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(j)(7) of the Federal Food, Drug, and Cosmetic Act (the 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 Under FDA regulations in part 314 (21 CFR part 314), drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162).

Under § 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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tablets, 30 mg, were discontinued from marketing on May 12, 1994, and at Solvay's request, approval of ANDA 89–572 was withdrawn effective August 11, 1994 (59 FR 35527, July 12, 1994).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that the agency determine whether PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis, were not withdrawn from sale for reasons of safety or effectiveness.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) syrup (NDA 15–193), 60 mg/5 milliliters, also appears in the active section of the Orange Book. 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 subpart I of the new drug regulations (§§ 314.600 through 314.650). NDA 20–414 is displayed in the ''Discontinued Drug Product List'' section of the Orange Book. Drug products approved for the U.S. Army are displayed in the discontinued section of the Orange Book because they are not commercially available. The agency notes that NDA 20–414 is not the subject of this determination. The issue here is whether PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis (i.e., ANDA 89–572), were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that, for the reasons stated in this document, PYRIDOSTIGMINE BROMIDE tablets, 30 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, 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 sponsors 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@cber.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 ofproviding 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 from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 24, 2005, page 3376 and allowed 60-days for public comment. Three requests for more information were received. Additional information on the proposed collection was sent to each requestor. The purpose of this notice is to allow an additional 30 days for public comment.

5 CFR 1320.5 (General requirements) Reporting and Recordkeeping Requirements: Final Rule requires that the agency inform the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. This information is required to be stated in the 30-day **Federal Register** Notice.

Proposed Collection: Title: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. *Type of Information Collection Request:* Revision, OMB control number 0925–0407, expiration date July 31, 2005. *Need and Use of Information Collection:* This trial is designed to determine if screening for prostate, lung, colorectal and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 263,000 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. The total sample size t is 154,938. The primary endpoint of the trial is cancer-specific mortality for each of the four cancer sites (prostate, lung, colorectum, and ovary). In addition, cancer incidence, stage shift, and case survival are to be monitored to help understand and explain results. Biologic prognostic characteristics of the cancers will be measured and correlated with mortality to determine the mortality predictive value of these intermediate endpoints. Basic demographic data, risk factor data for the four cancer sites and screening history data, as collected from all subjects at baseline, will be used to assure comparability between the screening and control groups and make appropriate adjustments in analysis. Further, demographic and risk factor information may be used to analyze the differential effectiveness of screening in high versus low risk individuals. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households. *Type of Respondents:* Adult men and women. The annual reporting burden is as follows: *Estimated Number of Respondents:* 145,852; *Estimated Number of Responses Per Respondent:* 1.14; *Average Burden Hours Per Response:* 0.14; and *Estimated Total Annual Burden Hours Requested:* 23,278. The annualized cost to respondents is estimated at: $232,780. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated annual number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adults	145,852	1.14	0.14	23,278

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,