From: "U.S. Food & Drug Administration (FDA)"
Subject: Drug Information Update - FDA Requesting Comment on Proposed Criteria for "First Generic" Submissions
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The Division of Drug Information (DDI) is CDER's focal point for public inquiries. We serve the public by providing information on human drug products and drug product regulation by FDA.

FDA is opening a public docket and requesting comments on proposed criteria for "first generic" abbreviated new drug application (ANDA) submissions.

Establishing clear criteria for this review prioritization category will allow FDA to appropriately prioritize ANDA submissions and track them in a manner consistent with the review prioritization commitments FDA made pursuant to GDUFA. Clear criteria for this category will also lead to less industry confusion and more consistent identification of "first generic" submissions.

FDA believes that these proposed criteria appropriately focus FDA's resources on approving new safe and effective generic drug products for patient use as quickly as possible.

For more information and the latest events regarding GDUFA, please visit our Generic Drug User Fee Amendments of 2012 website.

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