Pharmaceutical & Medical Device Regulatory Update
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JONES DAY


Pharmaceutical & Medical Device Regulatory Update

United States

FDA Delays Effective Date of Amended Regulations Affecting "Intended Use" Definition

One day before the final rule, "Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses,'" would have taken effect, the Food & Drug Administration ("FDA" or "Agency") announced it was delaying the rule's effective date until March 19, 2018, to obtain public comments on issues raised in an industry petition and on any other issues raised with respect to the rulemaking.
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The Continuing Story of Manufacturers' Off-Label Promotion of Approved or Cleared Medical Products

Prior to the end of the previous Administration, FDA released several draft guidance documents and a white paper addressing different types of communications about medical products. On January 18, 2017, FDA published two draft guidances answering questions and providing FDA's recommendations regarding different types of communications about medical products: "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities" and "Medical Product Communications That Are Consistent With the FDA-Required Labeling."
[read more]

IN THIS ISSUE

Cures Corner: FDA Launches Regenerative Medicine Advanced Therapy Designation Program

In late January 2017, FDA took the first steps to implement certain provisions of the 21st Century Cures Act ("Act"), signed into law on December 13, 2016, by launching a new designation program for regenerative medicine therapies. Implemented pursuant to Section 3033 of the Act, the Regenerative Medicine Advanced Therapy ("RMAT") Designation program aims to help foster the development and approval of regenerative medicine products. Despite the program's newness, on March 20, 2017, FDA issued one of the first RMAT designations to Humacyte's investigational human acellular vessel, "Humacyl."
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President Trump Proposes Dr. Scott Gottlieb as FDA Commissioner

According to a White House statement, President Trump intends to nominate Scott Gottlieb, M.D., as FDA Commissioner. Dr. Gottlieb has previously served in government in various capacities, including as deputy commissioner for medical and scientific affairs, and as a senior official at the Centers for Medicare and Medicaid Services during the Bush Administration.
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Europe

Ten Years of Conditional Marketing Authorizations

The European Medicines Agency published a report concerning the data collected over 10 years—between July 2006 and June 2016—on the so-called "conditional marketing authorizations".
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EMA Consultation on the Revised Policy on Access to Documents

The EMA has launched a public consultation on the proposed revision to its policy on access to documents. The policy describes the rules EMA applies to grant access to the documents that it holds, in accordance with Regulation (EC) No 1049/2001 ("FOI Regulation"). The FOI Regulation gives citizens a right to access EU documents. Comments from stakeholders may be submitted until May 18, 2017.

GCP Renovation ICH Reflection on "GCP Renovation"

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH") has released a reflection paper on Good Clinical Practice ("GCP") "Renovation," which contains the ICH proposal for further modernization of the ICH Guidelines related to clinical trial design, planning, management, and conduct. Comments were solicited through March 11, 2017. ICH will review the comments received to determine whether to make revisions to the currently proposed approach. The aim is to proceed with initiating needed renovation work as soon as practical, for example, within the next year.

EU-U.S. Agreement for Mutual Recognition of GMP Inspections Entered Into Force

On March 4, 2017, the "Decision No 1/2017 of March 1, 2017, of the Joint Committee established under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)" was published in the Official Journal of the EU.
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