

OMB

Display Date:	9/20/00
Publication:	9/21/00
Certified:	S. V. Reese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1316]

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 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 (the PRA).

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (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.

Description: As part of new animal drug development, sponsors often meet with the Center for Veterinary Medicine (CVM), scientists to formulate a rational approach for studies to be conducted, and to discuss how they 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 about new animal drug submissions are currently submitted to CVM on paper. CVM is responsible for developing and administering a guidance that explains how to adhere to the Electronic Records; Electronic Signatures regulations (21 CFR part 11). These regulations provide for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy and complies with the Government Paperwork Elimination Act (GPEA). 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 practical, as a substitute for paper.

This guidance document describes the procedure for persons who are new animal drug sponsors who wish to submit a request for a meeting or teleconference to the Office of New Animal Drug Evaluation by e-mail on FDA Form No. 3489. The information sponsors should include on the form are: The sponsor's name and address, a list of requested participants, an indication of audiovisual needs, and an agenda.

Description of Respondents: The likely respondents for this collection of information are sponsors who will be conducting clinical investigations under 21 CFR 511.1(b). In the **Federal Register** of June 29, 2000 (65 FR 40108), the FDA announced the availability of this guidance as a draft document and requested public comment on the proposed collection of information. No comments were received on the estimated annual reporting burden. We therefore believe the annual reporting burden of 116 hours should remain unchanged.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,489	190	.88	168	0.69	116

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

The estimates in table 1 of this document resulted from discussions with new animal drug sponsors. The estimated burden includes requests for meetings or teleconferences submitted by e-mail and on paper.

Dated: September 14, 2000



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

