Bean; FDA, Office of Operations; 301-796-3850; PRAStaff@fda.hhs.gov

82 FR 36797 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Drug and Biological Products/User Fee Waivers, Reductions and Refunds

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the submission of a continuing information collection request to the OMB concerning a guidance for industry regarding user fee waivers, reductions, and refunds for drug and biological products. The collection addresses the types of waivers and reductions permitted under the Federal Food, Drug and Cosmetic Act and specifies the procedures for submitting requests for waivers or reductions. The collection also addresses user fee exemptions for orphan drugs. The collection includes a revised burden estimate due to a processing change that requires waiver applicants to submit documentation directly to the FDA and to submit fewer supporting documents. Comments are due Sept. 6, 2017. Contact: Domini Bean; FDA, Office of Operations; 301-796-5733; PRAStaff@fda.hhs.gov

82 FR 36795 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Hydroelectric Incentive Program
GENERAL ENVIRONMENT AND SAFETY

Notice of the Energy Department announces the availability of guidance and the opening of the application period for the Hydroelectric Incentive Program. The guidance provides hydroelectric incentive payment requirements and specifies the information that owners or authorized operators of hydroelectric facilities can provide the department when applying for incentive payments. The notice specifies that the incentive payment is available for electric energy generated and sold during calendar year 2016. Applications are due Sept. 6, 2017. Contact: Timothy Welch; DOE, Office of Energy Efficiency and Renewable Energy; 202-586-7055; hydroincentive@ee.doe.gov

82 FR 36762 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Illinois/Brandon Road Lock and Dam Aquatic Nuisance Species Controls
GENERAL ENVIRONMENT AND SAFETY

Notice of the U.S. Army Corps of Engineers announces the availability of a draft integrated feasibility study and environmental impact statement for the plan to prevent the spread of aquatic nuisance species between the Great Lakes and Mississippi River basins through the Chicago Sanitary and Ship Canal and other aquatic pathways. The study and EIS evaluate structural and nonstructural options and technologies near the Brandon Road Lock and Dam, in Will County, Ill., to prevent the upstream transfer of aquatic nuisance species. The study and EIS also identify potential adverse impacts that alternatives may have on existing uses and users of the waterways. Meetings will be announced at a later date. Comments are due Sept. 21, 2017. Contact: Andrew Leichty; USACE, Rock Island District; 309-794-5399; Andrew.L.Leichty@usace.army.mil

82 FR 36760 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Oncologic Drugs Advisory Committee Meeting
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a meeting of the Oncologic Drugs Advisory Committee to discuss a supplemental new drug application for sunitinib malate oral capsules (sNDA 021938/033), submitted by C.P. Pharmaceuticals International C.V., represented by Pfizer Inc., of New York. The capsules are used for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy. The meeting is scheduled for Sept. 9, 2017, in Silver Spring, Md. Comments are due Sept. 5, 2017. Contact: Cindy Chee; FDA, Center for Drug Evaluation and Research; 301-796-9001; ODAC@fda.hhs.gov

82 FR 36789 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Prescription Drug Advertisements
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the submission of a continuing information collection request to the OMB regarding requirements for prescription drug and biological product manufacturers, packers, and distributors to disclose in advertisements certain information about the advertised product's uses and risks. The collection addresses requirements regarding disclosures, waiver requests, prior approval of advertisements, and programs for assuring significant new adverse information about the drug is publicized promptly and adequately to the medical profession. Comments are due Sept. 6, 2017. Contact: Domini Bean; FDA, Office of Operations; 301-796-5733, PRAStaff@fda.hhs.gov. Citations: 21 CFR 202.1

82 FR 36799 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Product-Specific Bioequivalence Recommendations
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of final guidances for industry to provide product-specific bioequivalence (BE) design recommendations to support abbreviated new drug applications for drug products containing various active ingredients. Comments may be submitted at any time. Contact: Xiaoqiu Tang; FDA, Center for Drug Evaluation and Research; 301-796-5850

82 FR 36792 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Products Containing Organohalogen Flame Retardants
GENERAL ENVIRONMENT AND SAFETY

Notice of the Consumer Product Safety Commission announces a meeting to receive comments on a petition (80 FR 50238; 08/09/2015) requesting a rulemaking to declare several categories of products containing additive organohalogen flame retardants to be "banned hazardous substances." The petition was filed by Earthjustice and the Consumer Federation of America and joined by various parties. The meeting is scheduled for Sept. 14, 2017, in Bethesda, Md. Contact: Michael Babich; CPSC, Division of Toxicology & Risk Assessment; 301-987-2606. Citations: 16 CFR 1500

82 FR 36705 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Regulatory Review Period/Cinqair
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the human biologic product Cinqair (reslizumab) in response to an application submitted by UCB Celltech, of Slough, U.K. The product is indicated for add-on maintenance treatment of patients with severe asthma who are 18 years of age or older and who have an eosinophilic phenotype. Comments are due Oct. 6, 2017. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due Feb. 5, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 36790 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Regulatory Review Period/Vonvendi
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the human biologic product Vonvendi (von Willebrand Factor (Recombinant)) in response to an application submitted by Baxalta GmbH, of Opfikon, Switzerland, and Baxalta Inc., of Bannockburn, Ill. The product is indicated for on-demand treatment and control of bleeding episodes in adults diagnosed with von Willebrand disease. Comments are due Oct. 6, 2017. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due Feb. 5, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 36794 (08/07/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Schedules I and II Controlled Substances 2018 Aggregate Production Quotas
GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Drug Enforcement Administration to establish the 2018 aggregate production quotas for controlled substances in Schedules I and II and an assessment of annual needs for list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The agency intends to adjust aggregate production quotas for numerous controlled substances and chemicals to provide for the estimated medical, scientific, research, and industrial needs of the U.S.; lawful export requirements; and the establishment and maintenance of reserve stocks. The quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes. Comments are due Sept. 6, 2017. Contact: Michael Lewis; DEA, Diversion Control Division; 202-598-6812. Citations: 21 CFR 1303, 1315

82 FR 36830 (08/07/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION
FMCSA Administrative and Rulemaking Procedure
HAZARDOUS MATERIALS TRANSPORTATION

Proposed rule of the Federal Motor Carrier Safety Administration would require use of a negotiated rulemaking or advance notice of proposed rulemaking process for all major rules regarding commercial motor vehicle safety and authorize the administrator to waive the requirement under certain circumstances. The rule would further revise the process for preparing and adopting rules by defining "petition" to include requests for a new regulation, regulatory interpretation or clarification, or determination that a regulation should be modified or eliminated. A process for filing and addressing petitions also would be established. In addition, the rule would provide that, on receipt of a comment, the comment period for direct final rules would be extended while the agency determines whether the comment qualifies as adverse. Finally, the rule would add definitions and make editorial corrections. Comments are due Oct. 6, 2017. Contact: Bivan Patnaik; FMCSA, Regulatory Development Division; 202-366-8092; Bivan.Patnaik@dot.gov. Citations: 49 CFR 389.3 through 389.39 (nonconsecutive)

82 FR 36719 (08/07/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION
Marine Portable Tanks
HAZARDOUS MATERIALS TRANSPORTATION

Notice announces the intention of the U.S. Coast Guard to seek OMB approval for a continuing information collection request regarding the approval of alterations to marine portable tanks and nonspecification portable tank designs used to transfer hazardous materials during offshore operations. Comments are due Oct. 6, 2017. Contact: Anthony Smith; USCG, Office of Information Management; 202-475-3532. Citations: 46 CFR 64

82 FR 36810 (08/07/2017)

Regulatory Update

OIL AND GAS INDUSTRY
Alaska/National Petroleum Reserve Oil and Gas Lease Sale
OIL AND GAS INDUSTRY

Notice of the Bureau of Land Management announces a request for nominations and comments on tracts for the upcoming National Petroleum Reserve in Alaska (NPR-A) oil and gas lease sale, including tracts currently unavailable for leasing under the 2013 NPR-A integrated activity plan. Nominations and comments are due Sept. 6, 2017. Contact: Wayne Svejnoha; BLM, Alaska Energy and Minerals Branch; 907-271-4407. Citations: 43 CFR 3131.2

82 FR 36827 (08/07/2017)

Regulatory Update

OIL AND GAS INDUSTRY

Federal Oil and Gas and Federal and Indian Coal Valuation/Repeal
OIL AND GAS INDUSTRY

Final rule of the Department of the Interior, Office of Natural Resources Revenue, repeals amendments included in a July 1, 2016, final rule (81 FR 43338) regarding valuation of oil and gas produced from federal onshore and offshore leases and coal produced from federal and Indian leases for royalty purposes. The July 2016 rule was subsequently delayed (82 FR 11823; 02/27/2016) in response to three separate petitions challenging the final rule filed in the U.S. District Court for the District of Wyoming. The current rule also reinstates provisions governing the valuation of oil, natural gas, and coal produced from federal leases and coal produced from Indian leases that were in effect before Jan. 1, 2017. In addition, the current rule applies the reinstated provisions prospectively and supersedes the notification of postponement of effectiveness of the 2017 Valuation Rule. The rule is effective Sept. 6, 2017. Contact: Elizabeth Dawson; ONRR; 303-231-3653. Citations: 30 CFR 1202.51, 1206.10 through 1206.473 (nonconsecutive)

82 FR 36934 (08/07/2017)

Regulatory Update

WATER
Commercial Vessels/Inspection or Examination Fees
WATER

Notice of the U.S. Coast Guard announces the submission of a continuing information collection request to the OMB regarding direct user fees for inspection or examination of U.S. and foreign commercial vessels. The collection addresses the identifying information required during vessel inspection and the option for vessel owners to pay inspection fees for future years. Comments are due Sept. 6, 2017. Contact: Anthony Smith; USCG, Office of Information Management; 202-475-3532

82 FR 36811 (08/07/2017)

Regulatory Update