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VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

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Issue 117

US Bans Indian APIs Complex Generics

US Bans Indian APIs

The US Food and Drug Administration inspected Ranbaxy's facility in Toansa, Punjab and issued a form 483 in January. Daiichi-Sankyo acquired Ranbaxy for \$ 4.5 bn and paid 0.5 bn in penalties to the US FDA for lapses at Ranbaxy's Paonta Sahib and Dewas facilities in India (<http://freepdfhosting.com/5c974b8bbb.pdf>). Ensuring API supply could be a problem due to addition of Toansa to the list of facilities under USFDA's scope. <http://www.in-pharmatechnologist.com/Regulatory-Safety/Daiichi-says-new-API-import-ban-will-effect-Ranbaxy-s-US-ops> Similarly, Hospira got a warning letter over cGMP practice in 2013. <http://www.sec.gov/Archives/edgar/data/1274057/000110465913045>

An FDA Form 483 is issued to firm management at the conclusion of an inspection when observed any conditions that in investigator's judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant. Observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become

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adulterated or rendered injurious to health. The FDA Form 483 notifies the company's management of objectionable conditions. At the conclusion of an inspection, the FDA Form 483 is presented and discussed with the company's senior management. Companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and then implement that corrective action plan expeditiously. The FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any of its relevant regulations. The FDA Form 483 is considered, along with a written report called an Establishment Inspection Report, all evidence or documentation collected on-site, and any responses made by the company. The Agency considers all of this information and then determines what further action, if any, is appropriate to protect public health.

Complex Generics

Complex generics include complex active ingredients such as LMWH, peptides, complex mixtures, and natural source products; complex formulations such as liposomes, iron colloids, etc.; complex route of delivery, locally acting drugs, complex drug-device combinations such as DPI, MDI, nasal spray, transdermal system, etc.

In the Generic Drug User Fee Amendments (GDUFA) of 2012, FDA committed to prepare a yearly list of regulatory science priorities based on input from industry and other stakeholders.

For Fiscal Year (FY) 2014, FDA's regulatory science priorities for generic drugs will be

- Post-market Evaluation of Generic Drugs
- Equivalence of Complex Products
- Equivalence of Locally Acting Products
- Therapeutic Equivalence Evaluation and Standards
- Computational and Analytical Tools

Because of the market penetration of generic drugs (84% of prescriptions in 2012) it is important that the generic drug program have a range of tools to monitor that these products are being successfully substituted and have the same safety and efficacy profile as their reference listed drug (RLD). Post-market Evaluation of Generic Drugs includes research into surveillance/ monitoring methods for generic drugs, and understanding of patient perceptions of generic drug quality and effectiveness. It also includes evaluation/verification of therapeutic equivalence via brand to generic switching studies in patients. These investigations provide additional data in therapeutic areas where there is concern expressed about substitutability of generic drugs. Based on public comments and issues within FDA, FY 14 priorities are anti-epileptic drugs, immuno- suppressant drugs, bupropion, ADHD drugs and cardiovascular drugs.

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<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM374191.pdf>

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Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih!

(Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

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