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 Study Protocol''—21 CFR 58.120; 21 CFR 514.117(b); (OMB Control Number 0910–0524)—Extension

Protocols for nonclinical laboratory studies (safety studies), are required under 21 CFR 58.120 for approval of new animal drugs. Protocols for adequate and well-controlled effectiveness studies are required under 21 CFR 514.117(b). Upon request by the animal drug sponsors, the Center for Veterinary Medicine (CVM), reviews protocols for safety and effectiveness studies that CVM and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application. Establishing a process for acceptance of the electronic submission of protocols for studies conducted by sponsors in support of new animal drug applications (NADAs), is part of CVM's ongoing initiative to provide a method for paperless submissions. Sponsors may submit protocols to CVM in paper format. CVM's guidance on how to submit a study protocol permits sponsors to submit a protocol without data as an e-mail attachment via the Internet. CVM's guidance on how to submit a study protocol electronically implements provisions of the Government Paperwork Elimination Act (GPEA). The GPEA required Federal agencies, by October 21, 2003, to provide for the: (1) Option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitution for paper; and (2) use and acceptance of electronic signatures, where applicable.

FDA is also seeking an extension of an existing paperwork clearance for form FDA 3536 to facilitate the use of electronic submission of protocols. This collection of information is for the benefit of animal drug sponsors, giving them the flexibility to submit data for review via the Internet.

In the **Federal Register** of November 8, 2006 (71 FR 65534), FDA published a 60-day notice soliciting public comment on the proposed collection of information requirements. In response to that notice, no comments were received.

The likely respondents for this collection of information are sponsors of NADAs.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
514.117 (b) 58.120 / Form 3536	25	4.2	103	0.20	20.6

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Electronic submissions received between July 1, 2005, and June 30, 2006.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (25). The number of total annual responses is based on a review of the actual number of such submissions made between July 1, 2005, and June 30, 2006. 103 x hours per response (.20) = 20.6 total hours.

Dated: February 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2577 Filed 2–14–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0381]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mammography Quality Standards Act Requirements

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 March 19, 2007.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (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.

The Mammography Quality Standards Act Requirements—21 CFR Part 900 (OMB Control Number 0910–0309)—Extension

Mammography Quality Standards Act requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation and certification bodies for mammography facilities, and standards for mammography equipment, personnel, and practices, including quality assurance. The intent of these regulations is to ensure safe, reliable, and accurate mammography on a nationwide level.

Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by an FDA approved accreditation body. This requires undergoing a review of their clinical images and providing the accreditation body with information showing that they meet the equipment, personnel, quality assurance and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer compliant mechanism. On the basis of this accreditation, facilities are then certified by FDA or an FDA-

approved State certification agency and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

In the **Federal Register** of September 22, 2006 (71 FR 55488), FDA published a 60-day notice soliciting public comments on the information collection requirements of the proposed collection. In response to that notice, no comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3(b)(1)	0.33	1	0.33	1	0.33		
900.3(b)(3) full[1]	0.33	1	0.33	320	106	$10,000	
900.3(b)(3) limited[2]	5	1	5	30	150		
900.3(d)(2)	0.1	1	0.1	30	3		
900.3(d)(5)	0.1	1	0.1	30	3		
900.3(e)	0.1	1	0.1	1	0.1		
900.3(f)(2)	0.1	1	0.1	200	20		$36
900.4(c) facility[3]	2,947	1	2,947	1.54	4,538		
900.4(c) AB[4]	6	1	6	378	2,268		$117,867
900.4(d) facility[3]	2,947	1	2,947	0.77	2,269		
900.4(d) AB[4]	6	1	6	189	1,134		
900.4(e) facility[3]	8,840	1	8,840	1	8,840		$8,840
900.4(e) AB[4]	6	1	6	1,473	8,838		
900.4(f)	336	1	336	7	2,352		$77,840
900.4(h) facility[3]	8,840	1	8,840	1	8,840		$3,536
900.4(h) AB[4]	6	1	6	10	60		
900.4(i)(2)	1	1	1	16	16		
900.6(c)(1)	0.1	1	0.1	60	6		
900.11(b)(3)	5	1	5	0.5	2.5		
900.11(c)	270	1	270	5	1,350		
900.12(c)(2)	8,840	4,072	36,000,000	0.083	3,000,000		$14,400,000[5]
900.12(c)(2) patient refusal[5]	89	1	89	0.5	44.5		
900.12(h)(4)	5	1	5	1	5		
900.12(j)(1) facility[3]	25	1	25	200	5,000		$250
900.12(j)(1) AB[4]	25	1	25	1,000	25,000		$750
900.12(j)(2)	3	1	3	100	300		$3,604
900.15(c)	5	1	5	2	10		
900.15(d)(3)(ii)	1	1	1	2	2		
900.18(c)	2	1	2	2	4		
900.18(e)	2	1	2	1	2		
900.21(b)	1	1	1	320	320	$30,000	$71
900.21(c)(2)	0.3	1	0.33	30	10		
900.22(h)	6	200	1,200	0.083	100		
900.22(i)	2	1	2	30	60		
900.23	6	1	6	20	120		
900.24(a)	0.3	1	0.3	200	60		$26
900.24(a)(2)	0.15	1	0.15	100	15		$13
900.24(b)	1.2	1	1.2	30	36		
900.24(b)(1)	0.3	1	0.3	200	60		$26
900.24(b)(3)	0.15	1	0.15	100	15		$13
900.25(a)	0.2	1	0.2	16	3.2		
FDA Form 3422	700	1	700	0.25	175		
TOTAL					3,072,138	$40,000	$14,612,872

[1] Refers to entities that are applying for the first time.
[2] Refers to accreditation bodies applying to accredit specific Full Field Digital Mammography units.
[3] Refers to the facility component of the burden for this requirement.
[4] Refers to the accreditation body component of the burden for this requirement.
[5] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

TABLE 2. —ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.4(g)	6	1	6	1	6		
900.12(a)(1)(i)(B)(2)	89	1	89	8	712		
900.12(a)(4)	8,840	4	35,360	1	35,360		
900.12(c)(4)	8,840	1	8,840	1	8,840	$25,000	
900.12(e)(13)	8,840	52	459,680	0.083	38,154		
900.12(f)	8,840	1	8,840	16	141,440		
900.12(h)(2)	8,840	2	17,680	1	17,680		

TABLE 2. —ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Section	Number of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.22(a)	6	1	6	1	6		
900.22(d)	6	1	6	1	6		
900.22(e)	6	1	6	1	6		
900.22(f)	3	1	3	1	3		
900.22(g)	6	1	6	1	6		$60
900.25(b)	6	1	6	1	6		
Total					242,225	$25,000	$60

This request for OMB approval now serves to consolidate previously issued information collection, OMB control number 0910–0580 into 0910–0309. The hourly burden as well as the associated operating costs were increased to better represent the actual burden and costs on facilities and accreditation bodies.

The following regulations were not included in the above burden tables because they were considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations. Therefore, they resulted in no additional reporting or recordkeeping burden: 21 CFR 900.12(c)(1) and (c)(3) and § 900.3(f)(1) (21 CFR 900.3(f)(1)).

The following regulations were not included in the above burden tables because they were not considered applicable during the information collection period or their burdens were reported under other regulatory requirements. Therefore, they resulted in no additional reporting or recordkeeping burden: § 900.3(c), 21 CFR 900.11(b)(1) and (b)(2), and 900.24(c).

Dated: February 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2578 Filed 2–14–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0434]

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 March 19, 2007.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (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.

How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office Of New Animal Drug Evaluation—21 CFR 10.65 (OMB Control Number 0910–0452)—Extension

The Center for Veterinary Medicine (CVM) holds meetings and /or teleconferences when a sponsor requests a presubmission conference under 21 CFR 514.5, or requests a meeting to discuss general questions. Generally, meeting requests are submitted to CVM on paper. However, CVM now allows registered sponsors to submit information electronically, and to request meetings electronically, if they determine this is more efficient and time saving for them. CVM's guidance ''On How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation'' provides sponsors with the option to submit a request for a meeting or teleconference as an e-mail attachment via the internet.

In the **Federal Register** of November 8, 2006 (71 FR 65535), FDA published a 60-day notice soliciting comments on the proposed collection of information requirements. In response to that notice, no comments were received.

The likely respondents are sponsors for new animal drug applications.

CVM estimates the burden for this information collection activity as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/FDA Form #	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
10.65/FDA Form 3489	25	6.24	156	.08	12.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Electronic submissions received between July 1, 2005 and June 30, 2006.