

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0057]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Final Guidance for Industry: How to Use E-Mail to Submit a Protocol

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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: 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, or e-mail: *Fumie__Yokota@omb.eop.gov*.

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:

How to Use E-Mail to Submit a Protocol

The Center for Veterinary Medicine (CVM) may review protocols for safety and effectiveness studies of new animal drugs submitted by sponsors. The review of protocols facilitates the drug review and approval processes.

Protocols for nonclinical laboratory studies (safety studies) are required under 21 CFR 58.120. Protocols for effectiveness studies are required under 21 CFR 514.117(b). The burden hours associated with preparing the protocols and appendices were reported and approved under OMB control number 0910–0119 for nonclinical laboratory studies and OMB control number 0910–0346 for adequate and well-controlled effectiveness studies. In this guidance document, CVM is giving sponsors the option to submit a protocol as an attachment via the Internet.

In the **Federal Register** of April 4, 2003 (68 FR 16522), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,536	190	0.52	100	0.20	20

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

The burden estimate was calculated as the time it takes to “submit” the protocol which consists of filling out the form and pressing the “insert submission” button, adding the password and pressing the “mail to” button, since the burden for protocol is already estimated under OMB control number

0910–0119 for nonclinical laboratory studies and OMB control number 0910–0346 for efficacy studies. The number of approved sponsors is 190, we routinely receive about 100 protocols a year, and the 12 minutes (.2 *60 minutes/hour) is an estimate based on talking to participating sponsors and our testing the use of the form.

Dated: October 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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