BRYAN CAVE
A Broader Perspective

Bulletin

To: Our Clients and Friends **February 5, 2010**

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin

Top News

FDA, CMS May Collaborate to Combat Off-Label Marketing

The CMS budget justification includes a provision that suggests that the FDA and CMS will be teaming up as part of a pilot program that, among other items, will focus on off-label marketing. CMS proposes to contribute $1.7 million for the effort. The project is not mentioned in the FDA's budget. FDA officials have indicated that the agency plans to spend nearly $6 million next year preparing to approve biosimilars, which it has noted will mainly go toward preparing for legislation.

Some Predicting FDA Inspections to Increase by 50%

Some are predicting that the number of FDA inspections at foreign manufacturing facilities, and particularly in China, India, and Mexico, will increase by 50% this year, due to an increase in the number of FDA offices and staff abroad.

CMS Publishes Report on Healthcare, Drug Spending

CMS has published a report in the journal Health Affairs that showed healthcare spending continued to grow in the US last year, and now constitutes 17.3% of the country's GDP. The CMS Office of the Actuary has also released a report finding that public and private spending on prescription drugs increased 5.2 percent in 2009, with spending on drugs equaling $246.3 billion. Growth is expected to reach 5.6% in 2010.

Medical Journal Retracts Article Linking Vaccine to Autism

British medical journal *The Lancet* has retracted a 1998 research paper that linked the MMR vaccine to autism. The 1998 paper, authored by Dr. Andrew Wakefield, led to a wealth of studies examining whether a link existed between the vaccine and autism. The retraction follows the decision of a British medical panel that Dr. Wakefield had been dishonest, violated research ethics rules, and showed a "callous disregard" for suffering of the children he studied.

FDA to Appeal Decision on E-Cigarettes

The FDA has announced that it plans to appeal a recent ruling that the agency lacks the authority to regulate electronic cigarettes. The FDA is arguing that the case upon which the judgment was based does not prohibit the agency from regulating tobacco products as drugs or devices, and that the court erred in finding that 2009 tobacco legislation would cover electronic cigarettes.

FDA Announces PREDICT System

FDA Commissioner Margaret Hamburg has stated that the agency's new PREDICT Program, an automated system that will identify the most likely sources of contaminated food and drugs in foreign shipments, will allow FDA inspectors to target for inspection those shipments posing the greatest risk.

FDA Finds No Conflict of Interest in Heparin Investigation

FDA legal counsel Ralph Tyler has stated that HHS's investigation into the collaboration between the FDA's Dr. Janet Woodcock and scientists for Momenta Pharmaceuticals Inc. regarding research during the 2008 heparin crisis has been dropped and that there was not a conflict of interest.

OGD to Hire Additional Staff

The FDA's Office of Generic Drugs Director Gary Buehler has said that the agency plans to hire more staff this year to work on ANDA supplements, original applications and related review work such as consults and citizen petitions.

Group Calls for Greater Increase in 2011 FDA Funding

The Alliance for a Stronger FDA is calling for a greater increase in FDA funding than that currently provided in the President's 2011 Budget. The group has stated that the 23 percent increase in the FDA's budget is consistent with the increase in FDA's annual costs.

Stakeholders Seek Clarification on CER Funding in 2011 Budget

Stakeholders supporting patient-centered comparative effectiveness research are praising the Administration's allocation of an addition $286 million to AHRQ for CER research, but have expressed that additional clarification will be needed on the decision-making process behind the expenditure of the funds.

Group Objects to Proposed Policy on Patenting Genes

The Biotechnology Industry Organization, the lobbying group for US biotechnology companies, released a letter to US Health and Human Services Secretary Kathleen Sebelius objecting to provisions of a proposed policy that would restrict the ability of companies and scientists to patent human genes and exclusively market tests that find them or measure their activity.

Russia May Cap Drug Prices

A letter from Russian government officials to drug producers and distributors indicates that the Russian government may impose price caps on certain drugs this year.

Publications

The FDA has published an update to its December 3, 2009, notice regarding concerns about the Steris System 1 Processor, Components, and Accessories.

The FDA's Center for Tobacco Products has written letters to R.J. Reynolds Tobacco Co. and Star Scientific Inc. asking for research and marketing data on dissolvable tobacco products.

The FDA and industry have published the findings of a study of how susceptible ICDs and pacemakers are to electromagnetic interference, finding that the devices do only "limited filtering" of low-frequency RFID.

The Center for Drug Evaluation and Research's Office of Compliance has stated that it will release a guidance on cross-contamination for manufacturers this year.

The European Medicines Agency has published a guidance on PIPs, waivers and modifications for drugmakers seeking multiple marketing authorizations for single products.

Approvals

The FDA has approved Auxilium Pharmaceuticals Inc.'s Xiaflex treatment.

Onyx Pharmaceuticals has announced that it has reached an agreement with the FDA regarding the design of a late stage trial of its cancer drug candidate carfilzomib.

The FDA has accepted Teva Pharmaceutical Industries Ltd.'s application to sell a biosimilar of Amgen Inc.'s Neupogen.

The FDA has granted marketing approval to Canadian drugmaker Labopharm Inc. for its antidepressant Oleptro.

The FDA has approved Food and Drug Administration approved the addition of the pain drug lidocaine to wrinkle treatments Restylane-L and Perlane-L.

Keryx Biopharmaceuticals Inc. has announced that it has reached an agreement with the FDA on the design of a late-stage study of its cancer drug candidate perifosine.

The FDA has approved Roxane’s morphine sulfate oral solution.

Recalls, Warnings, and Notifications

Sanofi Pasteur has stated that it is recalling its H1N1 vaccine due to a lack of potency.

The FDA is requesting additional data on manufacturing and chemistry for Protalix Biotherapeutics’ drug candidate Uplyso.

The FDA has issued a warning to Eli Lilly and Co. regarding its drug promotion for Adcirca, stating that the promotion failed to include information about the drug’s risks.

The FDA has announced a Class I recall of the SafeSheath CSG Sheath Introducer.

The FDA has issued a warning letter to orthopedic devicemaker Endotec for GMP violations.

The FDA has issued a warning letter to Sorin Biomedica, stating that the company must report adverse events involving its devices that occur outside the U.S. to the Center for Devices and Radiological Health (CDRH) if the devices are marketed in the U.S.

The FDA has issued a warning letter to Sunrise Pharmaceutical for manufacturing some of its products with excess active pharmaceutical ingredient (API) without justification in its batch records.

The FDA has issued a warning letter to Bracco Diagnostics for making false and unsubstantiated claims about its diagnostic agent Isovue and omitting or minimizing risks associated with the agent.

Design output and corrective and preventive action failures were among six observations in a Form 483 issued to Cardiac Science.

The FDA has issued a warning letter to Florida Atlantic University saying that its IRB needs to needs to specify how it plans to ensure staff assesses studies and risks.

Business News

Medco Health Solutions announced that it has acquired DNA Direct.

Poniard Pharmaceuticals has announced that it will cut 57 percent of its staff and replace its current CEO.

Bristol-Myers Squibb Co. has announced that it is freezing employee salaries for 2010 and that the company plans to cut more than $2.5 billion in costs by 2012.

Roche has stated that it is overhauling its sales efforts for its cancer drug Avastin, and that it is assigning the sales team responsible for the Herceptin breast cancer drug to also promote Avastin. Roche has stated that its net profits for 2009 were down 22 per cent following its acquisition of Genentech.

Pfizer has stated that it is considering cutting its R&D spending by as much as $3 billion by 2012, following its acquisition of Wyeth. Pfizer has also stated that profit in the fourth quarter missed analyst estimates on costs from its Wyeth acquisition and projected lower-than-expected earnings in 2010.

The Justice Department has announced that medical device maker AtriCure Inc. has agreed to pay $3.76 million to resolve allegations that the company marketed its medical devices for a use that is not approved by the FDA.

AstraZeneca Plc is currently facing up to 26,000 lawsuits regarding its antipsychotic drug Seroquel. The drugmaker is currently preparing for its first jury trial on the claim that the drug causes diabetes.

GlaxoSmithKline Plc has stated that it will halt research into drugs for depression and pain and begin making treatments for rare diseases, including Alzheimer's and Parkinson's.

UK cardiologists and arrhythmia patient groups are petitioning the UK National Institute for Health and Clinical Excellence in an effort to convince the agency to allow prescriptions of dronedarone to treat atrial fibrillation.

Stakeholders in the device and biotechnology sector are supporting the Administration’s focus on small business job creation as having the potential to spur increased innovation in the industry.

Some are estimating that retail drugstores such as CVS Caremark Corp. and Walgreen Co. may see profits rise by 20 percent or more next year as branded drugs, including Lipitor and Plavix, become available as generics.

Allergan has stated that sales of its Lap-Band gastric band fell 5.3 percent in the fourth quarter, but nonetheless showed positive signs at the conclusion of 2009.

A federal appeals court has upheld a Boehringer Ingelheim patent for its Parkinson’s disease drug Mirapex.

A recent Oregon state court jury decision imposed liability on I-Flow, a pain pump manufacturer, for a physician’s off-label use of a pain pump in combination with a catheter, and ordered the company to pay almost $5.5 million to a patient.

Almost five months into closeout letter program, the FDA has issued only one letter for a medical product, leaving companies wondering when they can expect to receive the official stamp of approval that clears them of concerns raised in warning letters.

Regulatory Notices

FDA Seeks Comments on Proposed Information Collections

The FDA has announced an opportunity for public comment on several proposed collections of information. The agency is seeking comment on information collection requirements for Postmarket Surveillance, its Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference in Electronic Format to The Center for Veterinary Medicine, and its Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway.

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.

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