

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

December 01, 2017 - Number 230

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Summaries

ENDANGERED SPECIES

Alaska/Marine Mammals Incidental Take

ENDANGERED SPECIES

Notice of the National Marine Fisheries Service announces the receipt of a request from the National Park Service for authorization to take marine mammals incidental to glaucous-winged gull and climate monitoring research activities in Glacier Bay National Park in Alaska. The authorization would allow the take of harbor seals by Level B harassment during ground and vessel surveys at four study sites up to five times per year and during weather station installation, maintenance, and operation at one of the sites up to four additional times per year. The authorization would be valid from March 1, 2018, to Feb. 28, 2019. The authorization also specifies mitigation, monitoring, and reporting requirements. Comments are due Jan. 2, 2018. Contact: Jonathan Molineaux; NMFS, Office of Protected Resources; 301-427-8401; ITP.molineaux@noaa.gov

82 FR 56953 (12/01/2017)

Regulatory Update

ENDANGERED SPECIES

Coastal California Gnatcatcher Incidental Take Permit

ENDANGERED SPECIES

Notice of the U.S. Fish and Wildlife Service announces the receipt of an application from Orange County Waste & Recycling for a five-year incidental take permit for the threatened coastal California gnatcatcher in connection with the construction, operation, and maintenance of the Olinda Alpha Landfill projects, in Brea, Calif. The agency has made a preliminary determination that the action qualifies as a low-effect habitat conservation plan and is categorically excluded from requirements to prepare an environmental assessment or an environmental impact statement. Comments are due Jan. 2, 2018. Contact: Karen Goebel; USFWS, Carlsbad Fish and Wildlife Office; 760-431-9440

82 FR 56990 (12/01/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Antimicrobial Drugs Advisory Committee Meeting

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a meeting of the Antimicrobial Drugs Advisory Committee. The agenda includes discussion of a new drug application (NDA 210693) for Ciprofloxacin dispersion for inhalation, sponsored by Aradigm Corp., of Hayward, Calif. The proposed indication is for the treatment of noncystic fibrosis bronchiectasis patients with chronic lung infections with *Pseudomonas aeruginosa*. The meeting is scheduled for Jan. 11, 2018, in Hyattsville, Md. Comments are due Jan. 10, 2018. Contact: Lauren Tesh; FDA, Center for Drug Evaluation; 301-796-9001; AMDAC@fda.hhs.gov

82 FR 56975 (12/01/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Atlantic Hurricanes/Streamlined Environmental Assessment Procedures

GENERAL ENVIRONMENT AND SAFETY

Notice of the Federal Emergency Management Agency, in consultation with the Department of Homeland Security, announces a determination that exigent circumstances exist for the use of streamlined procedures for activities in areas impacted by hurricanes Harvey, Irma, Maria, and Nate that require an environmental assessment. FEMA may provide a three-day comment period for actions involving group housing sites and certain interim and/or temporary facilities, and a 14-day comment period for all other actions. FEMA also may favor electronic media for public notifications, focus EA level analysis and documentation on the "no action" and "proposed action" alternatives, and discuss resource areas in detail only if it determines that there is a potential impact to the resources. Contact: Katherine Zeringue; FEMA; 202-212-2282; Katherine.zeringue@fema.dhs.gov. Citations: 40 CFR 1501.7, 1508.9

82 FR 56984 (12/01/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Determination Concerning Safety and Effectiveness/Meticorten

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination that Meticorten (prednisone) 1 milligram (mg) and 5 mg tablets, held by Schering Corp., were not withdrawn from sale for reasons of safety or effectiveness. The determination will allow the FDA to approve abbreviated new drug applications that refer to the product if relevant legal and regulatory requirements are met. Contact: Meadow Platt; FDA, Center for Drug Evaluation and Research; 301-796-1830; Meadow.Platt@fda.hhs.gov

82 FR 56974 (12/01/2017)

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 Nov. 20-24, 2017. Contact: Kelly Knight; EPA, Office of Federal Activities; 202-564-7146; knight.kelly@epa.gov. Citations: 40 CFR 1506.9

82 FR 56972 (12/01/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Hawaii/Lalamilo Wind Farm Repowering Project

GENERAL ENVIRONMENT AND SAFETY

Notice of the U.S. Fish and Wildlife Service announces the receipt of an application from Lalamilo Wind Co. and the associated draft environmental assessment and habitat conservation plan for a 20-year incidental take permit for the Hawaiian hoary bat and petrel in Kamuela, Hawaii. The applicant requests authorization for the incidental take that may occur as a result of the operation of the Lalamilo Wind Farm Repowering Project that would provide electricity to eight existing water wells in the Lalamilo-Parker well system. Comments are due Jan. 16, 2018. Contact: Michelle Bogardus; USFWS; 808-792-9400; lalamilohcp_ea@fws.gov

82 FR 56987 (12/01/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Withdrawal of Approval of Abbreviated New Drug Applications

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the withdrawal of approval for 68 abbreviated new drug applications (ANDAs) held by multiple applicants. The applicants have requested the withdrawals because the drug products are no longer marketed. The withdrawals are effective Jan. 2, 2018. Contact: Trang Tran; FDA, Center for Drug Evaluation and Research; 240-402-7945. Citations: 21 CFR 314.150

82 FR 56976 (12/01/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP

Massachusetts/Hatheway & Patterson Superfund Site

HAZARDOUS WASTE CLEANUP

Direct final rule of the EPA deletes the Hatheway & Patterson Superfund Site in Foxborough and

Mansfield counties in Massachusetts from the National Priorities List. The agency and the Massachusetts Department of Environmental Protection have determined that all appropriate response actions under CERCLA have been completed. This deletion does not preclude future actions under Superfund. The rule is effective Jan. 30, 2018, unless adverse comments are received by Jan. 2, 2018. Contact: Kimberly White; EPA Region 1, Office of Site Remediation and Restoration; 617-918-1752; white.kimberly@epa.gov. Citations 40 CFR 300, Appendix B

82 FR 56890 (12/01/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP

Massachusetts/Hatheway & Patterson Superfund Site

HAZARDOUS WASTE CLEANUP

Proposed rule of the EPA would delete the Hatheway & Patterson Superfund Site in Foxborough and Mansfield counties in Massachusetts from the National Priorities List. The agency and the Massachusetts Department of Environmental Protection have determined that all appropriate response actions under CERCLA have been completed. This deletion does not preclude future actions under Superfund. A concurrent direct final rule adopts the changes, effective Jan. 30, 2018. Comments are due Jan. 2, 2018. Contact: Kimberly White; EPA Region 1, Office of Site Remediation and Restoration; 617-918-1752; white.kimberly@epa.gov. Citations 40 CFR 300, Appendix B

82 FR 56939 (12/01/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH

National Occupational Research Agenda/Transportation, Warehousing, and Utilities 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 transportation, warehousing, and utilities (TWU). The agenda identifies the most important occupational safety and health research needed to prevent occupational injuries and illness in the TWU sector from 2016 to 2026 and provides a national strategic plan for government, higher education, and industry research and development entities. Comments are due Jan. 30, 2018. Contact: Emily Novicki; NIOSH; 404-498-2581; NORACoordinator@cdc.gov

82 FR 56973 (12/01/2017)

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