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From: Bloomberg BNA
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EHS Federal Regulatory Alert

November 09, 2017 - Number 216

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Summaries

ENDANGERED SPECIES

Oregon/Pinniped Removal Authority

ENDANGERED SPECIES

Notice of the National Marine Fisheries Service announces the receipt of an application from Oregon requesting authorization to intentionally take, by lethal methods, individually identifiable California sea lions in the Willamette River that are having a significant negative impact on the recovery of the threatened Upper Willamette River steelhead and Chinook salmon. NMFS has determined that the application provides sufficient evidence of the problem interaction to warrant establishing a Pinniped-Fishery Interaction Task Force. Comments are requested on factors to be considered by the task force in determining whether to approve or deny the application and on the impact of sea lion predation in the vicinity of Willamette Falls. Comments are due Jan. 8, 2018. Contact: Robert Anderson; NMFS, West Coast Region; 503-231-2226

82 FR 52038 (11/09/2017)

Regulatory Update

FOOD SAFETY

Assessment of Ill Worker Policies Study

FOOD SAFETY

Notice of the National Center for Environmental Health announces the submission of a new information collection request to the OMB for assessment of ill worker policies. The collection consists of a study by the Environmental Health Specialists Network program for identification and understanding of environmental factors associated with foodborne illness outbreaks and other food safety issues. The study will address assessment of restaurant manager and worker knowledge, attitudes, and practices concerning working while ill, and whether an educational intervention would result in enhancement of ill worker management procedures. Comments are due Dec. 11, 2017. Contact: Leroy Richardson; CDC, Office of Scientific Integrity; 404-639-7570; omb@cdc.gov

82 FR 52049 (11/09/2017)

Regulatory Update

FOOD SAFETY

Color Additive Petition/Synthetic Iron Oxide

FOOD SAFETY

Notice of the FDA announces the filing of a color additive petition by Colorcon Inc., of Harleysville, Pa., to expand the permitted uses of synthetic iron oxide as a color additive to include use in dietary supplement tablets and capsules with a proposed limit of 5 milligrams, calculated as elemental iron, per day for labeled dosages. The FDA has determined that neither an environmental assessment nor an environmental impact statement is required. Contact: Molly Harry; FDA, Center for Food Safety and Applied Nutrition; 240-402-1075. Citations: 21 CFR 73.200

82 FR 52037 (11/09/2017)

Regulatory Update

FOOD SAFETY

Infant Formula Recall Requirements

FOOD SAFETY

Notice of the FDA announces the submission of a continuing information collection request to the OMB concerning infant formula recall requirements. 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 Dec. 11, 2017. Contact: Ila Mizrahi; FDA, Office of Operations; 301-796-7726; PRAStaff@fda.hhs.gov. Citations: 21 CFR 107.230, 107.240, 107.250, 107.260, 107.280

82 FR 52055 (11/09/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Blood Products Advisory Committee Meeting

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a meeting of the Blood Products Advisory Committee to discuss bacterial risk control strategies for blood collection establishments and transfusion services. The committee also will meet as a device classification panel to consider classification of human leukocyte antigen, human platelet antigen, and human neutrophil antigen devices. In addition, the agenda includes discussion regarding Zika virus transmission prevention strategies and an information session on the Transfusion Transmissible Infections Monitoring System. Finally, the agenda includes a presentation on an April 6, 2017, FDA workshop on emerging tick-borne diseases and blood safety. The meeting is scheduled for Nov. 30-Dec. 1, 2017, in Silver Spring, Md. Comments are due Nov. 22, 2017. Contact: Bryan Emery; FDA, Center for Biologics Evaluation and Research; 240-402-8054; bryan.emery@fda.hhs.gov

82 FR 52060 (11/09/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Effect of Drugs on the Ability to Operate Motor Vehicles

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a final guidance for industry concerning evaluation of drug effects on the ability to operate a motor vehicle. The document is intended to assist sponsors in the evaluation of the effects of psychoactive drugs on the ability to operate a motor vehicle. The guidance establishes a systematic process to identify drugs for which evaluation of effects on driving abilities may be needed and the types of studies that such an evaluation entails. Comments may be submitted at any time. Contact: Naomi Lowy; FDA, Center for Drug Evaluation and Research; 301-796-0692

82 FR 52052 (11/09/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Environmental Impact Statements

GENERAL ENVIRONMENT AND SAFETY

Notice of the EPA announces the availability of environmental impact statements filed Oct. 30-Nov. 3, 2017. Contact: Kelly Knight; EPA, Office of Federal Activities; 202-564-7146; knight.kelly@epa.gov. Citations: 40 CFR 1506.9

82 FR 52043 (11/09/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Labeling of Natural Rubber Latex Condoms

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the FDA to seek OMB approval for a continuing information collection request regarding the class II special controls guidance document for manufacturers and repackagers of male condoms made of natural rubber latex without spermicidal lubricant. The collection addresses labeling requirements to provide information for condom users, including the extent of protection provided by condoms against various types of sexually transmitted diseases. Comments are due Jan. 8, 2018. Contact: Amber Sanford; FDA, Office of Operations; 301-796-8867; PRAStaff@fda.hhs.gov. Citations: 21 CFR 884.5300

82 FR 52056 (11/09/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Menu Labeling Guidelines

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a draft supplemental guidance for industry regarding menu labeling. The guidance addresses concerns raised by stakeholders regarding a May 4, 2017, interim final rule (82 FR 20825) to implement nutrition labeling requirements for foods sold in covered establishments. The guidance includes expanded and new interpretations of policy; contains graphical depictions; and addresses calorie disclosure signage for self-service foods, reasonable basis and the criteria for considering the natural variation of foods, various methods for providing calorie disclosure information, compliance and enforcement, and criteria for distinguishing between menus and other information presented to the consumer. The agency also is withdrawing certain questions and answers in a May 5, 2016, guidance (81 FR 27067) concerning menu labeling requirements for restaurants and retail establishments selling away-from-home foods. Comments are due Jan. 8, 2018. Contact: Ashley Rulffes; FDA, Center for Food Safety and Applied Nutrition; 240-402-2371. Citations: 21 CFR 11, 101

82 FR 52036 (11/09/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Texas/Lower Bois d'Arc Creek Reservoir

GENERAL ENVIRONMENT AND SAFETY

Notice of the U.S. Army Corps of Engineers announces the availability of the final environmental impact statement for the Lower Bois d'Arc Creek Reservoir, in Fannin County, Texas. The project, proposed by the North Texas Municipal Water District, includes construction of a dam, raw water intake pump station and electrical substation, a buried pipeline, a new water treatment plant, and a terminal storage reservoir to provide up to 175,000 acre-feet/year of new water for member cities and customers in nine counties. Comments are due Dec. 9, 2017. Contact: Andrew Commer; USACE, Tulsa District Regulatory Office; 918-669-7400

82 FR 52042 (11/09/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Tobacco Products Scientific Advisory Committee Meeting

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a meeting of the Tobacco Products Scientific Advisory Committee. The agenda includes discussion of modified risk tobacco production applications submitted by Philip Morris Products SA, of Neuchâtel, Switzerland, for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks. The meeting is scheduled for Jan. 24-25, 2018, in Silver Spring, Md. Comments are due Jan. 4, 2018. Contact: Caryn Cohen; FDA, Center for Tobacco Products; 877-287-1373; TPSAC@fda.hhs.gov

82 FR 52051 (11/09/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Use of Drug Master Files for Shared System REMS Submissions
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a draft guidance for industry regarding the use of drug master files for shared system risk evaluation and mitigation strategy (REMS) submissions. Shared system REMS are used in abbreviated new drug applications referencing an innovator drug for which the FDA has required that REMS include one or more elements to assure safe use. Shared system REMS also are used when multiple applicants coordinate the submission of identical documents to their respective applications. The FDA recommends that applicants that are part of a shared system REMS use a Type V drug master file for their REMS submissions to improve the efficiency of the submission and review process. Comments are due Jan. 8, 2018. Contact: Gita Toyserkani; FDA, Center for Drug Evaluation and Research; 301-796-1783, Gita.Toyserkani@fda.hhs.gov

82 FR 52058 (11/09/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Virginia/Norfolk Harbor Navigation Improvements
GENERAL ENVIRONMENT AND SAFETY

Notice of the U.S. Army Corps of Engineers announces the availability of a draft general reevaluation report and environmental assessment for navigation improvements to Norfolk Harbor in Hampton Roads, Va. The report is intended to identify whether the original authorized plan is still in the federal interest and to evaluate alternatives that have the potential to improve the current and future operational efficiency of commercial vessels currently using the harbor. The environmental assessment identifies the preferred alternative, which includes deepening of four channels, deepening an anchorage, and widening channel meeting areas. Comments are due Dec. 11, 2017. Contact: Kimberly Koelsch; USACE Norfolk District; 757-201-7837; kimberly.c.koelsch@usace.army.mil

82 FR 52041 (11/09/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH
Cranes and Derricks in Construction/Operator Certification
OCCUPATIONAL SAFETY AND HEALTH

Final rule of OSHA extends for one year, until Nov. 10, 2018, the enforcement date for crane operator certification and the existing employer assessment duty to ensure crane operator competency for construction work. The provisions were originally adopted in an Aug. 9, 2010, final rule (75 FR 47906), and the deadline for operator certification and existing employers duties was extended for an additional three years, until Nov. 10, 2017, in a Sept. 26, 2014, final rule (79 FR 57785). The rule extends the existing employer duty and enforcement date for an additional year to provide that covered operators are competent to operate the equipment safely. The rule is effective Nov. 9, 2017. Contact: Frank Meilinger; OSHA, Office of Communications; 202-693-1999; Meilinger.Francis2@dol.gov. Citations: 29 CFR 1926.1427(k)

82 FR 51986 (11/09/2017)

Regulatory Update

TOXIC SUBSTANCES

Child and Adult Blood Lead Surveillance

TOXIC SUBSTANCES

Notice of the National Center for Environmental Health announces the submission of a new information collection request to the OMB regarding the NCEH Childhood Blood Lead Surveillance Program and the National Institutes for Occupational Safety and Health Adult Blood Lead Epidemiology and Surveillance Program. The collection addresses the surveillance of blood lead over the human lifespan for children under 16 years and for adults 16 years and older to screen for and prevent exposure to lead and build state capacity for adult blood lead surveillance programs. Comments are due Dec. 11, 2017. Contact: Leroy Richardson; CDC, Office of Scientific Integrity; 404-639-7570; omb@cdc.gov

82 FR 52047 (11/09/2017)

Regulatory Update

TOXIC SUBSTANCES

Draft Report on Carcinogens Monograph on Antimony Trioxide

TOXIC SUBSTANCES

Notice of the National Institute of Environmental Health Sciences announces a peer review meeting to discuss a National Toxicology Program draft report on carcinogens (RoC) monograph on antimony trioxide found in halogenated flame retardants in textiles, plastics, and rubber. The main exposures to antimony trioxide are from inhalation of airborne solid dust and for workers in facilities producing or using the chemical. The draft RoC includes a cancer hazard assessment the chemical. The draft RoC will be available Nov. 30, 2017. The meeting is scheduled for Jan. 24, 2018, via webcast. Comments are due Jan. 10, 2018. Contact: Camden Byrd; ICF; 919-293-1660; camden.byrd@icf.com

82 FR 52066 (11/09/2017)

Regulatory Update

TOXIC SUBSTANCES

National Toxicology Program Board of Scientific Counselors Meeting

TOXIC SUBSTANCES

Notice of the NIH announces a meeting of the National Toxicology Program (NTP) Board of Scientific Counselors. The agenda includes discussion of new approaches to evaluate the safety of chemicals and medical products, approaches to hazard characterization and risk assessment, updates on NTP studies of glyphosate, and discussion of a draft report on carcinogens monograph on haloacetic acids. The meeting is scheduled for Dec. 7-8, 2017, in Research Triangle Park, N.C., and via webcast. Comments are due Nov. 30, 2017. Contact: Mary Wolfe; NIH, National Institute of Environmental Health Sciences; 984-287-3209; wolfe@niehs.nih.gov

82 FR 52064 (11/09/2017)

Regulatory Update

WATER

Confidential Business Information Under CWA

WATER

Notice announces the intention of the EPA to transfer confidential business information collected from numerous industries under a new contract to Eastern Research Group, of Chantilly, Va., and its subcontractors. The transfer would allow the contractor to assist the Office of Water in the preparation of effluent guidelines and standards under the Clean Water Act and with its effluent guidelines planning and review activities for a variety of industries. Comments are due Nov. 17, 2017. Contact: Ahmar Siddiqui; EPA, Engineering and Analysis Division; 202-566-1044; siddiqui.ahmar@epa.gov

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Regulatory Update

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