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.

[FR Doc. 05–12908 Filed 6–29–05; 8:45 am]

BILLING CODE 4160–01–S

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Determination That ZYVOX (Linezolid) Tablets, 400 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that ZYVOX (linezolid) tablets, 400 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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.

[FR Doc. 05–12909 Filed 6–29–05; 8:45 am]

BILLING CODE 4160–01–S

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

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 22, 2005, from 8 a.m. to 5 p.m.

Location: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD 20879.

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research, (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 22, 2005, the subcommittee will listen to presentations to further a dynamic, responsive, and cutting edge research program at the Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), that facilitates development of safe and effective biological products. The subcommittee's recommendations will be publicly discussed at a future meeting of the Blood Products Advisory Committee. Information regarding CBER's scientific program is outlined in its Strategic Plan of 2004 and is available to the public on the Internet at: *http://www.fda.gov/cber/inside/mission.htm*. Information regarding FDA's Critical Path to New Medical Products is available to the public on the Internet at: *http://www.fda.gov/oc/initiatives/criticalpath/*.

Procedure: On July 22, 2005, from 8 a.m. to 1:15 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by July 14, 2005. Oral presentations from the public will be scheduled between approximately 12:15 p.m. and 1:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by July 14, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Subcommittee Deliberations: On July 22, 2005, from 2:15 p.m. to 5 p.m., the meeting will be closed to the public. The meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)) and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The subcommittee will discuss the internal research programs in the Office of Blood Research and Review, CBER.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Pearline K. Muckelvene at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 23, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–12962 Filed 6–29–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0133]

''Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection'' dated June 2005. This guidance document provides revisions to the previously published recommendations for assessing donor suitability and product safety when donors are diagnosed with or suspected of West Nile Virus (WNV) infection based on symptoms and laboratory tests. This guidance revises recommended deferral periods for such donors, and updates information on component retrieval and quarantine. This guidance finalizes the draft ''Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection'' dated April 2005 and supersedes the final ''Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection'' dated May 2003. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing the guidance entitled ''Guidance for Industry: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection,'' dated May 2005.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,'' dated June 2005. FDA developed the information in this guidance after consulting with other Public Health Service Agencies of the Department of Health and Human Services.

This guidance does the following things: