

Unapproved Drugs Initiative

- Marketed Unapproved Drugs — Compliance Policy Guide (CPG):

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf

- **Initial CPG released June 2006; Revised in September 2011**

- Outlines the FDA's enforcement policies aimed at efficiently and rationally bringing unapproved drugs into the approval process
- Provides official notice that any illegally marketed product is subject to FDA enforcement at any time
- Clarifies that the FDA intends to use a risk-based approach to enforcement for those products marketed before 9/19/11
- Drugs entering the market after 9/19/2011 are subject to immediate enforcement action at any time, without prior notice and without regard to the enforcement priorities set forth in the CPG

Marketed Unapproved DrugsGScompliance Policy Guide

Michael Brown



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