Jones Day | Pharmaceutical & Medical Device Regulatory Update Issue Number 12 | August 2014

Top Stories

FDA Issues Draft Guidance on Reference Product Exclusivity for Biologics
On August 4, 2014, FDA issued a draft guidance titled *Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act*. The draft guidance is intended to help biological product sponsors and applicants in submitting appropriate information to FDA to enable the Agency to make a regulatory determination of the "first licensure" date of a reference biological product. Click here for a Jones Day *Commentary* on the new draft guidance.

FDA Notifies Congress of Intent to Regulate Laboratory Developed Tests
FDA recently notified Congress that it intends to end its long-standing policy of enforcement discretion in the area of Laboratory Developed Tests ("LDTs"). Letters from the Agency to Senate and House oversight committees included two attachments containing anticipated details of draft guidance documents on how the Agency intends to regulate LDTs. The first document, titled *Framework for Oversight of Laboratory Developed Tests*, is a self-described "risk-based framework for addressing the regulatory oversight" of LDTs aimed at clinical laboratories that manufacture LDTs. The second document, *FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs),* proposes specific instructions for laboratories to notify the FDA about its existing and future LDT products. Both documents describe FDA's priorities for pre- and post-market requirements for LDTs and how FDA will phase in different kinds of LDTs over time

FDA Announces FY 2015 User Fees for Several FDA-Regulated Products
FDA has announced 2015 user fees for the following:
- Prescription drugs
- Medical devices
- Biosimilars
- Outsourcing facilities
- Animal drug user fees
- Animal generic drug user fees

FDA Receives Second Biosimilar Application
Celltrion has announced that it completed the second

Contacts

Mark Mansour
Washington
+1.202.879.3883
mmansour@jonesday.com

Laurie A. Clarke
Washington
+1.202.879.3498
lclarke@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@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
Washington
+1.202.879.3604
mbowles@jonesday.com

Brigid C. DeCoursey
Washington
+1.202.879.3651
bdecoursey@jonesday.com

Stephanie L. Resnik
Washington
+1.202.879.5458
sresnik@jonesday.com

Resources

biosimilar application for its monoclonal antibody infliximab on August 8, 2014. Click here for a Jones Day *Commentary* on the new biosimilar application process.

FDA Issues Guidance on Substantial Equivalence in 510(k) Premarket Notifications
On July 28, 2014, FDA issued its final guidance on evaluating substantial equivalence in 510(k) submissions. The guidance, titled *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications*, is FDA's first update to the 1986 "blue book" document, *Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3*. FDA says it developed the guidance around current review practices and does not intend for it to implement significant policy changes. The guidance disallows split predicates, encourages the designation of a primary predicate when a 510(k) refers to more than one predicate device, and defines the terms "reference device," "intended use," and "indications for use." The guidance also uses illustrative examples to explain FDA policies for determining when new indications for use constitute a different intended use, as well as when differences in technological characteristics bring up safety and effectiveness issues. FDA will officially require performance data, encourage 510(k) summaries (rather than statements), and promote greater transparency in those summaries. The final guidance incorporates very few changes from the draft guidance issued in December 2011.

- *Pharmaceutical & Medical Device Regulatory Update* Issue 12 Printable Version
- Jones Day's FDA Regulatory & Compliance Practice
- Jones Day's Health Care Practice
- Jones Day's Life Sciences Practice

FDA Finalizes Guidance on Companion Diagnostics
On July 31, 2014, FDA issued its final guidance on the development, review, and approval or clearance of companion diagnostics, tests used to identify which patients will likely benefit or be harmed by treatment with a certain drug. Companion diagnostic tests are intended to aid physicians in selecting appropriate therapies for individual patients and are commonly used to detect certain types of gene-based cancers. The finalized guidance is intended to help companies identify the need for companion diagnostics during the earliest stages of drug development and to plan for the development of a companion test at that time. The ultimate goal of the guidance is to stimulate early collaborations.

FDA Posts Proposed Exemptions from 510(k) Requirements
On August 1, 2014, FDA released draft guidance proposing to exempt from premarket 510(k) review many low-risk medical devices. The guidance lists 107 devices it intends to exempt, including portable air compressors, fluid-filled teething rings, surgical lights, some mobile medical apps, and obstetrical forceps.

Other News
Doctors Raise Concerns Over Mobile Healthcare Apps

Biosimilar Naming Policy Possibly Under HHS Review

CBER is Changing Location

Forbes Critiques Study Linking Faster FDA Approvals With More Drug Safety Problems

FDA Warnings About Injectable Fillers

Regulatory Updates

FDA Announces FY 2015 User Fees for Several FDA-Regulated Products
- Prescription drugs
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- Animal generic drug user fees

CDRH Calls for Industry Participation in New Component of Experiential Learning Program
In the August 7, 2014, *Federal Register*, FDA's Center for Devices and Radiological Health ("CDRH") announced a new component of the Experiential Learning Program ("ELP"), identified as the ELP General Training Program. The new component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that affect the life cycle of device development. The notice invites industry, academia, and health care facilities to apply to participate in this formal training. *Requests for participation due September 8, 2014.*

FDA Amends Animal Drug Rules to Reflect Withdrawal and Approvals
In the July 31, 2014, *Federal Register*, FDA issued a final rule amending its animal drug regulations to reflect approval actions and to remove a combination drug medicated feed that is no longer codified. The changes reflect five applications approved in June 2014.

FDA Issued the Following Guidance Documents
Draft Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act. August 5, 2014, *Federal Register*. *Comments due October 6, 2014*. Click here for a Jones Day Commentary on the new draft guidance.

Draft Guidance for Industry: Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements. August 1, 2014, *Federal Register*. *Comments due September 30, 2014.*

Guidance for Industry and FDA Staff: In Vitro Companion Diagnostics Devices. August 6, 2014, *Federal Register*.

Guidance for Industry: Design Considerations for Devices Intended for Home Use. August 5, 2014, *Federal Register*.

Guidance for Industry: Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A. July 30, 2014, *Federal Register*.

Draft Guidance for Industry #218: Cell-Based Products for Animal Use. August 1, 2014, *Federal Register*. *Comments due September 30, 2014*.

Draft Guidance for Industry: Upper Facial Lines: Developing Botulinum Toxin Drug Products. August 6, 2014, *Federal Register*. *Comments due November 4, 2014.*

INFORMATION COLLECTION ACTIVITIES

FDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review. *Comments due September 30, 2014*.

Medical Device Labeling Regulations. *Comments due September 30, 2014*.

Food and Drug Administration Recall Regulations. *Comments due October 3, 2014*.

Application for Participation in FDA Commissioner's Fellowship Program. *Comments due October 3, 2014*.

State Petitions for Exemption from Preemption. *Comments due October 6, 2014*.

Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice. *Comments due October 10, 2014*.

Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic. *Comments due October 10, 2014*.

Blood Establishment Registration and Product Listing. *Comments due October 10, 2014*.

FDA Announced that the Following Collections Have Been Approved by OMB
FDA Safety Communication Readership Survey

Radioactive Drug Research Committees.

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics
Public Meeting on 2014 Scientific Meeting of the National Antimicrobial Resistance Monitoring System will be held on **August 12–13, 2014**, in Silver Spring, MD.

Public Meeting on Advancing the Use of Biomarkers and Pharmacogenomics will be held on **September 5, 2014**, in Washington, D.C.

Third Annual Patient Network Meeting, Under the Microscope: Pediatric Drug Development, will held **September 10, 2014**, in Washington, D.C.

Public Meeting on Methodological Considerations in Evaluation of Cancer as an Adverse Outcome Associated With Use of Non-Oncological Drugs and Biological Products in the Postapproval Setting will be held **September 10-11, 2014**, in Silver Spring, MD.

FDA/PQRI Conference on Evolving Product Quality will be held **September 16–17, 2014**, in Bethesda, MD.

Public Meeting on Patient-Focused Drug Development for Hemophilia A, Hemophilia B, von Willebrand Disease, and other heritable bleeding disorders will be held on **September 22, 2014**, in Silver Spring, MD.

Public Meeting on Patient-Focused Drug Development for idiopathic pulmonary fibrosis will be held on **September 26, 2014**, in Silver Spring, MD.

Training Course for Clinical Investigators on Scientific, Ethical, and Regulatory Aspects of Clinical Trials will be held **November 4–6, 2014**, in College Park, MD.

Medical Devices
Public Workshop on Hemostatic Medical Devices for Trauma Use will be held **September 3–4, 2014**, in Silver Spring, MD.

International Medical Device Regulators Forum will be held **September 15–19, 2014**, in Washington, D.C.

Public Workshop on Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing will be held **October 8–9, 2014**, in Silver Spring, MD.

Training Course for Clinical Investigators on Scientific, Ethical, and Regulatory Aspects of Clinical Trials will be held **November 4–6, 2014**, in College Park, MD.

Advisory Committees
August 14, 2014: Pulmonary-Allergy Drugs Advisory Committee Meeting

September 3, 2014: Nonprescription Drugs Advisory Committee Meeting

September 4–5, 2014: Nonprescription Drugs Advisory Committee Meeting

September 10, 2014: Cardiovascular and Renal Drugs Advisory Committee Meeting

September 11, 2014: Endocrinologic and Metabolic Drugs Advisory Committee Meeting

September 12, 2014: Endocrinologic and Metabolic Drug Products Advisory Committee Meeting

September 17, 2014: Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee

September 18, 2014: Joint Meeting of the Bone, Reproductive, and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee

September 18, 2014: Cellular, Tissue, and Gene Therapies Advisory Committee Meeting

September 23, 2014: Pediatric Advisory Committee Meeting

October 1, 2014: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

October 16, 2014: Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting

October 20, 2014: Dermatologic and Ophthalmic Drugs Advisory Committee

For more comprehensive listings of FDA meetings, please visit these FDA web pages:
Meetings, Conferences, and Workshops (Drugs)

Workshops, Meetings, and Conferences (Biologics)

Workshops & Conferences (Medical Devices)

FDA Advisory Committee Calendar

Enforcement Updates

Recent Product Recall
FDA announced one voluntary, company-initiated recall. A pharmaceutical company recalled certain lots of a drug for injection due to potential presence of glass particulate matter in vials produced by a contract manufacturer.

Click here for a complete listing of FDA Recalls.

Recent Warning Letters
Since the last *Update*, FDA cited one facility for failure to pay the facility fee as required by the Generic Drug User Fee Amendments Act of 2012.

FDA cited two medical device manufacturers for violating Quality System Regulation ("QSR") requirements. The warning letter to the first manufacturer included other violations, such as failure to ensure the presence of identification labels on each device product, failure to establish Device Master Records and Device History Records containing the required information for the devices, and failure to ensure manufacturing equipment is calibrated. FDA warned the second manufacturer for violating Medical Device Reporting regulations in addition to QSR violations.

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

The Office of Prescription Drug Promotion ("OPDP") did not issue any warning letters since the last *Update*.

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

Recent Drug and Device Approvals

FDA approves Orbactiv to treat skin infections (August 6, 2014)

FDA expands approval of drug to treat Pompe disease to patients of all ages (August 1, 2014)

FDA approves Jardiance to treat type 2 diabetes (August 1, 2014)

FDA approves Striverdi Respimat to treat chronic obstructive pulmonary disease (July 31, 2014)

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