Implementation of the generic drug labeling rules 2017

Description: FDA is due to release a major Generic Drug Labeling Rule in April 2017. Attend this training to review current generic drug labeling rules and requirements and how they will change with the new rule. Understand the obligations and responsibilities for complying with the new rule as well as how to make submissions to change the product labeling.

Objectives of the Presentation:
- Current generic drug labeling requirements
- New and changing generic drug labeling requirements
- Responsibilities for complying with the new rule
- How to implement the new rule
- How to make safety changes to the labeling of the product
- Timeline for compliance with the new rule

Why should you Attend:

Under current FDA regulations, generic drug companies with abbreviated new drug applications (ANDAs), unlike companies with new drug applications (NDAs) and biologics license applications (BLAs), cannot independently update product labeling with newly acquired safety information. In April 2017 FDA will release a major Generic Drug Labeling Rule. The new rule will permit a generic company that finds a safety issue not yet included in its reference product's label (or the reference product is no longer even produced) to update safety in the labeling.

Areas Covered
- Requirements to comply with innovator labeling
- Exceptions to compliance with innovator labeling
- New changes to safety information in generic labeling
- Requirements for generic manufacturers/distributors under the new rule
- Strategies for implementation of the new rule
- Timeline for compliance and what it means within operational activities
- Penalties and/or liabilities for non-compliance

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