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FDA axes approval of 27 Ranbaxy ANDAs

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Singapore: The FDA has withdrawn approval of 27 abbreviated new drug applications (ANDAs) held by Ranbaxy Laboratories. According to the letter posted on the website of the Federal Register, 27 drug products do not have permission for getting marketed as Ranbaxy requested that the approval of their applications be withdrawn.

The drug products that have been affected and are no longer been marketed in the US, include several formulations of Cefaclor, Cefadroxil, Cefuroxime Axetil tablets, Dispermox, Raniclor, Panixine Disperdose, Dispermox, Cefprozil, Etodolac tablets, Terazosin Hydrochloride (HCl) capsules, Ofloxacin tablets, Fluconazole tablets, Metformin HCl extended-release tablets, Pravastatin Sodium tablets, Ganciclovir capsules, Fosinopril Sodium tablets, Glimepiride tablets, Nitrofurantoin/Nitrofurantoin Macrocrystalline capsules, Zidovudine tablets and Ramipril capsules.

The company has also waived its opportunity for a hearing. Ranbaxy requested withdrawal of approval under a consent decree of permanent injunction entered on January 26, 2012. The decree specifies that Ranbaxy can never submit another application to the FDA for these withdrawn products and can also not transfer these ANDAs to a third party. This withdrawal comes into effect from September 21, 2012.

Ranbaxy, in a filing to the Bombay Stock Exchange, mentioned that this withdrawal will have negligible commercial impact. The move by the company is believed to be a step forward to resolve the quality and regulatory issue with the FDA for its two banned manufacturing plants at Dewas and Paonta Sahib in India. In September 2008, the FDA banned 30 drugs made at these two plants for violating US drug manufacturing norms.

Ranbaxy could not be reached for a comment. However, a statement on the company's website states that, "The company has determined that certain products with negligible commercial impact should be withdrawn to enable the organization to focus on other applications that are of greater importance and value to the US business and healthcare system". It adds that the ANDAs "do not pertain to current business and will have a negligible impact on the company's business in the US."