

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1316]

Draft Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#88) entitled "How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation" in the Center for Veterinary Medicine (CVM). This draft guidance is neither final nor is it in effect at this time. The purpose of this draft guidance document is to provide guidance to new animal drug sponsors (sponsors) on how to submit a request for a meeting or teleconference about a new animal drug submission as an e-mail attachment by Internet. These electronic submissions are part of CVM's ongoing initiative to provide a method for paperless submissions. This draft guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments on the draft guidance at any time, however, comments should be submitted by August 28, 2000, to ensure their adequate consideration in preparation of the final document. Submit written comments on the collection of information requirements by August 28, 2000.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

Copies of the draft guidance document entitled "How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation" may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/>. Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of March 20, 1997 (62 FR 13430), FDA published the Electronic Records; Electronic Signatures final regulation. This regulation (part 11 (21 CFR part 11)) provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. This rule also established public docket number 92S-0251 to provide a permanent location for a list of the documents or parts of documents that are acceptable for submission in electronic form without paper records and the agency units to which such submissions may be made. CVM will identify in this public docket the types of documents that may be submitted in electronic form as those documents that are identified in final guidances or regulations. This docket is accessible on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm>.

The electronic submission of requests for meetings and teleconferences is part of CVM's ongoing initiative to provide a method for paperless submissions. The draft guidance implements provisions of the GPEA. The GPEA of 1998 (Public Law 105-277) requires Federal agencies, by October 21, 2003, to provide for: (1) The option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) the use and acceptance of electronic signatures, when practicable.

In order to submit requests for meetings or teleconferences by e-mail, sponsors should first register and follow the instructions in draft guidance for industry (#108) "How to Use E-Mail to Submit Information to CVM" when it becomes final.

On request, CVM will hold meetings and/or teleconferences to assist sponsors with new animal drug

submissions and general questions. Currently, meeting and teleconference requests are submitted to CVM on paper. CVM would like to allow sponsors to request meetings and teleconferences in a manner more efficient and time saving to them. This draft guidance will give sponsors the option to submit a request for a meeting or teleconference as an e-mail attachment by the Internet.

II. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on submitting a request for a meeting or teleconference about new animal drug submissions by e-mail. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (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.

Title: 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 CVM scientists to formulate a rational approach to studies to be conducted and to discuss how to 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 NAD submissions are currently

submitted on paper to CVM. CVM is responsible for developing and administering a guidance that explains how to adhere to the Electronic Records; Electronic Signatures regulations (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 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 practicable as a substitute for paper.

This draft guidance describes the procedure for persons who are new animal drug sponsors 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 of the sponsors should include on the form: The sponsor's name and address, a list of requested participants, an indication of audio-visual needs, and an agenda. The likely respondents to this collection of information are sponsors who will be conducting clinical investigations under 21 CFR 511.1(b).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
3489	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.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments by August 28, 2000, to ensure adequate consideration in preparation of the final guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Written comments concerning the information collection requirements must be received by August 28, 2000. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1315]

Draft Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#108) entitled "How to Use E-Mail to Submit Information to the Center for Veterinary Medicine." This draft guidance is neither final nor is it in effect at this time. The draft guidance document is intended to provide guidance on how to submit information to the Center for Veterinary Medicine (CVM) as an e-mail attachment by Internet. These electronic submissions are part of CVM's ongoing initiative to provide a method for paperless submissions. This draft guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments on the draft guidance at any time, however, comments should be submitted by August 28, 2000, to ensure their adequate consideration in preparation of the final document. Submit written

comments on the information collection requirements by August 28, 2000.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance document and the docket number found in brackets in the heading of this document.

Copies of the draft guidance document entitled "How to Use E-Mail to Submit Information to the Center for Veterinary Medicine" may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/>. Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: