[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: October 17, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–21153 Filed 10–21–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004D–0283]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Fax written comments on the collection of information by November 23, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

The generic Animal Drug and Patent Term Registration Act of 1988 permitted generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based in part upon a demonstration of bioequivalence between the generic product and pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence by the stature does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision.

The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) may be waived for soluble powder or Type A medicated articles in either of two

alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s), is the same as the pioneer product, is soluble , and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in two ways: ''USP definition'' approach or ''Dosage Adjusted'' approach.

In the **Federal Register** of August 3, 2004 (69 FR 46553), the agency requested comments on this collection of information. In response to that notice, the agency received several comments on the guidance, two from individuals who were generally favorable and one from the Animal Health Institute (AHI), which was supportive of some aspects of the proposed guidance and not supportive of others. None of the comments received took issue with any aspect of the paperwork burden associated with the draft policy. The Center for Veterinary Medicine has revised the substance of the proposed guidance in several respects in response to AHI comments.

The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. FDA estimates the burden for this collection of information as follows in tables 1 and 2 of this document. The source of the data is records of generic drug applications over the past 10 years.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS[1]

| | No. of Respondents | Annual Frequency per Responses | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Same Formulation / Manufacturing Process Approach | 1 | 1 | 1 | 5 | 5 |
| Same API / Solubility Approach | 5 | 5 | 5 | 10 | 50 |
| Total Burden Hours | | | | | 55 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES[1]

| | No. of Respondents | Annual Frequency per Responses | Total Annual Responses | Hourse per Response | Total Hours |
|---|---|---|---|---|---|
| Same Formulation / Manufacturing Process Approach. | 2 | 2 | 2 | 5 | 10 |
| Same API / Solubility Approach | 10 | 10 | 10 | 20 | 200 |
| Total Burden Hours | | | | | 210 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 17, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005N–0209]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Food Contact Substances Notification

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by November 23, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Food Contact Substances Notification System—21 CFR 170.101 and 170.106—(OMB Control Number 0910–0495)—Extension

Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Section 409(h)(3) of the act requires that the notification process be used for authorizing the marketing of food contact substances