

§ 606.160(b)(1)(xi), only the 858 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the

300,000 autologous donors (13,500) will be deferred under § 610.41 and thus result in the notification of their referring physicians.

The hours per response and hours per record are based on estimates received

from industry or FDA experience with similar recordkeeping or reporting requirements.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.40(c)(1)(ii)	942	13	12,000	.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)	942	19	18,000	0.08	1,440
610.42(a)	1	1	1	1	1
630.6(a) <sup>2</sup>	311	1,393	433,333	0.08	34,667
630.6(a) <sup>3</sup>	47	191	9,000	1.5	13,500
630.6(d)(1)	43	140	6,000	1	6,000
Total					56,666

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.

<sup>3</sup> Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Records	Total Hours
610.40(g)(1)	858	1	858	.5	429
606.160(b)(1)(ix)	942	1,858	1,750,000	0.05	87,500
606.160(b)(1)(xi)	858	16	13,500	0.05	675
Total					88,604

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 9, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2000D-1314]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes

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

#### **ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**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 the **Federal Register** of January 8, 2004 (69 FR 1300), the agency announced that the proposed information collection had

been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0450. The approval expires on February 28, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: March 9, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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