

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. (140 x hours per response (.08) =11.2 total hours.)

Dated: November 2, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-18901 Filed 11-7-06; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006N-0436]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How To Use E-Mail To Submit A Study Protocol**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on extending OMB approval of existing reporting requirements for the information collection activity on guidance for industry on “How to Use E-Mail to Submit a Study Protocol.”

**DATES:** Submit written or electronic comments on the collection of information by January 8, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written

comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**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:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**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, 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 requires Federal agencies, by October 21, 2003, to provide for the following: (1) The option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitution for paper; and (2) the 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.

The likely respondents are sponsors of new animal drug applications.

FDA estimates the burden for this collection of information as follows<sup>1</sup>:

21 CFR Section/FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses <sup>2</sup>	Hours per Response	Total Hours
514.117(b), 58.120/Form 3536	25	4.2	103	.20	20.6

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

<sup>2</sup> 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: November 2, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0434]

#### Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on extending Office of Management and Budget (OMB) approval of existing reporting requirements on electronic submission of requests for meetings, in person or via teleconference, to discuss

with animal drug sponsors studies to be conducted and how to meet the statutory requirements for drug approval under the Federal Food, Drug, and Cosmetic Act. Requests for meetings about new animal drug submissions were previously submitted on paper copy to the Center for Veterinary Medicine (CVM).

**DATES:** Submit written or electronic comments on the collection of information by January 8, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**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:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice

of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### 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

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 entitled "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 by the Internet.

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<sup>1</sup>

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

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

<sup>2</sup> 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. (156 x hours per response (.08) = 12.5 total hours).