

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0478]

DDM	
Display Date	6-8-06
Publication Date	6-9-06
Compiler	D. Hawkins

**Guidance on Marketed Unapproved Drugs; Compliance Policy Guide;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Marketed Unapproved Drugs—Compliance Policy Guide." The guidance describes how FDA intends to exercise its enforcement discretion with regard to drugs marketed in the United States that do not have required FDA approval for marketing. This document supersedes section 440.100 entitled "Marketed New Drugs Without Approved NDAs or ANDAs" (CPG 7132c.02) of the Compliance Policy Guide (CPG). It applies to any new drug required to have FDA approval for marketing, including new drugs covered by the over-the-counter (OTC) review.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self addressed adhesive label to assist the office in processing your request. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration,

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5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Center for Drug Evaluation and Research (HFD-316), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-8964.

SUPPLEMENTARY INFORMATION:

I. Background

In the United States, as many as several thousand drug products are marketed illegally without required FDA approval. The manufacturers of these drugs have neither received FDA approval to legally market their drugs, nor have the drugs been marketed in accordance with a final OTC drug monograph. The drug approval and OTC monograph processes play an essential role in ensuring that all drugs are both safe and effective. Manufacturers of new drugs that lack required approval, including those that are not marketed in accordance with an OTC drug monograph, have not provided FDA with evidence demonstrating that their products are safe and effective. Therefore, FDA has an interest in taking steps to encourage the manufacturers of these products either to obtain the required evidence and comply with the approval provisions of the Federal Food, Drug, and Cosmetic Act or to remove the products from the market. FDA wants to achieve these goals without adversely affecting public health, imposing undue burdens on consumers, or unnecessarily disrupting the market.

In general, in recent years, FDA has employed a risk-based enforcement approach to marketed unapproved drugs that includes efforts to identify illegally marketed drugs, prioritization of those drugs according to potential

public health concerns or other impacts on the public health, and subsequent regulatory followup. Some of the specific actions the agency has taken have been precipitated by evidence of safety or effectiveness problems that has come to our attention either during inspections or through outside sources.

II. The Guidance

FDA is announcing the availability of a guidance entitled "Marketed Unapproved Drugs —Compliance Policy Guide." In the **Federal Register** of October 23, 2003 (62 FR 60702), FDA announced the availability of a draft guidance of the same title and gave interested persons an opportunity to submit comments by December 22, 2003. In response to comments received, the agency revised the guidance to include editorial corrections and clarification of policies, including clarification of when and how we intend to exercise our enforcement discretion. The revisions also clarify the discussion of "grandfather" status and expressly state that no part of the guidance is a finding as to the legal status of any particular drug product.

This document supersedes section 440.100 entitled "Marketed New Drugs Without Approved NDAs or ANDAs" (CPG 7132c.02) of the CPG. It applies to any new drug required to have FDA approval for marketing, including new drugs covered by the OTC review.

The goals of the guidance are to address the following issues: (1) Clarify for FDA personnel and the regulated industry how the FDA intends to exercise its enforcement discretion regarding unapproved drugs and (2) emphasize that illegally marketed drugs must obtain FDA approval.

The guidance reflects the agency's desire to address these issues with policies that are predictable, reasonable, and supportive of the public health. The agency's approach encourages companies to comply with the drug

approval process, but it also seeks to minimize disruption to the marketplace and to safeguard consumer health when there are potential safety risks. The guidance explains that FDA will continue to give priority to enforcement actions involving unapproved drugs with potential safety risks, that lack evidence of effectiveness, and that constitute health fraud. It also explains how the agency intends to address those situations in which a firm obtains FDA approval to sell a drug that other firms have long been selling without FDA approval. It confirms that the agency will continue longstanding policies regarding firms making unapproved drugs who are violating the act in other respects and clarifies how the agency plans to address formulation changes made to evade an enforcement action.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: Jeffrey Shuren 6/6/06
Jeffrey Shuren, June 6, 2006.
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S

