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Regulatory 101: Drug Name Modifiers – Definition, Categories, Generics, And CAPA

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The FDA Orange Book identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. Each edition includes a list of unexpired patents covering drugs, as of the date of publication.

INTRODUCTION Drug name modifiers are descriptive components of proprietary drug names. Drug name modifiers are letters, words, numbers, or combinations thereof that describe a unique product characteristic as part of the proprietary drug name. Examples of drug name modifiers include PM in Tylenol PM®, SR in Wellbutrin SR®, D in Claritin-D®, HFA in ProAir HFA®, and numerous others. Modifiers are developed primarily for commercial marketing purposes to distinguish a specific product.&

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