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Abstracts

FDA recently issued a complete response letter to MRK’s Suvorexant. As per the complete response letter, the USFDA will need manufacturing data on the 10mg dose and clinical data for the 5mg dose. Due to safety concerns; the higher doses (30mg and 40mg) would not be approved. We see the launch timelines delayed by atleast 12 to 18 months. In case of the 10mg dose Merck would have to conduct an additional stability study, which would take atleast 6 months. For the 5mg dose, there would be additional clinical studies that would be required, for which we believe PK/PD studies should suffice.

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