

electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product CETROTIDE (cetorelix acetate). CETROTIDE is indicated for the inhibition of premature luteinizing hormone surges in women undergoing controlled ovarian stimulation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CETROTIDE (U.S. Patent No. 5,198,533) from Administrators of the Tulane Educational Fund, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 6, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory

review period and that the approval of CETROTIDE represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CETROTIDE is 2,103 days. Of this time, 1,815 days occurred during the testing phase of the regulatory review period, while 288 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* November 10, 1994. The applicant claims October 10, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 10, 1994, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* October 29, 1999. The applicant claims October 28, 1999, as the date the new drug application (NDA) for CETROTIDE (NDA 21-197) was initially submitted. However, FDA records indicate that NDA 21-197 was submitted on October 29, 1999.

3. *The date the application was approved:* August 11, 2000. FDA has verified the applicant's claim that NDA 21-197 was approved on August 11, 2000.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,491 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 8, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 6, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0478]

#### 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, 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: June 6, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

*DNA Influenza Vaccine*

*Description of Technology:* The FDA is pleased to announce a single vector DNA vaccine against influenza as available for licensing. The single vector