Analysis of Complex Drug Product Landscape to Support Generic Drug User Fee Amendment (GDUFA) II Implementation

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Per the GDUFA II commitment letter, complex drug products generally include products with (1) complex active pharmaceutical ingredients (APIs); (2) complex formulations; (3) complex routes of delivery; (4) complex dosage forms; (5) complex drug-device combination and (6) other products where there is complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement. The objective of this study is to obtain a comprehensive overview on the landscape of complex drug products to best support GDUFA II implementation. We conducted a systematic analysis of complex drug products based on the established database from three perspectives: (1) drug product information (e.g., dosage form, route of administration, and therapeutic area); (2) generic status (e.g., ANDA submission, availability of approved generics, exclusivity and patent information); and (3) pharmacoeconomics (e.g., drug sales from 2011-2017). Our results show that, of all the complex products top two administration routes are topical and parenteral routes with the majority of topical products in the dermatologic therapeutic area. This systematic analysis of complex drug products can help facilitate OGD's preparation for GDUFA research prioritization, product-specific guidance development, and Pre-ANDA meeting planning. Furthermore, it could improve transparency of communication about complex generic drugs both within the FDA and with external stakeholders.