



Bulletin

To: Our Clients and Friends

April 9, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

FDA Issues Proposed DTC Advertising Rule

The FDA has indicated that it intends its new proposed rule on direct-to-consumer (DTC) prescription drug advertising to be consistent with a more flexible approach and that it does not intend to prescribe a set formula for “clear, conspicuous and neutral” statements of risk because there is more than one way to meet the agency’s standards. Industry has responded that, while some flexibility is desirable, the proposal is a double-edged sword because it won’t specify a particular way for companies to comply, but it will provide the agency with greater flexibility in enforcement. Although the draft rule proposes four standards to meet the “clear, conspicuous and neutral” standard, including presenting information in language that is readily understandable by consumers; presenting audio information at an understandable volume, articulation and pacing; appropriately placing textual information so that it can be easily read; and not including distracting statements, members of the industry have indicated that additional concrete examples from the agency would be helpful.

In Allergan Rebuttal, FDA Says it Cannot Define Promotion

In its most recent rebuttal in the case involving whether Allergan can provide to doctors dosing information for off-label uses of the drug Botox, the FDA stated that it cannot create a “precise and narrow” definition for the term “promotion” because manufacturers will continue to come up with new methods for advertising products. Members of the industry are responding that the agency is using a “parade of horrors” in an effort to convince the court that the entire drug approval process will be destroyed if the court rules in Allergan’s favor.

FDA Launches New Initiative to Measure Performance

The FDA announced the launch of its newest initiative, FDA-TRACK, this week. The initiative is designed to help measure the agency’s performance through using a series of quantifiable benchmarks that would give congressional appropriators a clear understanding of how well the FDA uses its money.

PREDICT Rollout Delayed Indefinitely

The nationwide rollout of the FDA’s PREDICT electronic ranking system, designed to help uncover adulterated and misbranded imports, has been delayed indefinitely, due primarily to issues relating to IT infrastructure.

FDA Announces New Process for Approval of Radiotherapy Equipment

The FDA has announced that it will [strengthen its approval process](#) for new radiotherapy equipment and will no longer allow new radiotherapy equipment to use the streamlined approval process, in an effort to reduce overdoses, underdoses and other errors in radiation therapy.

FDA Issues Final Rule on Device Pre-Market Submissions

Under the FDA's final rule published on March 31, pre-market approval applications, beginning in August, will be required to include additional data on pediatric patients who suffer from diseases or conditions treated by the sponsor's device. The rule requires MA applications, humanitarian device exemption (HDE) applications and PMA supplements for new intended uses to include "readily available" information on any pediatric subpopulations that suffer from the disease or condition addressed by the sponsor's device, as well as information on the number of pediatric patients who might be treated with the device.

FDA to Release UDI Database Proposed Rule

CDRH has indicated that it expects to release a proposed rule for a unique device identifier (UDI) database this summer and is aiming at having a final rule in place by April 2011. Once the final rule is out, manufacturers of Class III devices will have one year to comply.

FDA Continues to Gather Info on Use of Antibiotics in Animal Feed

The FDA has indicated that it is continuing to seek information and input from stakeholders regarding the use of antibiotics in animal feed, and it is examining how to phase out the use of such antimicrobials for animal growth promotion. The agency has also indicated that, although it has yet to develop a concrete strategy and time frame for increasing regulations on these drugs, it is continuing to reach out to stakeholders and other relevant parties for their input.

Montana Governor Presents Proposal to Lower Drug Costs

Montana Governor Brian Schweitzer has asked the US Department of Veterans Affairs to resell drugs it obtains at a discount from the pharmaceutical industry directly to state pharmacies. CMS has not yet responded to the request. Schweitzer also recently requested permission to import drugs from Canada.

Publications

The FDA has updated its [online overview of information](#) related to the agency's clearance of the STERIS System 1E (SS1E) Liquid Chemical Sterilant.

CDRH has updated its online listing of [guidance documents](#) pertaining to medical devices.

The FDA has stated that it intends to increase prosecutions against corporate officials as part of its drive to improve its Office of Criminal Investigations, in response to a [recent GAO report](#).

Approvals

The FDA has approved Lenstec Inc.'s Softec HD intraocular lens implant for treating patients with cataracts.

The FDA has approved Sun Pharmaceutical Industries Ltd. to sell [a generic version](#) of GlaxoSmithKline Plc's Wellbutrin SR.

Mylan Inc. announced that it received approval to sell a generic version of the laxative NuLytely.

APP Pharmaceuticals has received FDA approval for a generic version of Lundbeck's Indocin intravenous drug to treat neonates with a common congenital heart defect.

Recalls, Warnings, and Notifications

Kanec USA and the FDA are notifying healthcare professionals of a [nationwide recall](#) of Stud Capsule For Men [Lot #060607-01/060108-01, Exp 6-2013], after being informed by the FDA that laboratory analysis of a sample found the product to be adulterated with sildenafil, an FDA approved drug.

The FDA has issued [warning letters](#) to six U.S. based medical spas and a company in Brazil for making false or misleading statements on their Web sites about drugs they claim will eliminate fat in a procedure called "lipodissolve," or for otherwise misbranding lipodissolve products. The warning letters stated that the U.S. companies involved made claims that the drugs they use for their lipodissolve procedures are safe and effective; however, these products have not been evaluated or approved by the FDA for this use.

The FDA has updated information pertaining to the [Class I recall](#) of Teleflex Incorporated - Arrow International Custom Intravenous (IV) Administration Products (IV Tubing Sets and Accessories) and Certain Arrow Arterial Embolectomy Catheters.

The FDA has issued a warning letter to Edwards Lifesciences Corp. for failure to report six complaints of adverse events relating to use of mitral annuloplasty rings and pericardial prosthetic heart valves within the 30-day window required by the agency.

The FDA has issued a warning letter to Biogen Idec Corp., saying that its promotional webcast on the multiple sclerosis drug Tysabri is "false or misleading" and citing the company for not submitting the webcast for review 30 days before using it.

The FDA has issued a warning letter to Gilead Sciences for its direct-to-consumer print ad for Truvada that reportedly overstates the effectiveness of the drug.

The FDA has issued a warning letter to Salix Pharmaceuticals for omitting risk information about its Metozolv orally disintegrating tablets and suggesting the drug is safer and more effective than evidence has demonstrated.

Boston Scientific has stopped shipping and is recalling its implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators because of unapproved changes made in its manufacturing processes.

The FDA has issued a warning letter to Biological Controls for several quality system (QS) and documentation failures.

Business News

Cruce NV and GlaxoSmithKline PLC have announced that they will partner with one another to work on a new malaria vaccine composed of two drugs they were developing separately.

Pfizer Inc. has indicated that the company [expects to have more products with sales in excess of \\$1 billion](#) as it develops treatments for Alzheimer's disease and cancer. The company has also stated that it is betting on products in acquired when it bought rival Wyeth in October of last year. The company's patent on Lipitor expires in November 2011.

A federal appellate court has upheld a lower court's ruling dismissing the first product liability lawsuit alleging that AstraZeneca's drug Seroquel caused a patient to develop diabetes.

Sanofi-Aventis has announced that it has reached settlement agreements with six companies regarding the patent of its cancer drug Eloxatin, under which the companies will cease marketing unauthorized versions of the drug in the US, beginning in June of this year, until Aug. 9, 2012.

Eli Lilly and Co. has reached a settlement with the state of Louisiana over its marketing of the anti-psychotic drug Zyprexa, under which the state will receive \$20 million. To date, Louisiana is the 11th state to settle.

Although the FDA granted fast-track approval to ReGen for its Menaflex device, the agency's acknowledgement in September that its decision was influenced by political pressure leaves the company in limbo as it awaits the agency's decision upon re-examination of the earlier approval.

It is being reported that Boston Scientific Corp. is [seeking buyers](#) for its Target Therapeutics and neuromodulation units.

Novartis AG's pharmaceuticals unit faced [trial this week in federal court in Manhattan](#) on allegations that the company discriminated against female sales representatives.

Uromedica is appealing to Dr. Jeffrey Shuren to review the agency's decision not to approve its premarket-approval application for a balloon device used to treat urinary incontinence.

The UK's National Institute for Health and Clinical Excellence (NICE) has recommended Roche's MabThera plus methotrexate for rheumatoid arthritis when treatment with at least one tumor necrosis factor (TNF) inhibitor has failed.

Scripps Health exec and cardiologist Eric Topol has stated that the FDA's recent recommendation that individuals using Plavix be tested for gene variants that may impede the patient's ability to metabolize the drug can be a successful model for the nascent pharmacogenetic testing market.

Regulatory Notices

FDA Seeks Comments on Reporting Requirements

The FDA is seeking comments on the reporting requirements for submission and listing of patent information associated with a new drug application (NDA), an amendment, or a supplement. Comments are due by June 7, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-7891.htm>.

FDA Issues Debarment Order

The FDA is issuing an order, effective April 8, 2010, under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Kevin Xu from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Xu was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. More information is available at <http://edocket.access.gpo.gov/2010/2010-8023.htm>.

FDA Determines Regulatory Review Period for Mozobil

The FDA has determined that the applicable regulatory review period for Mozobil is 3,849 days. Anyone with knowledge that any of the dates as published are incorrect may submit comments and ask for a redetermination by June 8, 2010. Any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 6, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-8172.htm>.

Public Meetings

Vaccines and Related Biological Products Advisory Committee

The Vaccines and Related Biological Products Advisory Committee will meet on May 7, 2010, from 8 a.m. to around 4:30 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-8025.htm>.

FDA Co-Sponsors Public Educational Forum

The FDA Baltimore District, in co-sponsorship with the Association of Food and Drug Officials (AFDO), is announcing a public educational forum entitled "Drugs & Medical Device Supplier Management Forum." This 2-day public educational forum, a component of AFDO's Annual Educational Conference, is intended to provide information about FDA drug and device regulation to the regulated industry. The forum will be held on Monday, June 21, 2010, from 8 a.m. to 5 p.m. and Tuesday, June 22, 2010, from 8 a.m. to 5 p.m. in Norfolk, Virginia. More information is available at <http://edocket.access.gpo.gov/2010/2010-8087.htm>.

FDA/DIA Statistics Forum

The FDA will co-host the [4th Annual FDA/DIA Statistics Forum](#). The forum will be held April 18 through April 21 in North Bethesda, Maryland. The Forum provides a venue to discuss important statistical issues associated with the development and review of therapeutic drugs and biologics. The meeting is an annual, open dialogue to discuss FDA's issues, initiatives and guidances – emphasizing the statistical and regulatory challenges.

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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