The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e., adverse drug reaction, lack of effectiveness, and product defect reports) are derived from agency records and experience.

Dated: August 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–22637 Filed 9–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0587]

Agency Information Collection Activities; Announcement of OMB Approval; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling Forms FDA 356h and 2567; and Revocation and Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling Forms FDA 356h and 2567; and Revocation and Suspension'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 7, 2002 (67 FR 39406), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0338. The approval expires on August 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: August 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–22635 Filed 9–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1539]

Draft Guidance for Industry, Electronic Records; Electronic Signatures, Maintenance of Electronic Records; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records.'' The draft guidance describes the agency's current thinking on issues pertaining to maintaining electronic records to ensure that electronic records and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities.

DATES: Submit written or electronic comments on the draft guidance by December 4, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Information and Quality Assurance (HFC–240), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1060, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul J. Motise, Office of Enforcement (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0383, e-mail: *pmotise@ora.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records.'' In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a regulation providing criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper (part 11 (21 CFR part 11)). The preamble to part 11 stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to comment on draft guidance documents.

The draft guidance addresses issues pertaining to the maintenance of electronic records. Part 11 establishes requirements for such maintenance, and the draft guidance is intended to assist people who must meet these requirements; it may also assist FDA staff who apply part 11 to persons subject to the regulation.

The draft guidance provides specific information on key principles and practices, and it addresses some frequently asked questions. It also describes two examples of approaches to maintaining electronic records. However, this draft guidance is not intended to cover everything about maintaining electronic records, and it does not apply to electronic records that are submitted to FDA, but that submitters are not required to maintain.

By direct reference, this draft guidance incorporates definitions of terms contained in a companion draft guidance entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms'' that published in the **Federal Register** of September 24, 2001 (66 FR 48886).

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on maintaining electronic records in electronic form. It does not create or confer 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any nonelectronic 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. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ora/compliance_ref/part11/default.htm*.

Dated: August 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–22634 Filed 9–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0146]

Final Guidance for Industry and Reviewers on How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry and reviewers (#119) entitled ''How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug.'' This final guidance announces the Center for Veterinary Medicine's (CVM's) policy regarding the circumstances under which CVM intends to not accept for review submissions filed during the investigation of a new animal drug and notify the sponsor that CVM intends not to review the submission.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments on this final guidance 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*. All comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

Submit written requests for single copies of the final 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

FOR FURTHER INFORMATION CONTACT: Gail Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–1796, e-mail: *gschmer1@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 4, 2001 (66 FR 17914), FDA published a notice of availability for a draft guidance entitled ''How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug,'' giving interested persons until July 3, 2001, to submit comments.

CVM determined that there was a need for such a guidance for two reasons: (1) Having reviewers attempt to review submissions that have significant deficiencies is an inefficient use of CVM's limited resources, and (2) its practice of keeping submissions requiring significant additional information or rehabilitation ''active,'' (i.e., in the review queue), has contributed to a backlog in the review of pending submissions. This final guidance for industry and reviewers announces CVM's policy regarding the circumstances under which CVM intends to not accept for review submissions filed during the investigation of a new animal drug, notify the sponsor that the submission will not be reviewed, and remove the submission from the review queue.

CVM's primary goal is to approve safe and effective new animal drugs in a timely manner. To further this goal, CVM's responsibility is to ensure the quality of the review process. On the other hand, it is the sponsor's responsibility to ensure the quality of its submissions.

The quality of a submission can prevent or severely hinder its review. Poor quality submissions can be impossible or difficult to review. FDA received comments to the draft guidance suggesting that the problem CVM attributes to poor quality submissions is in part the variation in format and content of submissions as required by individual reviewers. However, an informal survey of reviewers in the Office of New Animal Drug Evaluation (ONADE) revealed that submissions were deficient because, among other things: They contained data discrepancies, incorrect statistical analyses, final reports that did not reflect actual data, electronic copies of data that did not match paper copies of raw data, or no documentation of drug source. ONADE has also received supplemental applications in which sponsors submitted the same data or information for the supplement that they submitted for the original application, i.e., without changing the relevant indications or conditions of use for which the supplement was submitted.

CVM has determined that it can no longer expend time and resources attempting to review submissions that have significant deficiencies. Poor quality submissions decrease the efficiency of the new animal drug application review and approval process by diverting limited resources from the review of submissions that are complete. Furthermore, as one comment to the draft guidance noted, a sponsor who submits a quality submission should not have its submission wait in the queue while a reviewer spends an inordinate amount of time reviewing a poor quality submission.

The final guidance clarifies that ONADE should use criteria and procedures similar to those found in 21 CFR 514.110 to determine whether it will not accept a submission for review, i.e., refuse to review the submission further. ONADE should, among other reasons, not review a submission if on its face the information is so inadequate that the submission is clearly not reviewable. ONADE should consider a submission to be inadequate if the numbers or types of errors in the submission or flaws in the development plan, call into question the quality of the entire submission to the extent it is deemed by ONADE that the submission cannot reasonably be reviewed.

ONADE should notify the sponsor by letter within 60 days of the receipt of the submission of its decision not to accept the submission for review. The letter notifying the sponsor that ONADE will not accept the submission for review should summarize in detail commensurate with the quality of the submission the reasons it cannot be