

DEPARTMENT OF HEALTH AND HUMAN SERVICES

RMB

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Food and Drug Administration

[Docket No. 00N-1504]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine

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 Information to the Center for Veterinary Medicine

Description: The Center for Veterinary Medicine (CVM), is responsible for developing and administering guidances that explain how to adhere to the electronic records and electronic signatures regulations (21 CFR 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 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 procedures for persons who are sponsors of new animal drugs who wish to file submissions by e-mail. The guidance document 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 for this collection of information are new animal drug sponsors. In the **Federal Register** of June 29, 2000 (65 FR 40109), FDA announced availability of this guidance as a draft document and requested public comment. In response to this notice, no comments were received on the estimated annual reporting burden. We therefore believe the annual reporting burden estimate of 140 hours should remain unchanged.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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

¹There 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.

Dated: September 14, 2000



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

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

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