

remedy, or otherwise combat fraud, waste, or abuse in such program.

8. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12-28-00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the "Standards for Privacy of Individually Identifiable Health Information." (See 45 CFR 164-512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals could, because of the small size, use this information to deduce the identity of the beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored electronically.

RETRIEVABILITY:

All records are accessible by HICN, SSN, and unique provider identification number.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational

and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records will be retained until an approved disposition authority is obtained from the National Archives and Records Administration. All claims related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Division of MMA Integrity, Program Integrity Group, Office of Financial Management, CMS, Mailstop: C3-02-16, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, HICN, address, date of birth, and gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), and SSN. Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also specify the record contents being sought. (These procedures are in accordance with department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These Procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORDS SOURCE CATEGORIES:

The data contained in this system of records are extracted from other CMS systems of records: Medicare Drug Data Processing System; Medicare Beneficiary Database; Medicare Advantage Prescription Drug System; State Medicaid Records; Medicaid Statistical Information System; Retiree Drug Subsidy Program; Common Working File; National Claims History; Enrollment Database; Carrier Medicare Claims Record; Intermediary Medicare Claims Record; Unique Physician/Provider Identification Number; Provider Enrollment Chain & Ownership System (PECOS); and Medicare Supplier Identification File. Information will also be provided from the participating state Medicaid agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E6-18454 Filed 11-1-06; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0431]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs

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 each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the

notice. This notice solicits comments on an information collection to meet specified requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug.

DATES: Submit written or electronic comments on the collection of information by January 2, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/eccomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, 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 the Chief Information Officer (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 proposed extension of an existing collection of information, 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 these topics: (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.

Substantial Evidence of Effectiveness of New Animal Drug—21 CFR 514.4(a) (OMB Control Number 0910-0356)—Extension

Section 512(d)(1)(E) of the Federal Food Drug and Cosmetic Act (the act) (21 U.S.C. 360b(d)(1)(E)) requires FDA to issue an order refusing to approve a New Animal Drug Application (NADA), if there is a lack of substantial evidence that a new animal drug will have the effect it is purported or represented to have under the conditions of use prescribed in the proposed labeling. Therefore, substantial evidence must be submitted to us as part of the NADA to establish effectiveness of a drug. Section 514.4(a) specifies requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug. This information collection requirement provides for submissions of substantial evidence of effectiveness information via electronic submissions to the Center for Veterinary Medicine.

We are continuously seeking ways through advances in information technology to reduce the burden on the government and sponsors. We are continuing to look at what information can be submitted electronically and will permit electronic submission of data to NADA files as technology and resources permit.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
514.4(a)	190	4,546	860	632.6	544,036

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

The estimate for the annual reporting burden for this collection of information was derived from discussion with industry and agency records.

Dated: October 27, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. E6-18432 Filed 11-1-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0430]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567

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 each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection related to general licensing provisions for biologics license applications (BLAs), changes to an approved application, labeling, revocation and suspension, postmarketing studies status reports, and Forms FDA 356h and 2567.