

To: Our Clients and Friends

May 7, 2010

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



### Top News

#### FDA Issues Report on McNeil, House Committee to Investigate

The FDA has published an [inspection report](#) detailing some of its findings regarding [positive test results](#) for bacterial [contamination](#) in children's products manufactured by McNeil Consumer Healthcare. The company has [issued a recall](#) for more than more than 50 variations of infant's and children's Tylenol, Motrin, Zyrtec and Benadryl. The report also found that the company [failed to investigate](#) 46 complaints of foreign materials in the products. Leaders of the [House Committee on Oversight and Government Reform](#) have [announced](#) that they will conduct an investigation into the circumstances leading up to the recall. Johnson & Johnson has announced that it has suspended operations at a Pennsylvania plant following an FDA inspection last month.

#### Shuren: CDRH to Use Outside Experts

As a recent conference, CDRH Director Jeffrey Shuren said that the agency is currently working to overcome a staffing shortage that has led to an increase in device review times. Shuren has said that the agency plans to rely on outside experts to assist in the review of 510(k) and PMA submissions.

#### Senate Finance Committee Wants CMS Briefing on Part D

Reports are indicating that Senate Finance Committee staff has requested a briefing from CMS regarding its recent Part D guidance that indicated that, due to a procedural glitch, drug manufacturers may not be required in 2011 to apply a fifty percent discount to Medicare beneficiaries for drugs in the Part D "doughnut hole." CMS Deputy Administrator Jonathon Blum has stated that the agency is considering a range of options, and he expects that all drug manufacturers will enter into rebate agreements for 2011. Senior organizations, including AARP, are calling for a requirement that manufacturers apply the discounts.

#### Biosimilars Not Required to Discount Under Part D

Although the health reform law omitted biosimilars from the requirements to pay a brand-drug fee or provide a 50 percent discount for drugs to beneficiaries in the Part D coverage gap, sources are indicating that makers of biosimilars may nonetheless feel pressured to apply such discounts in order to remain competitive.

## FDA, Canada Negotiating Single Device Inspection Process

Officials in the FDA's Center for Devices and Radiological Health and Health Canada have indicated that they are currently negotiating an agreement that would reduce redundant inspections conducted by both countries' regulators. The agreement could also include the development of a single audit form and harmonization of standards. Sources have indicated that the major obstacle in the negotiation process consists of rectifying the ISO 13485 standard and the quality systems regulation.

## USP Monographs May Be Updated

FDA Commissioner Margaret Hamburg has indicated that, as part of the FDA's efforts to combat counterfeited and adulterated drugs, the agency may update U.S. Pharmacopeia (USP) monographs for at-risk products. Hamburg said that the agency and USP will work together to identify drug ingredients and products that would benefit from updated monographs, beginning with products having the greatest impact on public health.

## Publications

The FDA is publishing modifications to the [list of standards](#) FDA recognizes for use in premarket reviews (FDA recognized consensus standards). The publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 023" (Recognition List Number: 023), is intended to assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

The FDA is publishing a [guidance for industry](#) entitled "Documenting Statistical Analysis Programs and Data Files." The guidance is provided to inform study statisticians of [recommendations for documenting](#) statistical analyses and data files submitted to the Center for Veterinary Medicine (CVM) for the evaluation of safety and effectiveness in new animal drug applications.

The FDA has [published a guidance](#) entitled "Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco." This [guidance document](#) discusses FDA's intended enforcement policies with respect to two provisions of the final regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.

EvaluatePharma has issued a statement predicting that Abbott Laboratories' Humira will become the [world's most lucrative drug](#) by 2016, outpacing Roche Holding AG's Avastin.

## Approvals

The FDA has granted orphan-drug designation to Osiris Therapeutics Inc.'s stem cell therapy Prochymal as a treatment for Type-1 diabetes.

Mylan, Inc. has announced that it has received FDA approval for a generic version of GlaxoSmithKline PLC's smoking cessation treatment Zyban.

The FDA has approved Bayer Healthcare's Natazia.

## Recalls, Warnings, and Notifications

The FDA and Teleflex Medical are notifying healthcare professionals of a [worldwide voluntary recall](#) affecting certain lot numbers of the Teleflex Medical AQUA+FLEX Hygroscopic Condenser Humidifier.

The FDA has issued a [warning letter](#) to Novartis Oncology for false and misleading websites for its drug Gleevec.

Alkermes and the FDA are notifying healthcare professionals and patients of an [update to the Warnings](#), Information for Patients, and Dosage and Administration sections of the Prescribing Information for Vivitrol.

The FDA is [notifying healthcare professionals](#) and consumers that it has [ordered Baxter](#) to [recall and destroy](#) all of its Colleague Volumetric Infusion Pumps (Colleague pumps) currently in use.

The FDA has issued a [warning letter](#) to GlaxoSmithKline PLC for promotional materials for its Altabax ointment.

The FDA issued an untitled letter to Genentech for a video overstating the efficacy and minimizing the risks of its breast cancer drug Herceptin.

## International News

The head of Novartis AG's vaccine unit has stated that of the fifteen countries that ordered the company's H1N1 vaccine, about half cancelled part of their order, and others are negotiating their payments.

The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks has adopted an [opinion](#) stated that the entire reprocessing cycle for reused single-use devices should be assessed and validated.

## Business News

Reports are indicating that the FDA is set to hold a public meeting in September to address ways in which to curb teen abuse of dextromorphan, found in cough suppressants.

Reports are indicating that Pfizer and Merck's [first quarter results](#) were better than expected, a sign to some that good results are offsetting the costs of health care reform.

Escalon Medical Corp. has announced that it has sold its two guided-needle product lines to Vascular Solutions Inc. for slightly less than \$5.8 million.

The Supreme Court has denied Pfizer Inc.'s appeal to block a lawsuit alleging that Pfizer purposely withheld findings that its drug Celebrex did not offer safety advantages over other, less expensive therapies.

A woman has filed suit against Secretary Sebelius alleging that the Gardasil vaccine caused physical and behavioral problems in her teenage daughter.

The FDA has indicated that it [will not grant approval](#) for Dainippon Sumitomo Pharma Co.'s drug Stedesa.

InterMune has stated that the FDA has asked the company to conduct [another clinical trial](#) of its drug pirfenidone, intended to treat [idiopathic pulmonary fibrosis](#).

Wyeth Pharmaceuticals Inc. is asking the Nevada Supreme Court to grant a new trial over its drugs Premarin and Prempro on the grounds that the jury did not receive proper instructions regarding punitive damages.

Novartis AG has stated that it has reached a settlement agreement under which the company will pay \$72.5 million to resolve allegations that the company improperly billed government programs for unapproved uses of the cystic fibrosis drug Tobi.

Eli Lilly has filed suit against Watson Pharmaceuticals Inc. to block the company from selling in the U.S. a generic version of its osteoporosis drug Evista.

Watson Pharmaceuticals Inc. has stated that it has asked the FDA to grant approval for the company to make a generic version of Abbott Laboratories' Simcor. Watson has also indicated that it will appeal a federal court decision upholding the validity of Teva Pharmaceutical's '969 patent on Seasonique.

Merck and Ariad Pharmaceuticals have announced that they will restructure their agreement regarding the development of potential cancer drug ridaforolimus. Under the restructuring, Merck will cover all development costs and will receive worldwide rights to the drug.

Endo Pharmaceutical Holdings, Inc. has announced that it will [purchase HealthTronics](#) for \$223 million.

The Utah Attorney General's Office has announced that it will file suit against Janssen Ortho, Ortho-McNeil-Janssen Pharmaceuticals Inc., and AstraZeneca Pharmaceuticals on the grounds that the companies misled the state's Medicaid program and sold the drugs Risperal and Seroquel for unapproved uses.

A jury has found that Baxter Healthcare Services and Teva Parenteral Medicine must pay more than \$5 million to a Nevada man who contracted hepatitis C due to their failure to label vials for the sedative propofol with appropriate warnings and for providing large vials of the drug to endoscopy centers.

Investor Carl C. Icahn has filed a [proxy statement](#) with the SEC indicating that he wants to replace Genzyme's chief executive, Henri A. Termeer, on the board of the company.

The *Wall Street Journal* has reported that the FDA has learned that Merck & Co.'s Rotateg rotavirus vaccine for infants contains two types of pig viruses. The agency may wait until the conclusion of the panel on the vaccine Rotarix to determine whether to advise against the use of the Rotateg vaccine.

Data provided at the recent annual meeting of the Biotechnology Industry Organization showed that the number of publicly traded biotechnology companies [contracted by 25 percent](#) last year due to difficulties in finding investors in the current economic climate.

Merck & Co. announced that it [won a second case](#) in which a plaintiff alleged that the company's drug Fosamax caused jaw death.

Boston Scientific stated that it suffered a loss of \$72 million in the first quarter due to a shipment hold on its implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy defibrillators.

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## Regulatory Notices

### FDA Seeks Comments on Premarket Notification, Informed Consent

The FDA is seeking comments on premarket notification. Comments are due July 6, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-10576.htm>.

The FDA has also submitted for OMB review and is seeking comments on an interim final rule to amend its regulations to establish a new exception from the general requirements for informed consent for certain medical devices. Comments are due by June 7, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-10656.htm>.

### FDA Amends Animal Drug Regulations

Effective May 17, 2010, the FDA is [amending the animal drug regulations](#) to withdraw approval two new animal drug applications (NADAs). More information is available at <http://edocket.access.gpo.gov/2010/2010-10564.htm>.

### FDA Issues Determination on Brevibloc

The FDA has determined that BREVIBLOC (esmolol hydrochloride (HCl)) Injection, 250 milligrams (mg)/milliliter (mL), 10-mL ampule, was withdrawn from sale for reasons of safety or effectiveness. This determination means the agency will not accept or approve abbreviated new drug applications (ANDAs) for esmolol HCl injection, 250 mg/mL, 10-mL ampule. More information is available at <http://edocket.access.gpo.gov/2010/2010-10559.htm>.

### Information Collection Approvals

OMB has approved "Administrative Detention and Banned Medical Devices." More information is available at <http://edocket.access.gpo.gov/2010/2010-10580.htm>.

OMB has approved "Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification." More information is available at <http://edocket.access.gpo.gov/2010/2010-10581.htm>.

OMB has approved "Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002." More information is available at <http://edocket.access.gpo.gov/2010/2010-10577.htm>.

OMB has approved "Medical Device User Fee Cover Sheet--Form FDA 3601." More information is available at <http://edocket.access.gpo.gov/2010/2010-10579.htm>.

OMB has approved "Investigational Device Exemptions Reports and Records--21 CFR Part 812." More information is available at <http://edocket.access.gpo.gov/2010/2010-10657.htm>.

OMB has approved "Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable." More information is available at <http://edocket.access.gpo.gov/2010/2010-10782.htm>.

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## Public Meetings

### FDA to Hold Town Hall with CDRH Director

The FDA has announced that it will hold a public meeting entitled "Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management." The purpose of this meeting is to present the Center for Devices and Radiological Health (CDRH) fiscal year 2010 priorities. The meeting will be held on June 22, 2010, from 9 a.m. to 5 p.m. in Woburn, MA. More information is available at <http://edocket.access.gpo.gov/2010/2010-10563.htm>.

### FDA Announces Public Meeting on Device Improvements

The FDA is announcing a public meeting entitled "Device Improvements to Reduce the Number of Under-doses, Over-doses, and Misaligned Exposures from Therapeutic Radiation." The purpose of the meeting is to discuss steps that could be taken by manufacturers of linear accelerators, radiation therapy treatment planning systems, and radiation therapy simulators to help reduce misadministration and misaligned exposures. The meeting will be held on June 9 and 10, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-10754.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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