unsuitability for transplant. In addition, there are an estimated 20,000 donors of conventional tissue and 47,796 donors of eye tissue each year.

Accredited members of the American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) adhere to standards of those organizations that are comparable to the recordkeeping requirement in part 1270 (21 CFR part 1270). Based on information provided by industry associations, 50 to 75 percent (average 63 percent) of the conventional tissue banks are members of AATB (166 x 63 percent = 105), and 99 percent of eye tissue banks are members of EBAA (134 x 99 percent = 133). Therefore, recordkeeping by these 238 establishments (105 + 133 = 238) is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the remaining 62 establishments, which is 21 percent of all establishments (300 - 238 = 62, or 62/300 = 21 percent).

Based on CBER's database system and information provided by industry, FDA estimates an average of two new tissue banks annually, which may be nonmembers of a trade association. Each new tissue bank requires an estimated 64 hours to prepare standard operating procedures (SOPs) under § 1270.31(a) through (d). The requirement for the development of these written procedures is considered an initial one-time burden. FDA assumes that all current tissue establishments have developed written procedures in compliance with part 1270. Therefore, their information collection burden is for the general review and update of written procedures estimated to take an annual average of 24 hours, and for the recording and justifying of any deviations from the written procedures for § 1270.31(a) and (b), estimated to take an annual average of 1 hour. The information collection burden for maintaining records concurrently with the performance of each significant screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (h), include documenting the results and interpretation of all required infectious disease tests and results and the identify and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates for the number of total annual records and hours per record are based on information provided by industry and FDA experience.

In the **Federal Register** of October 1, 2003 (68 FR 56635), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1270.31(a) through (d)	2	1	2	64	128
1270.31(a) through (d)[2]	62	1	62	24	1,488
1270.31(a) and (b)[3]	62	2	124	1	124
1270.33(a), (f), and (h) and 1270.35(a) and (b)	62	3,089	191,518	1	191,518
1270.35(c)	62	5,719	354,578	1	354,578
1270.35(d)	62	715	44,330	1	44,330
Total					592,166

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Review and update of standard operating procedures (SOPs).
[3] Documentation of deviations from SOPs.

Dated: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1493 Filed 1–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0329]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How To Use E-Mail To Submit Information to the Center for Veterinary Medicine

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 February 25, 2004.

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, rm. 4B–41, 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.

Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine, 21 CFR 11.2—(OMB Control N0. 0910–0454)—Extension

The Center for Veterinary Medicine (CVM) is responsible for developing and administering guidances that explain how to adhere to the electronic records; electronic signatures regulations (part 11 (21 CFR part 11)). These regulations allow sponsors to submit part or all of records to FDA electronically in lieu of paper, unless the paper records are specifically required by regulation, if the requirements of part 11 are met, and the documents to be submitted electronically are identified in Public Docket No. 92S–0251. These regulations comply with the Government Paperwork Elimination Act (GPEA) (Public Law 105–277). The GPEA requires Federal agencies, by October 21, 2003, to give persons who are required to maintain, submit, or disclose information the option of doing so electronically when practicable as a substitute for paper.

This guidance document describes the procedures persons who submit information to CVM should follow, if they want to file submissions electronically. This guidance instructs those who wish to submit information to CVM by e-mail to first register with the center. Registration entails sending a letter, on paper or electronically, to CVM with a sponsor password and the names, phone numbers, mail and e-mail addresses of a sponsor coordinator and each person who will submit information electronically to CVM. Other information collection provisions relate to electronic submissions by individuals and electronic submissions to make changes to the sponsor's registration. CVM will use all the information submitted to process electronic submissions. The likely respondents to this collection of information are new animal drug sponsors.

In the **Federal Register** of August 7, 2003 (68 FR 47077), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

We estimate the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,538	70	2	140	.5	70

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

The estimate of the times required for record preparation is based on agency communication with industry. Other information needed to calculate the total burden hours are derived from agency records and experience.+

Dated: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1494 Filed 1–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0327]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How To Use E-Mail To Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

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 February 25, 2004.

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.

Guidance for Industry on How To Use E-Mail To Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation—(OMB Control Number 0910–0452)—Extension

Any person intending to file a new animal drug application or abbreviated application is entitled to request meetings and/or teleconferences to reach agreement regarding a submission or investigational requirement (21 U.S.C. 3606(b)(3)). Every person outside the Federal Government may request a meeting with representative(s) of FDA to discuss a matter (21 CFR 10.65(c)).

Sponsors often meet with scientists in the Center for Veterinary Medicine's (CVM) Office of New Animal Drug Evaluation to formulate a rational approach to studies to be conducted and to discuss how to meet the statutory requirements for new animal drug approval under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). Requests for meetings and teleconferences are currently submitted on paper to CVM.

This guidance document describes the procedure for persons to submit a request for a meeting or teleconference electronically on FDA Form 3489. The information sponsors should include on the form includes the sponsor's name and address, a list of agency participants, an agenda, and notification of audio-visual equipment that will be