

April 7, 2017

DCAT**TOP**
Industry
NEWS

***BUSY WEEK?** Here are the
TOP INDUSTRY NEWS stories
you might have missed, as
selected by DCAT Editorial
Director Patricia Van Arnum.*



1. Eli Lilly to Invest \$850 Million in US Operations

Eli Lilly and Company plans to invest \$850 million across its US operations, including research laboratories, manufacturing sites, and general and administrative areas. The investments include plans for a new \$85-million expansion of its diabetes drug device assembly operations. [Read More](#)

2. Proposed FDA Commissioner Testifies Before Congress

Scott Gottlieb, MD, the nominee for FDA Commissioner, testified before the US Senate and addressed several key issues, including the generic drug approval process, the opioid addiction crisis, and his former work in the pharmaceutical industry. [Read More](#)

3. Congress Holds Hearing on Reauthorization of User Fees

Representatives from the generic drug, biotechnology, and pharmaceutical industries testified before Congress to urge for reauthorization of user fee measures under several pieces of legislation, including the Prescription Drug User Fee Act, the Generic Drug User Fee Amendments, and the Biosimilars User Fee Act, before their expiration in September 2017. [Read More](#)

4. Pfizer CentreOne Adds High Potency Solid Dose and Injectables Capabilities

Pfizer CentreOne has expanded its service portfolio to include contract manufacturing of highly potent solid oral dose medicines at its Ireland facility, following the recent expansion of its fill-finish services at its Michigan site. [Read More](#)

5. Amgen Gains European Approval for Biosimilar to AbbVie's Humira

Amgen has received marketing authorization from the European Commission for Amgevita (adalimumab), a biosimilar to AbbVie's Humira (adalimumab), the company's top-selling drug with 2016 sales of \$16 billion. [Read More](#)

6. GSK Recalls Nearly 600,000 Respiratory Drug Inhalers

GlaxoSmithKline has issued a voluntary Class II recall of 593,088 Ventolin HFA (albuterol sulfate) inhalers in the US and Puerto Rico due to a defective delivery system that resulted in an elevated number of units having a leak rate that is out of specification. [Read More](#)

7. Biogen Gains Positive Ruling on MS Drug Patent Dispute

The Patent Trial and Appeal Board of the US Patent and Trademark Office has ruled in favor of Biogen in a dispute between Biogen and Forward Pharma A/S, a Danish biopharmaceutical company, over a patent for dimethyl fumarate, the active ingredient in Biogen's top-selling multiple sclerosis drug, Tecfidera. [Read More](#)

8. [Mylan Recalls More Than Two Million Bottles of Generic Lipitor](#)

Mylan has issued a voluntary Class II recall of more than two million bottles of atorvastatin calcium tablets, the generic version of Pfizer's anti-cholesterol drug, Lipitor (atorvastatin), due to microbial contamination. [Read More](#)

9. [Roche, Sanofi, and Teva Gain FDA Approval for NMEs](#)

Several large pharmaceutical companies received FDA approval for new molecular entities: Roche's Ocrevus (ocrelizumab), a multiple sclerosis drug; Sanofi's Dupixent (dupilumab), an eczema drug; and Teva's Austedo (deutetrabenazine), an orphan drug for treating chorea associated with Huntington's disease. [Read More](#)

10. [Pfizer, QuintilesIMS Comment on Biosimilars Interchangeability Draft Guidance](#)

Pfizer and QuintilesIMS were among the stakeholders commenting on a recent FDA draft guidance on biosimilar interchangeability. Public comment on the draft guidance is open until May 2017. [Read More](#)

The DCAT organization is happy to provide this service to its members each Friday. Have a great weekend! Due to the holidays, we will not have an issue of DCAT Top Industry News on April 14, 2017. Our next issue will be April 21, 2017.

About Top Industry News

The DCAT organization recognizes its members have minimal time to keep up with the continuous flow of news covering this dynamic industry. To help ensure our members never miss the most important stories impacting the global pharmaceutical manufacturing industry, we will deliver each Friday, the week's Top Industry News, as selected by DCAT Editorial Director Patricia Van Arnum.



The Drug, Chemical & Associated Technologies Association (DCAT) is a not-for-profit, global business development association whose unique membership model integrates both innovator and generic drug manufacturers and suppliers of ingredients, development and manufacturing services, and related technologies. We are committed to provide programs, events and services that help our members meet their business objectives, expand their network of customers and suppliers, and gain insight into industry trends, markets, and those issues impacting pharmaceutical development and manufacturing.



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