Heard, Grants Management Specialist, Acquisition and Assistance Branch B., Procurement and Grants Office, Centers for Disease Control and Prevention, Announcement 02027, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: 770–488–2723, E-mail: *slh3@cdc.gov.*

For program technical assistance, contact: Jack Stubbs, National Center on Birth Defects and Developmental Disabilities, 4770 Buford Highway, Mail Stop F–15, Atlanta, Georgia 30341, Telephone number: 770–488–7096, E-mail: *jbs2@cdc.gov.*

Dated: January 22, 2002.

Robert L. Williams,

Chief, Acquisition and Assistance Branch B, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–1975 Filed 1–25–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0590]

Agency Information Collection Activities; Proposed Collection; Comment Request; Salmonella Discovery System Pilot Study

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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's burden estimates to construct and utilize a database from which FDA and pharmaceutical companies can share information based on their proprietary toxicology study data to predict the mutagenic response, mutagenic potency, and mechanism of mutagenesis of test chemicals in *Salmonella typhimurium*.

DATES: Submit written or electronic comments on the collection of information by March 29, 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, 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: Karen Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 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.

FDA's Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Informatics and Computational Safety Analysis Staff intends to conduct a *Salmonella* Discovery System Pilot Study (the pilot study). The primary goal of the pilot study is to construct and execute a mutually beneficial process by which FDA and pharmaceutical companies can share information based on their proprietary toxicology study data and thereby expand their own knowledge databases. This process will be designed and conducted using procedures that do not compromise the identity and chemical structures of the individual collaborator's proprietary chemicals.

The three major objectives of the pilot study are to:

- Build a joint and comprehensive FDA/pharmaceutical industry database for compounds tested in the *Salmonella t.* reverse mutagenicity assay;
- Use these data to construct a new enhanced *Salmonella t.* mutagenicity assay database module for the *Mu1tiCASE* quantitative structure activity relationship software program; and
- Employ the recently developed *Mu1tiCASE* expert system (*MCASE-ES*) to predict the mutagenic response, mutagenic potency, and mechanism of mutagenesis of test chemicals in *Salmonella t.*

The pilot study will be a joint venture designed to maximize the benefits and minimize the risks to all collaborators. FDA intends to send letters to companies that have purchased either *MultiCASE* or *CASETOXII* software programs to invite them to become a collaborator in the project.

FDA intends to request that each collaborator submit the following data electronically: (1) Test compound chemical structures; and (2) assay data, identifying the type of *Salmonella* mutagenicity assay used in the studies, the source and concentration of any exogenous activation system used, and the average number of revertants/plate for the negative control, positive control, and each of the test compound treatment groups. Although there is no minimum requirement for the number of test compounds to be submitted to FDA, the agency would expect to receive at least 200 compounds from each collaborator. Each company will be able to identify its own compounds in the resulting discovery system, and the more data submitted, the greater the coverage will be for each company's molecular universe.

FDA intends to act as the broker for the pilot study and will be responsible for the confidentiality and integrity of each collaborator's proprietary data. The number of compounds in the database module will depend upon the number of collaborators and the size of the data sets they contribute to the pilot study. After the enhanced *Salmonella* discovery system has been constructed and tested, FDA intends to custom prepare individual discovery systems for each collaborator.

The anticipated benefits to collaborators include:

- Receipt of a new expanded

Salmonella in silico discovery tool at no cost;
- Access to proprietary molecular fragment data derived from *Salmonella t.* mutagenicity studies from FDA and other collaborator archives;
- Comprehensive lists of molecular structural alerts correlated with mutagenicity in *Salmonella t.*, including previously uncharacterized alerts derived from heretofore inaccessible undeveloped lead pharmaceutical test data; and
- A *Salmonella* discovery system that should provide high coverage and high predictive performance for organic chemicals in each company's combinatorial and lead chemical data sets.

The *Salmonella* discovery system provided by FDA will be compatible with each company's current *MCASE* software program and will supplement current *Salmonella* modules purchased from MultiCASE, Inc.

Participation in this pilot study will be voluntary. FDA estimates that approximately 12 companies will participate and that it will take each company approximately 8 hours to compile the information from electronic archives and submit the requested data and information.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12	1	12	8	96

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

Dated: January 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–1989 Filed 1–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0589]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals

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 for an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for development of residue detection methodology for human or animal drugs prescribed for extralabel use in animals when the agency has determined there is reasonable probability this use may present a risk to public health due to residues exceeding a safe level.

DATES: Submit written or electronic comments on the collection of information by March 29, 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, 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 Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–26; 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 listed below. 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.

Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control No. 0910–0325)—Extension

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) (Public Law 103–396) amended the Federal Food, Drug, and Cosmetic Act to permit licensed veterinarians to prescribe extralabel use in animals of approved human and animal drugs. Regulations implementing provisions of AMDUCA are codified under part 530 (21 CFR part 530). A new provision under these regulations in § 530.22(b) permits FDA to establish a safe level for extralabel use in animals of an approved human or animal drug when the agency determines there is reasonable probability that this use may present a risk to the public health. The extralabel use in animals of an approved human or animal drug that results in residues exceeding a safe level is considered an unsafe use of a drug. In conjunction with the establishment of a safe level, the new provision permits FDA to