

FDA News Flash January 26, 2012

FDA REGULATORY NEWS

- FDA's Center for Devices and Radiological Health (CDRH) released its 2012 strategic priorities focusing on four areas: implementing a total product life cycle approach, enhancing its internal and external communication and transparency, strengthening its workforce, and proactively facilitating innovation. The initiatives include a pilot program set to begin April 1, 2012 to triage premarket applications to increase review efficiency, and a proposal by December 31, 2012 to clarify the circumstances when CDRH could rely on clinical studies conducted in and for other countries. [[Strategic Priorities](#)] (MassDevice)

FDA COMPLIANCE NEWS

- This month, FDA and the European Medicines Agency (EMA) launched an initiative to rely on each other's domestic drug GMP inspections. In a document issued by both agencies, the joint initiative will focus on surveillance inspections of sites with good track records, and sets forth a strategy for deferring or waiving some inspections. [[Joint Document](#)] (The Gold Sheet)

POLICY AND LEGISLATION NEWS

- US Representative John Carney (Democrat – Delaware) plans to introduce legislation to the US House of Representatives which would mandate that FDA create a more detailed critical drug shortage list and notification system. In addition to the new system providing more information on the drug shortage, such as estimated mitigation date, reason for the shortage, and potential alternative therapies, the agency would be allowed to formally notify competitors about a specific shortage. (The Pink Sheet Daily)

CLIENT NEWS

- Amgen to acquire Micromet at a transaction valued at \$1.16B (Amgen Press Release)
- Fenwal receives FDA clearance for the Fenwal Amicus separator and Fenwal DXT™ Relay productivity software (MassDevice)
- Roche implements new packaging line for Coagucheck diagnostic strips (Pharmaceutical Business Review)
- Sanofi partners with Nichi-Iko for biosimilar infliximab in Japan (Scrip)

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MEETINGS

- **NEW:** Vaccines and Related Biological Products Advisory Committee. February 28-29, 2012. On February 28, hear an overview of the research program in the Laboratory of Mycobacterial Diseases and Cellular Immunology, Division of Bacterial, Parasitic and

Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA, and discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2012 and 2013 influenza season. On February 29, discuss licensure pathways for pandemic influenza vaccines. [[FR Notice](#)]

Next week

- Pediatric Advisory Committee. January 30, 2012. Discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act for Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein), Cervarix (Human Papillomavirus Bivalent (Types 16 and 18) vaccine, recombinant, Focalin XR (dexamethylphenidate), Daytrana (methylphenidate), Seroquel (quetiapine), Pancreaze (pancrelipase), Zenpep (pancrelipase), Creon (pancrelipase), Xerese cream 5%/1% (acyclovir and hydrocortisone), Xolair (omalizumab), Benicar (olmesartan medoxomil), Atacand (candesartan cilexetil), Mirena (levonorgestrel—releasing intrauterine system), Plan B One Step (levonorgestrel), and Flomax (tamsulosin). [[FR Notice](#)]

Next 30 days

- Oncologic Drugs Advisory Committee. February 8, 2012. Discuss supplemental biologics license application 125320/28 for XGEVA (denosumab) injection, application submitted by Amgen, Inc. The proposed indication for this product is for the treatment of men with castrate-resistant prostate cancer at high risk of developing bone metastases, or spread of cancer to the bones. Amgen, Inc., (NASDAQ:AMGN). [[FR Notice](#)]
- Oncologic Drugs Advisory Committee. February 9, 2012. Discuss supplemental new drug application (NDA) 21790/010 for DACOGEN (decitabine) for injection, application submitted by Eisai, Inc. The proposed indication for this product is for the treatment of acute myelogenous leukemia (AML) in adults 65 years of age or older who are not considered candidates for induction chemotherapy. Discuss NDA 022481, with the proposed trade name PIXUVRI (pixantrone dimaleate) injection, application submitted by Cell Therapeutics, Inc. The proposed indication for this product is as a single agent treatment for patients with relapsed or refractory, aggressive Non-Hodgkin's Lymphoma who received two or more prior lines of therapy. Cell Therapeutics, Inc., (NASDAQ:CTIC). [[FR Notice](#)]
- Anesthetic and Analgesic Drug Products Advisory Committee. February 9, 2012. Discuss the available efficacy and safety data for supplemental new drug application (sNDA) 22395/S-013, QUTENZA (capsaicin 8%) Patch, by NeurogesX, Inc., for the proposed indication of management of neuropathic pain (nerve pain) related to HIV-associated peripheral neuropathy. NeurogesX, Inc., (NASDAQ:NGSX). [[FR Notice](#)]
- Neurological Devices Panel of the Medical Devices Advisory Committee. February 10, 2012. Discuss and make recommendations regarding the possible reclassification of cranial electrotherapy stimulator (CES) devices. [[FR Notice](#)]
- Cellular, Tissue, and Gene Therapies Advisory Committee. February 10, 2012. Hear updates of the research programs in the Cellular and Tissue Branch, Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research, FDA. [[FR Notice](#)]
- Public Workshop. February 15, 2012. Ethical and Regulatory Challenges in the Development of Pediatric Medical Countermeasures. Plenaries and breakout sessions on the ethical and regulatory challenges in the development of medical countermeasures for the pediatric population. [[FR Notice](#)]

Next 90 days

- Endocrinologic and Metabolic Drugs Advisory Committee. February 22, 2012. Discuss the safety and efficacy of new drug application (NDA) 22-580, proposed trade name QNEXA (phentermine/topiramate) Controlled-Release Capsules, manufactured by VIVUS, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index (BMI) equal to or greater than 30 kilograms (kg) per square meter or a BMI equal to or greater than 27 kg per square meter if accompanied by weight-related comorbidities. VIVUS, Inc., (NASDAQ:VVUS). [\[FR Notice\]](#)
- Cardiovascular and Renal Drugs Advisory Committee. February 23, 2012. Discuss the new drug application (NDA) 203202, proposed trade name NORTHERA (droxidopa capsules), submitted by Chelsea Therapeutics, Inc., for the treatment of symptomatic neurogenic orthostatic hypotension in patients with primary autonomic failure (Parkinson's Disease, Multiple System Atrophy, and Pure Autonomic Failure), Dopamine Beta-Hydroxylase Deficiency, and Non-Diabetic Autonomic Neuropathy. Chelsea Therapeutics, Inc., (NASDAQ:CHTP). [\[FR Notice\]](#)
- Dermatologic and Ophthalmic Drugs Advisory Committee. February 27, 2012. Comment on the following topics related to the use of ophthalmic drug products: Appropriate types of clinical evidence for developing anti-inflammatory drugs for the treatment of postoperative drugs and reduction of ocular pain in patients who have undergone ocular surgery; and the appropriateness of marketing a single bottle of ophthalmic product for use in both eyes for postsurgical indications as it relates to the potential risk for infection. [\[FR Notice\]](#)
- FDA Rare Disease Patient Advocacy Day. March 1, 2012. Meeting to enhance the awareness of the rare disease community as to FDA's roles and responsibilities in the development of products (drugs, biological products, and devices) intended for the diagnosis, prevention, and/or treatment of rare diseases or conditions. [\[FR Notice\]](#)
- Public Workshop. March 7-8, 2012. FDA Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice. Co-sponsored by the FDA Los Angeles District Office and the Society of Clinical Research Associates (SoCRA). Aid the clinical research professional's understanding of the mission, responsibilities, and authority of the FDA and to facilitate interaction with FDA representatives; focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRB). [\[FR Notice\]](#)
- Arthritis Advisory Committee Meeting. March 12, 2012. Discuss the anti-nerve growth factor (Anti-NGF) drug class that is currently under development and the safety issues possibly related to these drugs. [\[FR Notice\]](#)
- Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting. March 14, 2012. Discuss the clinical pharmacology aspects of pediatric clinical trial design and dosing to optimize pediatric drug development. [\[FR Notice\]](#)
- Public Workshop. May 3, 2012. Clinical Development Programs for Sedation Products. Solicit information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups as FDA develops guidance on clinical development programs for sedation products. [\[FR Notice\]](#)
- Public Workshop. April 12, 2012. Role of Naloxone in Opioid Overdose Fatality Prevention. [\[FR Notice\]](#)
- **POSTPONED:** Immunology Devices Panel. TBD. Discuss, make recommendations, and vote on a premarket approval application for the ProgenSA PCA3 assay, which is indicated to

aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended based on current standard of care, before consideration of PCA3 assay results. Gen-Probe, Inc., (NASDAQ:GPRO). [[FR Notice](#)]

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