

Generic Advair - 3 years to go, but which generic companies are better poised?

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Abstracts

The USFDA has finally announced the draft guidance for the development of generic version of GSK's Asthma / COPD drug – Advair (Fluticasone propionate + Salmeterol Xinafoate). The guidelines pave the way for generic companies to launch a substitutable and interchangeable version of Advair in the US market, which should allow easy and larger penetration for generic copies. Apart from ANDA filings, we should also see a few companies which are developing an improved formulation or using a different device file through the 505(b) (2) route. We see Mylan and Sandoz are well positioned to enter the market in 2016 with a fully substitutable version, while we are not sure if Cipla could also do the same. Sun Pharma also has access to dry powder inhaler technology (starhaler), but the efficacy profile of its formulation is quite different from Advair, hence it may have to come through the 505(b) (2) route. Teva has recently acquired Microdose therapeutx, which gives it access to DPI technology, hence there is a chance that Teva could also accelerate development of a fully substitutable version of Advair.

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