TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(b)[2]	82	1	82	20	1,640
610.40(c)(1)(ii)	1,628	8	12,000	0.08	960
610.40(g)(2)	1	1	1	1	1
610.40(h)(2)(ii)(A)	1	1	1	1	1
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	40	12	480	0.2	96
610.40(h)(2)(vi)	1,628	11	18,000	0.08	1,440
610.42(a)	1	1	1	1	1
610.46(a)	1,709	16	26,544	0.17	4,512
610.46(b)	1,709	16	26,544	0.17	4,512
610.47(b)	134	1	134	1	134
630.6(a)[3]	570	760	433,333	0.08	34,667
630.6(a)[4]	85	106	9,000	1.5	13,500
630.6(d)(1)	81	37	3,000	1	3,000
Total					64,464

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).
[3]Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[4]Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b)[2]	249[5]	1	249	24	5,976
606.100(c)	249[5]	10	2,490	1	2,490
606.110(a)[3]	39[6]	1	39	0.5	20
606.151(e)	249[5]	12	2,988	0.083	248
606.160[4]	249[5]	1,928	480,000	0.75	360,000
606.160(b)(1)(ix)	1,709	1,024	1,750,000	0.05	87,500
606.160(b)(1)(xi)	1,628	4	6,750	0.05	338
606.165	249[5]	1,928	480,000	0.083	39,840
606.170(a)	249[5]	12	2,988	1	2,988
610.40(g)(1)	1,628	1	1,628	0.5	814
Total					500, 214

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The recordkeeping requirements in §§ 640.3(a)(1), 640.4(a)(1), and 640.66, which address the maintenance of SOPs, are included in the estimate for § 606.100(b).
[3]The recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for the plateletpheresis, are included in the estimate for § 606.110(a).
[4]The recordkeeping requirements in §§ 640.3(a)(2) and (f); 640.4(a)(2); 640.25(b)(4) and (c)(1); 640.31(b); 640.33(b); 640.51(b); 640.53(b) and (c); 640.56(b) and (d); 640.61; 640.63(b)(3), (e)(1), and (e)(3); 640.65(b)(2); 640.71(b)(1); 640.72; and 640.76(a) and (b), which address the maintenance of various records are included in the estimate for § 606.160.
[5]Five percent of CMS transfusion services and FDA-registered blood establishments (0.05 X 4,980).
[6]Five percent of plateletpheresis and leukopheresis establishments (0.05 X 773).

Dated: June 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12180 Filed 6–20–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0501]

Determination That PYRIDOSTIGMINE BROMIDE Tablets, 30 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 PYRIDOSTIGMINE BROMIDE tablets, 30 milligrams (mg), for the treatment of myasthenia gravis, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for PYRIDOSTIGMINE BROMIDE tablets, 30 mg, for the treatment of myasthenia gravis.

FOR FURTHER INFORMATION CONTACT: S. Mitchell Weitzman, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5535.

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 under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise

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]

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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