Top News

FDA Panel Split Over Meridia Approval

The FDA advisory panel tasked with making a recommendation on whether the agency should allow for the continued use of Meridia and which warnings should accompany the drug, was split in its recent decision, with half the members of a sixteen member panel urging that the drug be withdrawn. Those eight members concluded that the heart risks of the drugs outweighed its potential benefits. Members of the panel also pressed the agency to release development standards for weight-loss drugs. An FDA panel also recommended against the agency approving a different weight loss drug, known as lorcaserin, finding that drug’s benefits did not outweigh its risks.

Industry, Consumer Advocates Differ in Views of MDUFMA User Fee Negotiations

While consumer advocates are pushing the FDA to increase user fees as part of its next round of negotiations under the Medical Device User Fee and Modernization Act (MDUFMA), industry has indicated that it does not support an increase in such user fees because the FDA has thus far failed to meet its goals put forward in the last round of negotiations. The Medical Device Manufacturers Association has indicated that it is not pleased with the FDA’s progress in meeting its goals, including increased collaboration, predictability, and timeliness, under the MDUFMA and is calling on the agency to work harder toward meeting those goals before it further increases user fees. The agency has indicated that it intends to release draft recommendations regarding user fee reauthorization in about a year’s time and then hold another public meeting. Final recommendations are due to Congress by January 2012. Agency officials have indicated that the changes that the agency is considering with regards to the 510(k) process will also have implications for user fees.

Members of Congress Introduce Bill for Inspection Parity

Four House Democrats in the House of Representatives have released draft legislation that aims to create parity in foreign and domestic inspections of drug manufacturing sites. The legislation would also provide the FDA with mandatory recall authority over drugs.
Agency News

The FDA and DOJ have announced that Forest Pharmaceuticals, Inc. has agreed to pay over $300 million to settle criminal and civil allegations that it distributed a misbranded drug and an unapproved drug and that it obstructed an FDA inspection.

The FDA has indicated that it has begun a safety review of the drug Actos following its receipt of preliminary results from a long-term study designed to evaluate the risk of bladder cancer associated with use of the drug.

An FDA panel has voted 15-9 against a proposal that would require that dextromethorphan only be dispensed with a prescription.

Publications

The FDA has published a summary of drug products with safety labeling changes.

The FDA has published updated dosing recommendations for Valcyte oral tablets and solution used by children and adolescents receiving a kidney or heart transplant.

The FDA has published fee rates for using a tropical disease priority review voucher for fiscal year 2011.

The FDA has published a draft guidance entitled "Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment."

CBO has issued a report finding that the use of generic medications resulted in government and Medicare beneficiaries savings of approximately $33 billion in 2007.

Advamed has published a report finding that there have been 101 of the most serious kinds of recalls of medical devices from Jan. 1, 2005 to May 1, 2010. Advamed’s report argues that that is a remarkable number given the number of devices in the market, and has indicated that it will present the report in its meetings with FDA officials about proposed changes to the current 510(k) device approval process.

According to a recent report published in the Archives of Internal Medicine, less than half of physicians receiving at least $1 million in consulting fees from medical device companies in 2007 disclosed those ties in articles they authored about the industry.

According to a recent analysis by the ISI Group, cancer drugs face the greatest difficulty in gaining a positive opinion from the UK’s National Institute for Health and Clinical Excellence.

Approvals

The FDA has approved a new indication for three cardiac resynchronization therapy defibrillators used to treat certain heart failure patients.

The FDA has approved Krystexxa to treat gout in adults.

An FDA panel has recommended that the agency approve Alkermes Inc.’s drug Vivitrol as a treatment for addiction to opioid drugs.

The FDA has approved Medtronic’s Integrity bare-metal stent.

An FDA panel has recommended approval of Boehringer Ingelheim’s anticoagulant Pradaxa.

Recalls, Warnings, and Notifications

Westmed, Inc. has announced that it is initiating a nationwide recall of 24,384 units of BagEasy Manual Resuscitation Devices.
The FDA has announced that it will require gadolinium-based contrast agents carry new warnings on their labels about the risk of a rare and potentially fatal condition.

The FDA has announced a Class I recall of Hospira Symbiq One-Channel and Two-Channel Infusers.

The FDA has issued a warning to Bristol-Myers Squibb Co. for violations of good manufacturing practices at one of the company’s Puerto Rico plants.

**International News**

The *Washington Post* recently reported on the number of counterfeit drugs produced in India.

The UK’s National Institute for Health and Clinical Excellence has recommended that the National Health Service not pay for the treatment of patients having immune thrombocytopenic purpura with GlaxoSmithKline PLC’s drug Revolade.

Health ministers in Canadian provinces and territories have agreed to pool their resources when buying drugs and medical equipment in an effort to lower their costs. The ministers plan to use their powers as a collective to negotiate lower prices for drugs and devices.

Singapore’s Health Sciences Authority has announced that all devices imported and sold in the country must be registered by Jan. 1, 2012.

**Business News**

Genzyme Corp. has indicated that it intends to eliminate jobs. Meanwhile, Laboratory Corp. of America Holdings announced that it will acquire Genzyme Corp.'s genetic-testing business for $925 million and reports are indicating that Sanofi-Aventis SA may be readying itself for a bid to buy Genzyme. Genzyme has also indicated that it expects that the shortage of the drug Fabrazyme will end during the first half of 2011.

GlaxoSmithKline has announced that it has received a contract for $21.3 million to provide medical supplies to the US Army, Navy and Air Force.

AstraZeneca has reached an agreement with Cancer Research UK's Cancer Research Technology to begin early clinical trials on an experimental class of cancer metabolism drugs.

Covidien has indicated that it expects its annual sales growth for 2010 to be between 6 and 9 percent.

Roche Holding AG's has indicated that its drug Avastin failed to meet the primary goal of a late-stage study. Meanwhile, the FDA has indicated that it will require more time to evaluate the use of the drug to combat breast cancer.

Johnson & Johnson has indicated that it plans to purchase the remainder of vaccine maker Crucell NV for $2.3 billion. The company has also announced that the senior executive in charge of the company's consumer products division, Colleen A. Goggins, will retire in March of next year. The company has announced that its CEO William Weldon will testify before a House panel on Sept. 30 to answer questions on the drugmaker's recall of consumer healthcare products.

A lawsuit has been filed against Acura Pharmaceuticals Inc., accusing the company of misleading shareholders about the prospects of winning FDA approval for its drug Acurox.

Bayer’s chief has indicated that the company is predicting that the market for new blood thinners could reach up to $15 billion a year.

Boston Scientific has announced that it will acquire Asthmatx for up to $443.5 million.
Regulatory Notices

FDA Seeks Comments on Parallel Review of Medical Products

The FDA and the Centers for Medicare and Medicaid Services (CMS) have indicated that they are considering establishing a process for overlapping evaluations of premarket, FDA-regulated medical products when the product sponsor and both agencies agree to such parallel review. This process is intended to reduce the time between FDA marketing approval or clearance decisions and CMS national coverage determinations (NCDs). The agencies are seeking public comment on what products would be appropriate for parallel review by the two agencies, what procedures should be developed, how a parallel review process should be implemented, and other issues related to the effective operation of the process. The agencies also intend to create a pilot program for parallel review of medical devices. More information is available at http://edocket.access.gpo.gov/2010/2010-23252.htm.

Public Meetings

Cardiovascular and Renal Drugs Advisory Committee to Meet

The FDA has announced that the Cardiovascular and Renal Drugs Advisory Committee will meet on October 18, 2010, from 8 a.m. to 5 p.m. in Adelphi, Maryland. More information is available at http://edocket.access.gpo.gov/2010/2010-23514.htm.

Risk Communication Advisory Committee to Meet

The FDA has announced that the Risk Communication Advisory Committee will meet on November 8, 2010, from 8 a.m. to 5 p.m. and November 9, 2010, from 8 a.m. to 2 p.m. in Silver Spring, Maryland. More information is available at http://edocket.access.gpo.gov/2010/2010-23368.htm.

Peripheral and Central Nervous System Drugs and Drug Safety and Risk Management Advisory Committees to Meet

The FDA has announced that the Peripheral and Central Nervous System Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee will meet on November 3, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at http://edocket.access.gpo.gov/2010/2010-23044.htm.

Transmissible Spongiform Encephalopathies Advisory Committee to Meet

The FDA has announced that the Transmissible Spongiform Encephalopathies Advisory Committee will meet on October 28, 2010, from 8:30 a.m. to approximately 5 p.m. and on October 29, 2010, from 8:30 a.m. to approximately 12:30 p.m. in Gaithersburg, Maryland. More information is available at http://edocket.access.gpo.gov/2010/2010-22805.htm.

Neurological Devices Panel of the Medical Devices Advisory Committee to Meet

The FDA has announced that the Neurological Devices Panel of the Medical Devices Advisory Committee will meet on October 8, 2010, from 8 a.m. to 6 p.m. in Gaithersburg, Maryland. More information is available at http://edocket.access.gpo.gov/2010/2010-22804.htm.

Arthritis Advisory Committee to Meet

The FDA has announced that the Arthritis Advisory Committee will meet on November 16, 2010, from 8 a.m. to 5 p.m. in Adelphi, Maryland. More information is available at http://edocket.access.gpo.gov/2010/2010-22867.htm.
More Information

Archived issues of the Bryan Cave Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin and other FDA news bulletins are available at www.bryancave.com on the FDA Practice Bulletins web page.

If you have any questions regarding any of these issues, please contact:

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