

To: Our Clients and Friends

March 30, 2010

## Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



### *Top News*

#### **Industry Submits Comments on 510(k) Review, Use of DeNovo Process**

Reports are predicting that, as the FDA considers changes to its 510(k) review process, it will face difficulties in expanding or creating a vehicle for the review of novel medical devices without requiring those technologies to go through the more cumbersome premarket approval process. Although some industry groups have called for the increased use of the DeNovo process for novel technologies, industry experts are indicating that the use of that avenue is complicated by a lack of resources and by the requirement that the FDA develop specific guidance documents for each approved device, a process that consumes agency resources and may make the agency more hesitant to such expansion.

Others are also submitting comments on the [510\(k\) review](#) process, as it undergoes reevaluation from the FDA. Comments include that the database requiring manufacturers to enter exact keywords to locate a predicate device is ineffective. In addition, industry has submitted comments regarding whether the FDA should have rescission authority for its 510(k) substantial equivalence decisions. Industry lobbyists have commented that such rescission authority should be limited to extreme cases of fraud. These groups state that the agency can make use of other means to remove problematic devices from the market, such as banning the product, mandating a recall, or ordering a product seizure.

#### **Industry Turns to New Biosimilars Implementation**

As industry stakeholders turn their attention toward FDA implementation of biosimilars, they expect to learn more from studying how the agency handles the first set of applications than from formal regulations or guidance documents. Industry stakeholders have indicated that they don't expect the FDA to fill in those gaps before accepting applications, but rather to learn from the experience of initial reviews and put that knowledge toward developing guidance down the road.

#### **House May Hold Hearing on Antimicrobial Resistance**

Reports are indicating that members of the House of Representatives are considering holding hearings on antimicrobial resistance, in response to increased calls from stakeholders to provide economic incentives, including tax credits, for the development of antibiotics and limit the use of antibiotics in animal feed.

## **New Precautionary Approach Seen in FDA's Rotarix Suspension Recommendation**

Consumer advocates are applauding the FDA's recent decision to recommend that physicians suspend the use of rotavirus vaccine Rotarix due to the presence of extraneous material present in the vaccine, saying that it demonstrates that the agency is taking a more precautionary approach. Others in the industry however, have expressed concern that the decision reflects a "play-it-by-ear" approach and could result in wasting agency resources and causing greater confusion.

## **FDA's Tobacco Products Scientific Advisory Committee to Meet**

The FDA's [Tobacco Products Scientific Advisory Committee](#) will meet Tuesday to discuss [menthol flavored cigarettes](#). The issue is a charged one, as opponents of smoking are calling for a ban on menthol in tobacco, saying that it is being used to conceal the taste of cigarettes and lure younger people into smoking. The Committee's task will be to review evidence and issue a recommendation as to what could be done. The FDA is scheduled to issue a report on menthol next year and take action by 2012.

## **Court Invalidates Breast Cancer Gene Patents**

A federal judge in New York [struck down patents](#) on two genes linked to breast and ovarian cancer on Monday. The ruling, which [invalidated](#) the patents held by Myriad Genetics on [the BRCA1 and BRCA2 genes](#), which are linked to breast and ovarian cancer. Reports are indicating that Myriad Genetics likely will appeal the decision.

## **Some Officials Worry about New H1N1 Outbreak**

Although incidents of H1N1 flu remain low around the U.S., [a recent increase of incidents](#) of the flu throughout the Southeast, and particularly in Georgia, has some officials worried that a third wave of the flu may be imminent.

## **CDRH Adopts Standard for Electronic Devices**

Carol Herman, director of standards management at CDRH, has stated that manufacturers will have three years to comply with the international standard International Electrotechnical Commission's 60601-1, recently adopted by CDRH.

## **Pharmacies Urge CMS to Stop Illegal Fees**

Pharmacies are urging CMS to stop health insurance companies from delaying statutory payment deadlines and from charging fees on each prescription, including post-processing fees, and in-network and out-of-network fees, which Part D network pharmacies say are illegal and extraneous.

## **Germany to Introduce Legislation on Drug Pricing**

German lawmakers have indicated that they intend to introduce and enact in 2010 "short-term measures" to prohibit price hikes on branded drugs and impose discounts of as much as 16% on pharmaceutical products. According to a Health Ministry spokesman, the bill could take effect as early as August and could save public health insurers \$667 million this year.

## **Publications**

The FDA has published a [guidance](#) for industry entitled "[Standards for Securing the Drug Supply Chain-Standardized Numerical Identification for Prescription Drug Packages](#)."

The FDA has updated its [online listing](#) of Medical, Statistical, and Clinical Pharmacology Reviews of Pediatric Studies Conducted under Section 505A and 505B of the Federal Food, Drug, and Cosmetic Act.

A recent [New York Times article](#) states that, according to documents and interviews with FDA scientists, the agency was warned about the potential dangers of the routine use of powerful CT scans but failed to inquire further into those risks.

The *New York Times* has published an article regarding doctor's concerns that their patients received [nitroglycerin tablets](#) that were unapproved by the FDA.

CMS has issued a National Coverage Determination stating that it will start paying for facial injections used by depressed HIV patients with sunken cheeks and other wasting effects caused by their medication.

## Approvals

The FDA has [approved the use](#) of Xifaxan for reduction in the risk of the recurrence of overt hepatic encephalopathy (HE) in patients with advanced liver disease.

## Recalls, Warnings, and Notifications

The FDA has issued a warning letter to Paddock Laboratories, giving the company until July 24 to submit a supplemental NDA for its oral morphine sulfate solution to treat pain.

The FDA has issued a warning letter to G3 Medical citing several good manufacturing practice issues.

## Business News

A recent column in the *Wall Street Journal* is predicting that Sanofi-Aventis SA may be considering selling pumps and glucose monitors in addition to insulin, based on statements made by the company's CEO.

K-V Pharmaceutical Co. has announced that it will not be able to resume sales of its products until at least October and may have to make additional cuts to its operations.

The Medicines Co. has stated that it has filed a federal lawsuit against the U.S. Patent and Trademark Office, the Food and Drug Administration and the Department of Health and Human Services over the denial of an extension for the principal US patent covering its drug Angiomax.

Vivus Inc. has announced that an FDA panel is scheduled to review its obesity drug candidate Qnexa on July 15, and the agency is expected to make a decision on the drug by October 28.

The *Financial Times* is reporting that GlaxoSmithKline has expressed an interest in investing in or collaborating with small and medium-sized drug companies in Japan in an attempt to improve global distribution.

Collegium Pharmaceuticals has submitted its drug candidates COL-172 and COL-003 for FDA approval as pain treatments.

Arca BioPharma has secured a U.S. patent for its approach covering the use of Gencaro as a treatment for heart failure based on genetic testing.

GlaxoSmithKline has indicated that Emma Walmsley, a former L'Oreal executive with a track record of building brands in China and established markets, will lead its consumer division.

The Wall Street Journal is reporting that the US Department of Justice and the Securities and Exchange Commission are investigating the recent recall by Boston Scientific Corp. of its implantable heart defibrillators. The company has stated that it is working on a plan to prevent a repeat of its ongoing implantable defibrillator recall and providing additional details to physicians about the two manufacturing changes that prompted the move two weeks ago.

Cephalon Inc. has lost its bid to dismiss antitrust suits, including one by the US Federal Trade Commission, accusing the company of using patent-infringement settlements to [delay generic competition](#) for its sleep-disorder drug Provigil. Cephalon also announced that the FDA has [declined to approve](#) use of its drug Nuvigil to [treat jet lag](#).

Z-Medica has become the first company to receive a closeout letter from the FDA— three months after it received an FDA warning letter citing validation and complaint-handling issues.

Baxter has stated that it is responding to good manufacturing practice observations by FDA inspectors in a recent 483 for one of its manufacturing facilities.

CDRH Director Jeffrey Shuren has announced that the FDA will announce the outcome of its re-review of ReGen Biologic's 510(k)-cleared Menaflex knee repair device in the coming weeks.

FDA device center director Jeffrey Shuren is encouraging manufacturers to focus more on prevention and to ensure their quality systems are doing what they are supposed to do prior to receiving FDA warning letters.

FDA Office of Oncology Drug Products Director Richard Pazdur used the decision of the Oncologic Drugs Advisory Committee's to reject Cell Therapeutics' *Pixuvri* treatment for relapsed/refractory non-Hodgkins lymphoma as an opportunity to urge sponsors to look beyond late-stage settings to test cancer drugs.

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## ***Regulatory Notices***

### **FDA Amends Public Hearing Regulations**

The FDA is amending its regulations on public hearings before public advisory committees to reflect an internal change with respect to the staff that handles the nomination and selection process for nonvoting members representing consumer interests for standing technical advisory committees. The FDA is also revising the address where the nominations for nonvoting members representing consumer interests should be submitted. More information is available at <http://edocket.access.gpo.gov/2010/2010-6861.htm>.

### **FDA Proposes Amendments to DTC Advertising Regulations**

The FDA is proposing to amend its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. Specifically, the proposed rule would implement a new requirement of the Federal Food, Drug, and Cosmetic Act, added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), that the major statement in DTC television or radio advertisements relating to the side effects and contraindications of an advertised prescription drug intended for use by humans be presented in a clear, conspicuous, and neutral manner. Written comments are due by June 28, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-6996.htm>.

### **FDA Announces ANPRM on VFD Drugs**

The FDA is announcing an advance notice of proposed rulemaking (ANPRM) to solicit comments from the public regarding potential changes to its current regulation relating to veterinary feed directive (VFD) drugs. Comments are due by June 28, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-6872.htm>.

### **FDA Proposes Amendment to Biologics Regulations**

The FDA is proposing to amend the biologics regulations to permit the Director of the Center for Biologics Evaluation and Research (CBER) or the Director of the Center for Drug Evaluation and Research (CDER), as appropriate, to approve exceptions or alternatives to the regulation for constituent materials. Comments on the proposed rule are due by June 28, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-7073.htm>.

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## ***Public Meetings***

### **FDA to Cosponsor Public Conference**

The FDA Cincinnati District, in co-sponsorship with Xavier University, is announcing a public conference entitled "FDA/Xavier University Global Medical Device Conference." This 3-day public conference includes presentations from key FDA officials, global regulators, and industry experts. The conference will be held on May 5, 2010, from 8 a.m. to 5 p.m.;

May 6, 2010, from 8 a.m. to 5 p.m.; and May 7, 2010, from 8 a.m. to 1 p.m. in Cincinnati, Ohio. More information is available at <http://edocket.access.gpo.gov/2010/2010-6865.htm>.

## FDA to Host Public Workshop

The FDA, in partnership with the Centers for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Diseases (NIAID), is announcing a public workshop entitled “Advancing the Development of Diagnostic Tests and Biomarkers for Tuberculosis (TB).” The purpose of the workshop is to provide an environment for FDA, CDC, and NIAID to engage other interested parties in identifying intellectual and procedural gaps in the current development of TB diagnostic tests, and in exploring models and strategies that would expedite the development of new diagnostic tests and biomarkers for TB. The public workshop will be held on June 7 and 8, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-6864.htm>.

## FDA to Hold Public Meeting on Advisory Panel Nominations, Membership

The FDA is announcing a public meeting for individuals and groups interested in nominating voting and nonvoting consumer representatives to FDA advisory committees and panels. This public meeting also is for individuals interested in serving as voting and nonvoting representatives of FDA advisory committees and panels. The purpose of the public meeting is to inform individuals and groups with consumer interests on how to participate in the nomination and selection process for members representing consumer interests on advisory committees, provide information on the structure and function of advisory committees seeking individuals to serve as consumer representatives, and update individuals and consumer groups and individuals on current committee vacancies. The meeting will be held on April 30, 2010, from 8:15 a.m. to approximately 4:30 p.m. in Rockville, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-6967.htm>.

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## 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](http://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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