any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

This guidance is effective immediately because prior public participation is not feasible or appropriate due to the risks to the public health presented by these products.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/ora/fiars/ora_import_ia8610.html.*

VI. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Food and Drug Administration (FDA), Compliance Policy Guide (CPG) 7128.04 (revised August 1996) (hair brushes); (*http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg590–400.htm*).

2. FDA, CPG 7128.05 (revised September 1, 1986) (wigs); (http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg590–600.htm).

3. Hutt, Peter Barton, ''Reconciling the Legal, Medical, and Cosmetic Chemist Approach to the Definition of a 'Cosmetic,' '' *Cosmetic, Toiletry, and Fragrance Association Cosmetic Journal*'', vol. 3, 1971 (excerpted in Peter Barton Hutt & Richard A. Merrill, Food and Drug Law: Cases and Materials, p. 824–825 (2d ed. 1991)).

4. FDA, CPG 7128.03 (revised August 1996) (mascara is an eye-contact cosmetic); (*http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg590–300.htm*).

Dated: April 1, 2003.

John R. Marzilli,

Acting, Associate Commissioner for Regulatory Affairs.

[FR Doc. 03–8315 Filed 4–2–03; 11:42 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0057]

Guidance for Industry: How to Use E-mail to Submit a Protocol; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#107) entitled ''How to Use E-mail to Submit a Protocol.'' This guidance describes how sponsors can use e-mail to submit protocols for studies intended to be conducted in support of New Animal Drug Applications (NADAs) to the Center for Veterinary Medicine (CVM). Electronic submission is part of CVM's ongoing initiative to provide a method for paperless submissions. This guidance is intended to implement provisions of the Government Paperwork Elimination Act (GPEA).

DATES: General comments on agency guidance documents are welcome at any time.

Submit written or electronic comments on the information collection requirements by June 3, 2003.

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Comments should be identified with the full title of the guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT: Elizabeth L. Parbuoni, Center for Veterinary Medicine (HFV–16), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–3845, e-mail: *eparbuon@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), sets forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. Electronic records that meet the requirements of part 11 and are identified in public docket 92S–0251 as being the type of submission the agency will accept in electronic format may be used in lieu of paper records unless paper records are specifically required. CVM has identified protocols in this public docket. The public docket is accessible on the Internet at *http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm.*

Establishing a process for acceptance of the electronic submission of protocols for studies conducted by sponsors in support of NADAs is part of CVM's ongoing initiative to provide a method for paperless submissions. Upon request, CVM reviews protocols for safety and effectiveness studies. This protocol review facilitates the animal drug review process by improving the likelihood that the study design will be relevant to NADA approval.

Currently, sponsors submit protocols to CVM in paper format. CVM is publishing this guidance to give sponsors the option to submit a protocol as an e-mail attachment via the Internet. This guidance implements provisions of the GPEA. The GPEA 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, where applicable.

In order to submit a protocol for an NADA study by e-mail, sponsors should first register and follow the general instructions in guidance #108 entitled ''How to Use E-mail to Submit Information to the Center for Veterinary Medicine.''

II. Significance of Guidance

This level 2 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking about using e-mail to submit a protocol. The document does not create or confer any rights for or on

any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

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 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 Protocol

Description: CVM may review protocols for safety and effectiveness studies of new animal drugs submitted by sponsors. The review of protocols facilitates the drug review and approval processes.

Protocols for nonclinical laboratory studies (safety studies) are required under 21 CFR 58.120. Protocols for effectiveness studies are required under § 514.117(b). The burden hours associated with preparing the protocols and appendices were reported and approved under OMB control number 0910–0119 for nonclinical laboratory studies and OMB control number 0910–0346 for adequate and well-controlled effectiveness studies. In this guidance document CVM is giving sponsors the option to submit a protocol as an attachment via the Internet.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3536	190	0.52	100	0.20	20

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

The burden estimate was calculated as the time it takes to submit the protocol which consists of filling out the form and pressing the ''insertsubmission'' button, adding the password and pressing the ''mail to'' button, since the burden for protocol is already estimated under OMB control number 0910–0119 for nonclinical laboratory studies and OMB control number 0910–0346 for efficacy studies. The number of approved sponsors is 190, we routinely receive about 100 protocols a year, and the 12 minutes (.2 *60 minutes/hour) is an estimate based on talking to participating sponsors and our testing the use of the form.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two hard copies of any written comments, except that individuals may submit one hard 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 the Dockets Management Branch by June 3, 2003. 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.

V. Electronic Access

Electronic comments on the guidance document may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments.* Once on the Internet site, select ''03D–0057 How to Use E-mail to Submit a Protocol'' and follow the directions. A copy of this document may be obtained on the Internet at *http://www.fda.gov/cvm.*

Dated: March 21, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–8166 Filed 4–3–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0094]

Annual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual guidance document agenda. FDA committed to publishing, on an annual basis, a list of possible topics for future guidance document development or revision during the next year, and seeking public comment on additional ideas for new guidance documents or revisions of existing ones. This commitment was made in FDA's September 2000 good guidance practices (GGPs) final rule, which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to seek public comment on possible topics for guidance documents and possible revisions to existing guidance.