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FDA issues new guidance for developers of complex generics

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Singapore - The FDA has released new guidance documents aimed at advancing development of generic versions of transdermally and topically administered drugs, formulations that are more complex and more challenging to copy. The types of products in these categories include inhaled drugs, topical skin patches and eye drops that act on the surface of the eye.

FDA Commissioner Scott Gottlieb, M.D. says, “As part of the U.S. Food and Drug Administration’s efforts to promote drug competition and patient access, we’ve advanced many policies aimed at making it more efficient to bring generic competition to the market. We have been especially focused on a category of medicines known as complex drugs. These are drugs that, by nature of their formulation or delivery systems for example, are harder to “genericize” under our traditional approaches. As a result, these drugs often face less competition.”

In addition to these documents, the FDA also issued 25 product-specific guidance documents. These include two new and 23 revised guidances. These documents will support industry in identifying appropriate science-based methodologies and evidence for developing generic TDS products.