Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine—21 CFR 11.2 (OMB Control Number 0910–0454)—Extension

CVM is responsible for developing and administering guidances that explain how to adhere to the Electronic Records; Electronic Signatures regulations (part 11 (21 CFR part 11)). These allow sponsors to submit part or all of records to FDA electronically in lieu of paper, unless the paper records are specifically required by regulation, if the requirement of part 11 are met, and the documents to be submitted electronically are identified in Docket No. 92S–0251. These regulations comply with the Government Paperwork Elimination Act (GPEA) (Public Law 105–277). The GPEA requires Federal agencies 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 by October 21, 2003.

This guidance document describes the procedures persons who submit information to CVM should follow if they want to file submissions electronically. This guidance instructs those who wish to submit information to CVM by e-mail to first register with the center. Registration entails sending a letter, on paper or electronically, to CVM with a sponsor password and the names, phone numbers, mail, and e-mail addresses of a sponsor coordinator, and each person who will submit information electronically to CVM. Other information collection provisions relate to electronic submissions by individuals and electronic submissions to make changes to the sponsor's registration. CVM will use all the information submitted to process electronic submissions. The likely respondents to this collection of information are new animal drug sponsors.

We estimate the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
70	2	140	.5	70

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

The estimate of the times required for record preparation is based on agency communication with industry. Other information needed to calculate the total burden hours is derived from agency records and experience.

Dated: July 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20060 Filed 8–6–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0328]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter

AGENCY: Food and Drug Administration, HHS

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for sponsors electronically submitting notices of final disposition of investigational animals not intended for immediate slaughter.

DATES: Submit written or electronic comments on the collection of information by October 6, 2003.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under 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, including each proposed extension of an existing collection, 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 proposed 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 FDAs 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.

Guidance for Industry on How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter 21 CFR Part 511 (OMB Control Number 0910–0453)—Extension

CVM monitors the final disposition of food animals treated with

investigational new animal drugs in situations where the treated animals do not enter the human food chain immediately at the completion of the investigational study. CVM believes that monitoring of the final disposition of such food animals is consistent with its responsibility to protect the public health under the Federal Food, Drug, and Cosmetic Act. In addition, CVM believes that acceptable standards of study conduct such as those set out in 21 CFR 514.117 would include sponsors accounting for the disposition of all animals treated with investigational new animal drugs.

This guidance document describes the procedures that should be followed by sponsors who wish to file a notice of disposition electronically on FDA Form #3487. The information sponsors should include on the form includes the sponsor's name and address, and information about the investigational animals. The form has been revised at the request of the sponsors to add a box that can be checked if the submission amends a notice of disposition previously submitted to CVM and to allow for consistency across forms. The likely respondents to this collection of information are new animal drug sponsors who have conducted clinical studies under 21 CFR 511.1(b).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency per Respondents	Total Annual Responses	Hours per Response	Total Hours
3487	12	27	324	0.81	262

[1] There are no capital 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 notices of disposition submitted on paper and by e-mail.

Dated: July 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20061 Filed 8–6–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0327]

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 an opportunity for public comment on the proposed collection of certain certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits public comment on the reporting requirements for sponsors electronically requesting meetings or teleconferences with the Center for Veterinary Medicine's (CVM), Office of New Animal Drug Evaluation (ONADE).

DATES: Submit written or electronic comments on the collection of information by October 6, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under 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, including each proposed extension of an existing collection, 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.

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—21 CFR Part 511 (OMB Control Number 0910–0452)—Extension

''Any person intending to file a new animal drug application or abbreviated application is entitled to request meetings and/or teleconferences to reach agreement regarding a submission or investigational requirement (21 U.S.C. 360b(b)(3)). Every person outside the Federal Government may request a meeting with representative(s) of FDA to discuss a matter (21 CFR 10.65(c))''.

Sponsors often meet with CVM scientists in CVM's Office of New Animal Drug Evaluation 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