

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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D. Hawkins

[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 *[insert date 30 days after date of publication in the Federal Register]*.

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.

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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 BURDEN¹

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

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

²Electronic submissions received between July 1, 2005 and June 30, 2006.

The number of respondents in Table 1 of this document are 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.)

Dated: 2/8/07

February 8, 2007.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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Dawn P. Hawkins