Top Stories

FDA Subjects Tanning Beds to 510(k) Review, Black Box Warning, and Other Special Controls
On May 29, FDA finalized an order that requires once-exempt tanning beds and booths, officially known in FDA regulations as "sunlamp products," to submit to a premarket clearance process and to warn consumers of indoor tanning risks, among a host of new regulatory requirements. The final order, published in the June 2 *Federal Register,* reclassifies sunlamp products and their accompanying ultraviolet ("UV") lamps from low risk, Class I medical devices, exempt from many FDA regulations, to moderate-risk, Class II medical devices, subject to additional special controls. FDA reclassified the device on its own initiative, based on evidence that UV radiation from indoor tanning significantly increases the risk of melanoma, the deadliest form of skin cancer. In conjunction with the order, FDA issued a consumer alert discussing these risks and how the reclassification will promote safety and better inform consumers.
- read more below

CDER Focused on Getting New Drugs to Market Faster, Supports 'Special Medical Use' Approval Process as Next Initiative
Expressing a commitment to helping develop new drugs, the Center for Drug Evaluation and Research ("CDER") continues to tweak its regulatory processes, including recently finalized guidance on its expedited review programs. In a recent blog post, CDER Director Janet Woodcock discussed other achievements and expressed support for "Special Medical Use or Limited Population" policies that would allow new drug sponsors to seek initial approval for use in a specific subgroup of patients. Although FDA has some existing authority to approve products for subpopulations, the proposal would allow sponsors to pursue a narrower development program and achieve market entry for specified groups faster than the traditional process.
- read more below

FDA, CBP Crack Down on Online Sales of Unapproved Drugs
As part of an international initiative to shore up the integrity

Contacts

Laurie Clark
Washington
+1.202.879.3498
lclarke@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@jonesday.com

Mark Mansour
Washington
+1.202.879.3883
mmansour@jonesday.com

Christopher M. Mikson
Washington
+1.202.879.3738
cmikson@jonesday.com

Emily K. Strunk
Washington
+1.202.879.3778
estrunk@jonesday.com

Matthew R. Bowles and Stephanie L. Resnik, associates in the Washington Office, assisted in the preparation of this Update.

Resources
- *Pharmaceutical & Medical Device Regulatory Update* Issue 7 Printable Version
- Jones Day's Health Care Practice
- Jones Day's Life Sciences Practice

of the global drug supply chain, FDA and the U.S. Customs and Border Protection ("CBP") collaborated to crack down on websites and distributors marketing unapproved prescription drugs to American consumers. In May, the two agencies conducted extensive inspections of mail facilities in New York, Los Angeles, and Chicago, where many prescription drug packages enter the country. More than 580 packages were seized or detained, and FDA also informed internet service providers and registries of 1,975 websites that they are selling products in violation of federal law. This program corresponded with an annual Interpol initiative known as Operation Pangea VII, through which 111 countries collaborate to identify the manufacturers and distributors of illegal drug products and medical devices sold over the internet.

Agencies Continue to Collaborate on Health IT Safety
Acting on mandates of the FDA Safety and Innovation Act ("FDASIA"), FDA, the Federal Communications Commission, and the Office of the National Coordinator for Health Information Technology continue to focus on developing a common, risk-based regulatory framework for addressing health information technology ("health IT"). At a three-day workshop last month, representatives from these agencies met with consumer and industry stakeholders, including the American Medical Association, who urged regulators to act soon in developing a central program to provide guidelines on health IT safety. Promoting continual improvement and evidence-based care in health IT were key themes of the discussion. In April, the three agencies released a report calling for the creation of a Health IT Safety Center, and their joint policy committee plans to meet in July to hammer out details of the Center's governance, function, and data-collection activities. The public comment period on the proposed risk-based regulatory framework closes July 7.

EMA Issues New Clinical Trials Regulation
The European Union has adopted new regulations on clinical trials that will come into force in 2016. Regulation (EU) No. 536/2014 will significantly alter the European clinical trial landscape by replacing national legislation that was harmonized by a European directive with a regulation that is directly applicable in each Member State. This is intended to synchronize the legal environment throughout the EU. In addition, the new regulations provide for a streamlined approval system, setting out defined timelines. It remains to be seen whether the authorities will be able to comply with these. Another important aspect is the publication of clinical trial data, which will allow the sponsor to redact confidential information.

Court Rules that Hospitals Cannot Get 340B Discounts for Common Uses of Orphan Drugs
Last month, a U.S. district court judge ruled that hospitals participating in the Department of Health and Human Services' 340B program cannot take advantage of discounted pricing when using high-cost orphan drugs to treat common conditions. According to a *Modern Healthcare* article, a group of pharmaceutical manufacturers challenged a 2013 rule requiring them to sell orphan drugs at significantly reduced prices to eligible providers, such as rural hospitals and cancer centers, that prescribe such drugs for common ailments instead of the rare diseases for which they were approved. Orphan drugs are sometimes used for treatments other than their original indications, based on clinical studies supporting the expanded applications. However, this court order may, in effect, scale back this use as it limits the scope of 340B discounts.

Other News
FDA Launches openFDA, With User-Friendly Access to Public Data Including 3.6 Million Adverse Event Reports

Senate Committee Urges FDA to Engage Stakeholders Before Regulating Compounding Pharmacies

Delaware Senate Unanimously Passes Legislation to Promote Substitution to Biosimilars

Health Affairs: FDA Readies for Action Under Compounding Quality Act

FDA Inspecting U.S. Branches of Indian Drug Firms

OIG Issues Special Bulletin on Drug Companies' Donations to Independent Charities

President Obama Hosts Panel on Sports Concussions; Participants Pledge Millions for Research

Senate Majority Leader Says Chamber Will Not Vote on Medical Device Tax Repeal

"Smart Pills" With Microchips, Robotics Coming Under Public Scrutiny.

Regulatory Updates

FDA Reclassifies Tanning Beds From Class I to Class II with Special Controls
In the June 2 *Federal Register*, FDA published a final order reclassifying tanning beds and booths, officially called "sunlamp products," and their accompanying ultraviolet lamps, as Class II medical devices subject to special controls. These products were previously exempt from many FDA medical device regulations but now will be subject to premarket notification, quality systems regulation, medical device reporting, and other requirements that generally apply to Class II devices. In addition, FDA laid out six special controls the agency will require specifically of sunlamp manufacturers so that there is a reasonable assurance the products are safe for their intended use. Among the special controls requirements is that a black box warning must be permanently affixed to the device in a prominent location stating that no one under the age of 18 should use the device. Manufacturers must include this and other warnings citing increased skin cancer risks in the product labeling, catalogs, and other promotional materials. ***The order is effective on September 2, 2014, with an August 26, 2015, compliance date***. At that time, all products in the marketplace must have the updated labeling, and manufacturers who wish to keep selling sunlamp products must have submitted a 510(k) or received 510(k) clearance.

FDA Issues Final Rule on Administrative Detention of Drugs
In the May 29 *Federal Register*, FDA issued a final rule creating the implementing regulation for the administrative detention of drugs. This new authority was granted to FDA through FDASIA and enhances the agency's ability to protect the integrity of the drug supply chain, specifically by detaining drugs encountered during an inspection that are believed to be adulterated or misbranded. The new regulation was closely modeled on the analogous medical device regulation and does not contain major changes from the proposed rule. ***The rule is effective June 30***.

FDA Announces Independent Auditor's Final Findings and Recommendations After Review of Medical Device Submissions
In the May 29, 2014 *Federal Register*, FDA announced the December 2013 report containing priority recommendations for premarket device reviews under MDUFA II/III. The report follows an independent assessment of the medical device review process. The assessment and accompanying report were part of FDA's performance commitments under MDUFA. Key priority recommendations included ways of improving consistency, enhanced training, and adopting a new approach to standardize process lifecycle management activities.

FDA Announces Pilot Project to Evaluate Systems for Receiving Postmarketing Vaccine Safety Reports
In the May 28 *Federal Register*, the Center for Biologics Evaluation and Research ("CBER") announced a pilot project to evaluate its current systems for receiving postmarketing safety reports involving vaccine products. The goal of the project is to provide industry and CBER with a chance to evaluate the ability of the Vaccine Adverse Event Reporting System ("VAERS") to send and receive these survey reports. Firms that submit postmarketing reports into VAERS are eligible to participate in the pilot project. ***Requests to participate are due to CBER_eSubmitter_program@fda.hhs.gov by June 27***.

FDA Announces Grant Funds for Increasing Quality, Efficiency of Clinical Trials
In the May 23 *Federal Register*, FDA announced the availability of grant funds to support the efforts of CDER to increase the quality and efficiency of clinical trials. CDER announced its intent to accept and consider a single-source application for the award of a grant to Duke University's Duke Translational Medicine Institute. ***Applications are due June 30***.

FDA Proposes Reclassification of Antigen-Based Rapid Influenza Virus Detection Systems From Class I to Class II
In the May 22 *Federal Register*, FDA proposed a reclassification of antigen-based rapid influenza virus detection test systems intended to detect influenza virus direction from clinical specimens that are currently regulated as influenza virus serological reagents from Class I to Class II with special controls and into a new device classification regime. ***Comments are due August 20***.

FDA Issues Final Order Downclassifying Certain IVDs
In the May 30 *Federal Register*, FDA issued a final order reclassifying nucleic acid-based in vitro diagnostic ("IVD") devices for the detection of *Mycobacterium* tuberculosis complex in respiratory specimens from class III into class II. ***This rule is effective June 30***.

FDA Classifies Dengue Reagents and Pancreatic Stent as Class II with Special Controls
FDA recently issued final classification orders for dengue virus serological reagents and a pancreatic drainage stent and delivery system, assigning both to Class II with special controls to provide a reasonable assurance of safety and effectiveness of the device.

FDA Issued the Following Guidance Documents
Guidance on Expedited Programs for Serious Conditions—Drugs and Biologics. May 30 Federal Register.

Draft Guidance For Industry on Best Practices in Developing Proprietary Names for Drugs. May 29 Federal Register. ***Comments due July 28***.

Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another Institutional Review Board. May 23 Federal Register.

FDA Determines Regulatory Review Periods for Drug, Biological Patents
FDA recently published determinations regarding the regulatory review periods for patent extensions of the following drugs: LINZESS, INLYTA, INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM, MENHIBRIX, MYRBETRIQ, XARELTO, ZACTRAN, KALYDECO, and PROGENSA PCA3 ASSAY. FDA published determinations regarding the regulatory review periods for patent extensions of the following biologics: ADCETRIS (BLA 125399) and ADCETRIS (BLA 125388).

FDA Determines Certain Drugs Not Withdrawn for Safety or Effectiveness
In the May 29 *Federal Register*, FDA determined that certain SODIUM PERTECHNETATE (technetium Tc-99m sodium pertechnetate) products were not withdrawn for reasons of safety or effectiveness.

FDA Published the Following Notices Regarding Information Collections
Request for comments on proposed information collection concerning Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program. FDA is seeking comments on the eligibility criteria and process used by medical device establishments when seeking to have an accredited party conduct an inspection instead of FDA under the Accredited Persons Inspection Program. ***Comments due July 28.***

Notice of information collection submission to OMB, Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health.

Notice of information collection submission to OMB, Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing.

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics
Public Workshop on Immune Responses to Enzymes Replacement Therapies: Role of Immune Tolerance Induction will be held June 9, in Silver Spring, MD.

Public Meeting on Inborn Errors of Metabolism Patient-Focused Drug Development will be held June 10, in Silver Spring, MD.

Public Conference on FDA Small Business Regulatory Education for Industry will be held June 16–17, in Burlingame, CA.

Public Hearing Before the Commissioner on Confidentiality of Interim Results in Cardiovascular Outcomes Safety Trials; Part 15, will be held August 11, in Silver Spring, MD.

Medical Devices
Public Workshop on Center for Devices and Radiological Health Guidance Development and Prioritization, with an opportunity for comment. The meeting will be held June 5, in Silver Spring, MD. ***Comments are due July 7.***

Public Meeting on FzioMed, Inc.'s Petition for Review of FDA's Denial of Premarket Approval of Oxiplex/SP Gel will be held June 10, in Gaithersburg, MD.

Public Workshop on Proteomics in the Clinic will be held June 13, in Silver Spring, MD.

Public Workshop on Hemostatic Medical Devices for Trauma Use will be held September 3–4, in Silver Spring, MD.

Public Workshop on Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing will be held October 8–9, in Silver Spring, MD.

Advisory Committees
June 10: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee Meeting

June 11–12: Anesthetic and Analgesic Drug Products Advisory Committee Meeting

June 12: Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting

June 17: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting

June 25: Oncologic Drugs Advisory Committee Meeting

October 16: Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting

For more comprehensive listings of FDA meetings, please visit these FDA webpages:
Workshops & Conferences (Medical Devices)
Meetings, Conferences, and Workshops (Drugs)
Workshops, Meetings, and Conferences (Biologics)
FDA Advisory Committee Calendar

Enforcement Updates

Recent Product Recalls
Since the last Jones Day *Pharmaceutical & Medical Device Regulatory Update*, FDA posted a recall of a liquid concentrate product used in hemodialysis machines out of concern about potential bacterial contamination. Also, an Indian drug manufacturer recalled an allergy-relief drug in the United States after finding that one of the packages was contaminated with a different tablet used for treating high-blood pressure.

There have been no new medical device recalls or biologic recalls since the last Update.

Click here for a complete listing of FDA Recalls.

Recent Warning Letters
FDA recently published warning letters to several medical device manufacturers. Two medical device manufacturers failed to comply with the Quality Systems Regulation. The warning letters cite several violations, including inadequate procedures for supplier qualifications, inadequate controls for the device design, failure to implement corrective and preventative actions, and improper documentation of complaint investigations. The Agency warned a third manufacturer for failing to obtain 510(k) clearance before marketing its products. After finding another manufacturer's product to be adulterated, FDA issued a warning letter citing numerous violations related to the quality system regulation.

FDA also warned a pharmaceutical compounding company for not having valid prescriptions for its drug products and for producing drug products in a nonsterile environment.

Click here for FDA's Warning Letters Home page (scroll down for listing of recently posted Warning Letters).

The Office of Prescription Drug Promotion ("OPDP") issued three untitled letters to drug manufacturers for omitting risk information or material facts.

Click here for a complete listing of 2014 OPDP Warning Letters.

Recent Drug and Device Approvals
FDA approves first generic versions of celecoxib (May 30).

FDA allows marketing of first noninvasive test to help in identifying cause of certain kidney disease (May 29).

FDA approves first implantable wireless device with remote monitoring to measure pulmonary artery pressure in certain heart failure patients (May 28).

FDA approves Dalvance to treat skin infections (May 23).

FDA approves first molecular (gene-based) test to determine red blood cell types in transfusion medicine (May 21).

FDA approves Entyvio to treat ulcerative colitis and Crohn's disease (May 20).

For additional information on drug and device approvals and clearances, please visit FDA's webpages on Drug Approvals and Databases (includes biologics) and Device Approvals, Denials, and Clearances.

Top Stories

FDA Subjects Tanning Beds to 510(k) Review, Black Box Warning, and Other Special Controls
On May 29, FDA finalized an order that requires once-exempt tanning beds and booths, officially known in FDA regulations as "sunlamp products," to submit to a premarket clearance process and to warn consumers of indoor tanning risks, among a host of new regulatory requirements. The final order, published in the June 2 Federal Register, reclassifies sunlamp products and their accompanying ultraviolet ("UV") lamps from low risk, Class I medical devices, exempt from many FDA regulations, to moderate-risk, Class II medical devices, subject to additional special controls. FDA reclassified the device on its own initiative, based on evidence that UV radiation from indoor tanning significantly increases the risk of melanoma, the deadliest form of skin cancer. In conjunction with the order, FDA issued a consumer alert discussing these risks and how the reclassification will promote safety and better inform consumers.

In addition to the general requirements for Class II medical devices, including 510(k) premarket clearance, quality system regulation, labeling requirements, and medical device reporting, manufacturers must also comply with special controls. FDA outlines six special controls, including performance testing, safety features such as timers and alarms, software verification/validation, biocompatibility, and electrical safety, as well as a controversial requirement for stronger warnings in product labeling. By August 26, 2015, all sunlamp products in the market place must contain a black box warning, permanently affixed to the product that says the product should not be used by anyone under the age of 18. In addition, product labeling (including catalogs, user instruction manuals, and other materials) must include this warning and three other statements (i) contraindicating tanning with open wounds, (ii) warning against use by individuals with an individual or family history of skin cancer, and (iii) warning users who repeatedly expose themselves to UV radiation to be regularly evaluated for skin cancer.

The order is effective September 2, 2014. Products not marketed on or before the effective date must receive a 510(k) clearance prior to marketing. Manufacturers with

sunlamp products on the market before the order is effective must submit a 510(k) and comply with the new labeling requirements by August 26, 2015, if they wish to keep selling the device. All sunlamp products still in use on August 26, 2015, must comply with the new labeling requirements, regardless of whether the sunlamp product is still being marketed or whether the manufacturer is still in business. Under those circumstances, the owners of the sunlamp products are responsible for applying the required labels.

Top Stories

CDER Focused on Getting New Drugs to Market Faster, Supports 'Special Medical Use' Approval Process as Next Initiative

Expressing a commitment to helping develop new drugs, the Center for Drug Evaluation and Research ("CDER") continues to tweak its regulatory processes, including recently finalized guidance on its expedited review programs. In a recent blog post, CDER Director Janet Woodcock discussed other achievements and expressed support for "Special Medical Use or Limited Population" policies that would allow new drug sponsors to seek initial approval for use in a specific subgroup of patients. Although FDA has some existing authority to approve products for subpopulations, the proposal would allow sponsors to pursue a narrower development program and achieve market entry for specified groups faster than the traditional process.

Woodcock also discussed CDER's milestone achievements since the President's Council of Advisors on Science and Technology in 2012 recommended policy initiatives to spur the discovery and development of innovative drugs. Among those achievements, CDER has engaged in 22 "science-driven, public-private partnerships" to advance new research platforms and predictive models for studying diseases and drug safety, pursued agency management reforms, and invested in new technology systems to improve its review of drug applications.

In a related development, last week FDA finalized its expedited programs guidance, outlining four expedited programs that drug and biologic manufacturers can use to bring products to market faster: fast track designation, breakthrough therapy designation, accelerated approval, and priority review.