

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

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