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In this issue...

AAHRPP Lengthens Reaccreditations, Tightens Compliance Policies

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) is extending its reaccreditation period for drug sponsors and institutional review boards while tightening some of its other compliance policies. AAHRPP lengthened the current reaccreditation period from three years to five, beginning Jan. 1. "We want to reduce the burden on organizations, so they can spend more time doing what they have to do in order to remain accredited," AAHRPP spokesman David Ward said.
Drug Industry Daily

PhRMA Says $80 Billion Agreement Unchanged, But It Keeps Open Mind

PhRMA is denying that its $80 billion deal with the White House to help finance healthcare overhaul legislation has been increased. The trade group's denial follows a statement from Sen. Byron Dorgan (D-N.D.) that an anticipated increase may have led Senators to vote against his amendment allowing for the reimportation of prescription drugs. "No one has asked us to date to provide any additional funding," Ken Johnson, senior vice president at PhRMA, said. "We made an $80 billion ironclad commitment to help make healthcare reform a reality back in June, and we have never, at any time, retrenched from that position. That said, we will continue to keep an open mind as the Senate moves toward a final vote."
Washington Drug Letter

Guidance: Sponsors Should Define Role PRO Endpoint Plays in Clinical Trial

After three years of comment review, the FDA has issued a final guidance on patient-reported outcome (PRO) instruments submitted in applications. Sponsors should define the role a PRO endpoint plays in trials so appropriate statistical methods can be planned and applied, the guidance says. It revises a February 2006 draft, for which the agency received 22 comments.
Clinical Trials Advisor

Drug World Daily

Sanofi-Aventis Stops Development of Two Medicines

Sanofi-Aventis SA stopped tests on two medicines for insomnia and atrial fibrillation because of setbacks in development and said it is making progress with potential drugs to prevent clots and treat prostate cancer.
Bloomberg

China Aoxing Receives GMP Recertification of Four Drug Dosage Forms at New Facility

China Aoxing Pharmaceutical Company, Inc., a pharmaceutical company specializing in research, development, manufacturing and distribution of narcotic and pain-management products, Monday announced that it has successfully passed the Good Manufacturing Practice (GMP) re-certification of four dosage forms, including capsule, tablet, granule and oral solution formulations, at its new manufacture and packaging facility.
CNNMoney

OncoGenex Grabs $60 Million Upfront From Teva for Rights to Cancer Drug

Bothell, WA-based OncoGenex Pharmaceuticals announced Monday it has clinched $60 million in upfront payments from Israel-based Teva Pharmaceutical for the right to co-develop an experimental prostate cancer drug that has been shown to prolong patients' lives in a small study.
Xconomy

Cell Therapeutics Granted Pixantrone Orphan Drug Designation by EMEA for DLBCL

Monday, Cell Therapeutics Inc. said it has been granted pixantrone orphan drug designation by European Medicines Agency or EMEA for the treatment of [diffuse large B-cell lymphoma] DLBCL which accounts for around 80% of aggressive non-Hodgkin's lymphoma.
RTTNews

Actelion Shares Sink on Almorexant Safety Woes

Shares of biotech company Actelion Ltd. fell Monday after initial late-stage data for its experimental sleeping pill almorexant raised safety concerns.
Easybourse

UCB Says Crohn's Study Fails to Prove Drug

Belgian pharmaceutical group UCB said on Monday a test of a drug to treat Crohn's disease did not achieve the required results, casting doubt on its chances of approval in the European Union.
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Pharma Blog Watch

Genzyme Founder Says CEO Termeer Must Go (Pharmalot)

Ed Silverman comments on rumors of a high-level change at Genzyme, which has added an independent director and shuffled its management. Sheridan Snyder, the company's founder who recruited Henri Termeer as its CEO, is saying Termeer should go. "Genzyme has endured nothing but trouble this year as quality control problems forced the biotech to suspend shipments of key products for such ailments as Gaucher's and Fabry diseases, and the subsequent shortages prompted the FDA to allow rivals to jumpstart plans to produce their own meds to fill the void," Silverman says.

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FDAnews, 300 N. Washington St., Suite 200, Falls Church, VA 22046-3431