necessary to gain approval of an 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(jj)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(jj)(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 Under FDA regulations in part 314 (21 CFR part 314), drugs are withdrawn from sale for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162).

Under § 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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.

PYRIDOSTIGMINE BROMIDE (mestinon) tablets (NDA 009–829), 60 mg, were originally approved on April 6, 1955, to treat myasthenia gravis. They were deemed effective under the Drug Efficacy Study Implementation on November 4, 1970 (35 FR 16992).

A suitability petition was submitted under section 355(j)(2)(C) of the act and was approved for a change in strength for PYRIDOSTIGMINE BROMIDE (mestinon) tablets (i.e., from 60-mg tablets to 30-mg tablets) for the treatment of myasthenia gravis (see January 22, 1986, letter; Docket No. 1985P–0412). FDA approved ANDA 89–572, held by Solvay Pharmaceuticals, Inc., (Solvay), on November 27, 1990, for PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis. Solvay’s PYRIDOSTIGMINE BROMIDE tablets, 30 mg, were discontinued from marketing on May 12, 1994, and at Solvay’s request, approval of ANDA 89–572 was withdrawn effective August 11, 1994 (59 FR 35527, July 12, 1994).

On October 29, 2003, Lachman Consultant Services, Inc., submitted a citizen petition (Docket No. 2003P–0501) under 21 CFR 10.30 requesting that the agency determine whether PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis, were withdrawn from sale for reasons of safety or effectiveness. The agency has determined that PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis, were not withdrawn from sale for reasons of safety or effectiveness. The original basis for approving the suitability petition has not changed. PYRIDOSTIGMINE BROMIDE (mestinon) tablets, 60 mg, currently appear in the active section of the Orange Book. The agency notes that PYRIDOSTIGMINE BROMIDE (mestinon) tablets, 60 mg, are still being marketed by several other manufacturers (e.g., Impax Labs, Corepharma, and Barr). PYRIDOSTIGMINE BROMIDE (mestinon) tablets, 60 mg, were still being marketed by several other manufacturers (e.g., Impax Labs, Corepharma, and Barr).

In approving the suitability petition, the agency noted that:

[a]lthough the proposed strength is less than the currently approved product, the labeling of the currently approved products indicates that doses of 30 mg or even less may be utilized. Additionally, incremental doses are encouraged in approved labeling, especially “for children and brittle myasthenic patients who require fractions of 60-mg doses” (see Docket No. 1985P–0412). The currently available, relevant information does not call into question the agency’s January 22, 1986, determination that ANDAs for PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis, are suitable for submission.

The agency notes that PYRIDOSTIGMINE BROMIDE tablets, 30 mg, are also indicated for prophylaxis against the lethal effects of soman nerve agent poisoning, and are the subject of NDA 20–414. The U.S. Army submitted NDA 20–414, which was approved on February 5, 2003, under the Federal Register.

The agency will continue to list PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis, in the “Discontinued Drug Product List” section of the Orange Book. ANDAs that refer to PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis, may be approved by the agency.

Dated: June 14, 2005.

Jeffrey Shruen,
Assistant Commissioner for Policy.

[FR Doc. 05–12108 Filed 6–20–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0227]

Update on Leukocyte Reduction of Blood and Blood Components; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled “Update on Leukocyte Reduction of Blood and Blood Components.” The public workshop topics are FDA; the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute (NHLBI); and the Office of Public Health and Science (OPHS) in the Department of Health and Human Services. The purpose of the public workshop is to address current issues related to leukocyte-reduced blood and blood components.

Date and Time: The public workshop will be held on July 20, 2005, from 8 a.m. to 5:30 p.m.

Location: The public workshop will be held at the National Institutes of Health, Lister Hill Center Auditorium, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894.

Contact: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, FAX: 301–827–2843, e-mail: dawsonr@cbcr.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Rhonda Dawson (see Contact) by July 1, 2005. Because seating is limited, we recommend early registration. Registration at the site on the day of the public workshop will be
provided on a space available basis beginning at 7:15 a.m. There is no registration fee for the public workshop. If you need special accommodations due to a disability, please contact Rhonda Dawson at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, NHLBI, and OPHS are sponsoring a public workshop entitled “Update on Leukocyte Reduction of Blood and Blood Components.” The workshop will include the following topics:

- Leukoreduction in targeted and non-targeted recipients;
- Current data on the potential advantages and hazards of providing leukocyte-reduced blood and blood components;
- A review of observed clinical adverse events and manufacturing failures associated with leukoreduction procedures;
- FDA’s current considerations for regulatory standards for leukocyte-reduced components and approaches to quality control testing; and

New scientific developments in filtration, including developing technologies for prion removal from blood components.

Transcripts: Transcripts of the public workshop may be requested in writing approximately 15 working days after the workshop. If you need special accommodations due to a disability, contact: Jeffrey Shuren, Assistant Commissioner for Policy, at least 7 days in advance.

The workshop will be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: June 14, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.
[FR Doc. 05–12185 Filed 6–20–05; 8:45 am]

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Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235,