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Dated: June 23, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0118]

#### International Conference on Harmonisation; Guidance on Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The purpose of the guidance is to provide principles for assessing the comparability of biotechnological/biological products before and after changes are made in the manufacturing process for the drug substance or drug product. The guidance is intended to assist in the collection of relevant technical information that serves as evidence that the manufacturing process changes will not have an adverse impact on the quality, safety, and efficacy of the drug product.

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

**ADDRESSES:** 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>. Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and

Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### FOR FURTHER INFORMATION CONTACT:

*Regarding the guidance:* Barry Cherney, Center for Drug Evaluation and Research (HFD-122), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-1790; or Andrew Chang, Center for Biologics Evaluation and Research (HFM-340), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-496-4833.

*Regarding the ICH:* Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers

Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of March 30, 2004 (69 FR 16580), FDA published a notice announcing the availability of a draft tripartite guidance entitled "Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process." The notice gave interested persons an opportunity to submit comments by May 19, 2004.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2004.

The document provides guidance on the principles for assessing the comparability of biotechnological/biological products before and after changes are made in the manufacturing process for the drug substance or drug product. The document does not prescribe any particular analytical, nonclinical, or clinical strategy. The main focus of the document is on quality aspects.

This guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The guidance represents the agency's current thinking on Q5E comparability of biotechnological/biological products subject to changes in their manufacturing process. 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.

Note that FDA may have existing guidance on this or related topics, such as "FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products," available at <http://www.fda.gov/cber/gdlns/comptest.txt>.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. 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 may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

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

Dated: June 22, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004P-0295]

#### **Determination That ZYVOX (Linezolid) Tablets, 400 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that ZYVOX (linezolid) tablets, 400 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for linezolid tablets, 400 mg.

**FOR FURTHER INFORMATION CONTACT:** Nicole Mueller, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved

under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ZYVOX (linezolid) tablets, 400 mg, are the subject of approved NDA 21-130 held by Pharmacia and Upjohn Co., a subsidiary of Pfizer, Inc. ZYVOX (linezolid) tablets, 400 mg, are indicated for the treatment of certain infections caused by susceptible strains of certain microorganisms.

In a citizen petition dated July 9, 2004 (Docket No. 2004P-0295), submitted under 21 CFR 10.30, Lachman Consultant Services, Inc., requested that the agency determine, as described in § 314.161, whether ZYVOX (linezolid) tablets, 400 mg, were withdrawn from sale for reasons of safety or effectiveness. The holder of the NDA for ZYVOX (linezolid) tablets never marketed the 400 mg strength. In previous instances, the agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale (see 67 FR 79640, December

30, 2002 (addressing a relisting request for Diazepam Autoinjector)).

The agency has determined that Pfizer's ZYVOX (linezolid) tablets, 400 mg, were not withdrawn from sale for reasons of safety or effectiveness. FDA has reviewed its files for records concerning the withdrawal of ZYVOX (linezolid) tablets, 400 mg, from sale. There is no indication that the decision not to market ZYVOX (linezolid) tablets, 400 mg, commercially is a function of safety or effectiveness concerns, and the petitioner has identified no data or information suggesting that ZYVOX (linezolid) tablets, 400 mg, pose a safety risk. FDA has independently evaluated relevant literature and data for possible concerns regarding the safety or effectiveness of this drug product. FDA has found no information that would indicate that this product was withdrawn for reasons of safety or effectiveness.

For the reasons outlined, FDA determines that Pfizer's ZYVOX (linezolid) tablets, 400 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ZYVOX (linezolid) tablets, 400 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ZYVOX (linezolid) tablets, 400 mg, may be approved by the agency.

Dated: June 22, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### **Research Review Subcommittee of the Blood Products Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a subcommittee of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Subcommittee:* Research Review Subcommittee of the Blood Products Advisory Committee