

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This draft guidance describes the procedure for persons who are new animal drug sponsors to submit a request for a meeting or teleconference to the Office of New Animal Drug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 BURDEN<sup>1</sup>

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

<sup>1</sup> 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This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time.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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**BILLING CODE 4160-01-F**

## 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](mailto:jmessenh@cvm.fda.gov).

#### SUPPLEMENTARY INFORMATION:

## I. Background

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records and 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 which may be submitted in electronic form as those documents are identified in final guidance or regulations. This docket is accessible on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm>. The GPEA of 1998 (Public Law 105-277) requires Federal agencies, by October 21, 2003, to provide: (1) For the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.

CVM accepts certain types of submissions by e-mail with no requirement for a paper copy. These types of documents are listed in public docket number 92S-0251 as required by § 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the electronic records and electronic signatures regulation. This guidance outlines general standards which should be used for the submission of any information by e-mail.

## 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 about using e-mail to submit information electronically. 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, regulation, 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 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 Information to the Center for Veterinary Medicine.

**Description:** CVM is responsible for developing and administering guidances that explain how to adhere to the electronic records and electronic signatures regulations (part 11). The electronic records and electronic signatures regulations provide for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. These regulations comply 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.

The draft guidance document describes the procedures for persons who are sponsors of new animal drugs who wish to file submissions by e-mail. The draft guidance instructs those who wish to submit information to CVM by e-mail to first register with them. Registration entails sending a letter to CVM with a sponsor password and the names, phone numbers, and mail and e-mail addresses of a sponsor coordinator and any person who will submit information electronically to CVM. This letter is sent on paper and electronically. Other information collection provisions described in the guidance are the submission of e-mails with the individual passwords of those who submit information electronically and e-mails with any changes to the sponsor's registration. CVM will use all the information submitted to process electronic submissions.

**Description of Respondents:** The likely respondents to this collection of information are new animal drug sponsors.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190	0.74	140	1	140

<sup>1</sup> 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.

## IV. Comments

The 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 document. 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.

Submit written comments concerning the information collection requirements to the Dockets Management Branch by August 28, 2000. A copy of the document 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.*

[FR Doc. 00-16395 Filed 6-26-00; 10:07 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration, HHS.

[Document Identifier: HCFA-10012]

#### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR part

1320. This collection of information will be used to test the effectiveness of three possible Medicare smoking cessation benefits and to make inferences that are generalizable to the Medicare program. Using a comparison trial with restricted randomization of study locales, this study will compare three variations in a potential Medicare smoking cessation benefit on smoking cessation and abstinence rates. Smoking cessation for seniors is currently receiving attention from Congress and the White House. Senator Graham (D-FL) has proposed a smoking cessation Medicare benefit, while the White House provides for a smoking cessation demonstration in the *President's Plan to Modernize and Strengthen Medicare for the 21st Century*. In response to this White House initiative, HCFA is launching this demonstration to test smoking cessation as a possible covered benefit under the Medicare program. If this information is not collected, public harm is likely to occur. Considerable evidence indicates that much greater improvement in health status could be accomplished if currently existing, effective and commonly available preventative practices and services were implemented more widely; therefore, this demonstration could help improve the health of the Medicare population.

HCFA is requesting OMB review and approval of this collection by July 5, 2000, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by July 3, 2000. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

*Type of Information Collection*

*Request:* New Collection;

*Title of Information Collection:* Healthy Aging Smoking Cessation Demonstration;

*Form No.:* HCFA-10012 (OMB no. 0938-NEW);

*Use:* The goals of the Healthy Aging Project are to test the effectiveness of three possible Medicare smoking cessation benefits and to make inferences that are generalizable to the Medicare program. Using a comparison trial with restricted randomization of study locales, this study will compare three variations in a potential Medicare smoking cessation benefit on smoking cessation and abstinence rates.;

*Frequency:* Semi-annually;

*Affected Public:* Individuals or Households;

*Number of Respondents:* 43,500;

*Total Annual Responses:* 130,500;

*Total Annual Hours:* 58,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of Information requirements. However, as noted above, comments on these Information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by July 3, 2000:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395-6974 or (202) 395-5167, Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: June 1, 2000.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 00-16455 Filed 6-28-00; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-901-1]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send