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**From:** Bloomberg BNA  
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## **EHS Federal Regulatory Alert**

July 12, 2017 - Number 132

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### Summaries

#### *FOOD SAFETY*

##### New Animal Drug Applications/Withdrawal of Approval

#### **FOOD SAFETY**

Notice of the FDA announces the withdrawal of approval of two new animal drug applications for bulk dihydrostreptomycin sulfate (NADA 065-291) and bulk streptomycin sulfate (NADA 065-324). The actions are taken at the request of the sponsor, Zoetis Inc., of Kalamazoo, Mich., because the products are no longer manufactured or marketed. The withdrawals are effective July 24, 2017. Contact: Sujaya Dessai; FDA, Center for Veterinary Medicine; 240-402-5761; sujaya.dessai@fda.hhs.gov. Citations: 21 CFR 514.116

82 FR 32188 (07/12/2017)

#### Regulatory Update

#### **GENERAL ENVIRONMENT AND SAFETY**

##### Controlled Substances/Removal of Naldemedine

#### **GENERAL ENVIRONMENT AND SAFETY**

Proposed rule of the Drug Enforcement Administration would remove the opium alkaloid derivative naldemedine and its salts from Schedule II of the Controlled Substances Act. The rule is issued in response to a request by new drug application sponsor, Shionogi Inc., of Florham Park, N.J. The FDA has approved naldemedine for marketing under the trade name Symproic® (0.2 mg tablets) for the treatment of opioid-induced constipation in adults with chronic noncancer pain and has determined that it is unlikely the substance possesses abuse-related indications. Comments and hearing requests are due Aug. 11, 2017. Contact: Michael Lewis; DEA, Diversion Control Division; 202-598-6812. Citations: 21 CFR 1308.12

82 FR 32153 (07/12/2017)

#### Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Vermont/Highgate Transmission Interconnection

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Energy Department announces the receipt of an application from Vermont Electric Power Co., of Rutland, Vt., to amend a presidential permit (PP-82) regarding ownership of the Highgate Transmission Interconnection Facility. The amendment specifies that Vermont Transco LLC will acquire 87.03 percent of the ownership interest in the facility, and Stowe Electric Department will acquire 5.27 percent of the ownership. In addition, Burlington Electric Department will remain a joint owner with 7.7 percent interest. Comments or motions to intervene are due Aug. 11, 2017. Contact: Christopher Lawrence; DOE; 202-586-5260; Christopher.Lawrence@hq.doe.gov

82 FR 32182 (07/12/2017)

Regulatory Update

**RADIATION**

Advisory Committee on the Medical Uses of Isotopes Meeting

**RADIATION**

Notice of the NRC announces a meeting of the Advisory Committee on the Medical Uses of Isotopes. The agenda includes updates on medical-related events, licensing guidance for yttrium-90 microsphere brachytherapy, category 3 source security and accountability evaluation initiatives, and the patient release project. The committee also will discuss medical event reporting and its impact on safety culture; training and experience requirements for authorized individuals; nursing mother guidelines for exposure to diagnostic and therapeutic radiopharmaceuticals; and the physical presence requirements for the Leksell Gamma Knife® Icon™. The meeting is scheduled for Sept. 11-12, 2017, in Rockville, Md., and via webcast. Comments are due Sept. 6, 2017. Contact: Sophie Holiday; NRC; 301-415-7865; sophie.holiday@nrc.gov. Citation: 10 CFR 35

82 FR 32207 (07/12/2017)

Regulatory Update

**WATER**

Addressing Cyber Risks at Maritime Transportation Security Act Regulated Facilities

**WATER**

Notice of the U.S. Coast Guard announces the availability of the draft Navigation and Inspection Circular (05-17) guidance for addressing cyber risks at Maritime Transportation Security Act regulated facilities. The document clarifies existing requirements under the MTSA to incorporate analysis of computer and cyber risks and provides guidance for addressing those risks. The document also addresses incorporation of cybersecurity risks into an effective facility security assessment and policies and procedures that may reduce cyber risk to operators of maritime facilities. The document may be used as a benchmark to develop and implement measures and activities for effective self-governance of cyber risks. Comments are due Sept. 11, 2017. Contact: Jason Warren; USCG; 202-372-1106; Jason.S.Warren@uscg.mil

82 FR 32189 (07/12/2017)

Regulatory Update

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