compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because of an unanticipated event and possible public harm.

It is widely acknowledged that the elderly are going without critical pharmaceutical therapy and that there are morbidity and mortality consequences. The Administration has developed a proposal for paying for prescriptions for low-income elderly Medicaid recipients. This proposal will allow States to run 1115 demonstration projects specifically for a drug benefit for the elderly.

CMS has recently completed work on an innovative, electronic approach for easing the burden of States in applying for participation in the Pharmacy Plus demonstration initiative. We are seeking approval of the forms that would be used to collect data from applicants under this initiative.

The initiative will greatly reduce the time period required for States to develop and apply for demonstration authority; in addition the initiative is intended to expedite the review and approval time required by CMS. The initiative specifies the requirements of States to participate in the initiative—if the criteria are met by the State then deliberation by CMS on the application should be minimal. The result will be an expeditious approval, implementation and operation of demonstration programs that will provide prescription coverage to lessen the morbidity and mortality that is occurring. Without approval of these forms on an emergency basis, millions of Seniors will continue to under-utilize pharmaceutical therapy for chronic and acute morbidity. The use of the forms will expedite prescription coverage and utilization of important medicines.

CMS is requesting OMB review and approval of this collection by September 17, 2002 with a 180-day approval period. Written comments and recommendation will be accepted from the public if received by the individuals designated below by September 16, 2002.

Type of Information Collection Request: New collection; *Title of Information Collection:* Pharmacy Plus Template for Low Income Seniors under Medicaid; *Form No.:* CMS–10067 (OMB# 0938–XXXX); *Use:* The template for the Pharmacy Plus program for low income seniors under Medicaid will enable states to apply, via a standard format, to provide a drug benefit to elderly recipients; use of this format will expedite the process of obtaining CMS review and approval of an application; *Frequency: Other:* 3 years after initial submission for the 1915 (c) waiver; 5 years after initial submission for the 1115 demonstration; *Affected Public:* State Government; *Number of Respondents:* 51; *Total Annual Responses:* 25; *Total Annual Hours:* 115.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by September 16, 2002.

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Fax Number: (410) 786–0262, Attn: Julie Brown, CMS–10067

and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Brenda Aguilar, CMS Desk Officer.

Dated: August 28, 2002.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 02–22672 Filed 9–3–02; 10:47 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0383]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report

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 renewal of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements obligating holders of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to submit information on adverse drug reactions, lack of effectiveness and product defects.

DATES: Submit written or electronic comments on the collection of information by November 4, 2002.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm.* Submit written comments on the collection of information to the Dockets Management Branch (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 renewal 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.

Veterinary Adverse Drug Reaction, Lack of Effectivenss, Product Defect Report—21 CFR Part 510—(OMB Control Number 0910–0012)—Extension

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(l)), and 21 CFR 510.300, 510.301, and 510.302 require that applicants of approved NADAs submit within 15 working days of receipt, complete records of reports of certain adverse drug reactions and unusual failure of new animal drugs. Other reporting requirements of adverse reactions to these drugs must be reported annually or semiannually in a specific format. This continuous monitoring of approved new animal drugs, affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Data already on file with FDA is not adequate because animal drug effects can change over time and less apparent effects may take years to manifest themselves. Reports are reviewed along with those previously submitted for a particular drug to determine if any change is needed in the product or labeling, such as package insert changes, dosage changes, additional warnings or contraindications, or product reformulation.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA Forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Likewise, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own detection of a problem or complaints from product users or their veterinarians using forms FDA Forms 1932 and 1932a. Form FDA 2301 is available for the required transmittal of periodic reports and promotional material for new animal drugs. Respondents to this collection of information are applicants of approved NADAs.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 2301	510.302(b)	190	10.94	2,079	0.5	1,040
Form FDA 1932	510.302(b)	190	96.76	18,385	1.0	100
Form FDA 1932a	510.302(b)	100	1.0	100	1.0	100
Total Burden Hours						19,525

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Responses	Hours per Recodkeeper	Total Hours
510.300(a) and 510.301(a)	190	13.16	2,079	10.35	21,518
510.300(b) and 510.301(b)	190	94.74	18,385	0.50	9,193
Total Burden Hours					30,711

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

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.