

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](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](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](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](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](mailto: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