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

request development of an acceptable residue detection method for an analysis of residues above any safe level established under part 530. The sponsor may be willing to provide the methodology in some cases, while in others, FDA, the sponsor, and perhaps a third party (e.g., a State agency or a professional association), may negotiate a cooperative arrangement to develop the methodology. If no acceptable analytical method is developed, the agency would be permitted to prohibit extralabel use of the drug. The respondents may be sponsors of new animal drugs, State or Federal government, or individuals.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22 (b)	2	1	2	4,160	8,320

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

The Center for Veterinary Medicine (CVM) has not found circumstances to require the establishment of a safe level and subsequent development of an analytical methodology. However, CVM believes there will be instances when an analytical methodology will be required. Thus, we are estimating the reporting burden on one methodology being required annually.

Dated: January 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–2051 Filed 1–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Marlene Shinn, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 285; fax: 301/402–0220; e-mail: *shinnm@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Novel Vectors for Identifying Transgenic and Gene Targeting Animals

Dr. Dan Buchholz et al. (NICHD)

DHHS Reference No. E–319–01/0—Research tool

Advances in vertebrate genetics have led to the development of gene knockout animals that allow for the study of gene function and transgenic analysis. This has also encouraged the development of gene-based therapies through introduction of exogenous genes to enhance and/or replace dysfunctional or missing genes. Yet, although the advances have been many, the analysis remains complicated with tedious screening of animals containing the desired genotype.

The NIH announces a double-promoter plasmid that carries a transgene under the control of any preferred promoter and the Green Fluorescent Protein (GFP) under the control of the eye-specific crystalline-promoter for transgenesis. This construct creates a green fluorescence in the eyes of the transgenic animals thus allowing for easy identification. Companies that work in the transgenic or gene targeting areas would find this plasmid useful in quickly and efficiently identifying desired transgenic animals with biological functionality of their gene of interest.

Combined Inhibition of Phosphodiesterase-4 (PDE-4) and Phosphodiesterase-3 (PDE-3) as a Therapy for Th1 Mediated Autoimmune Diseases

Dr. Bibiana Bielekova et al. (NINDS)

DHHS Reference Nos. E–077–00/0 filed 22 Dec 2000 and E–077–00/1 filed 21 Dec 2001

Hyperactive Th1-mediated immune responses are thought to be involved in the pathogenesis of many autoimmune diseases, including rheumatoid arthritis, diabetes, inflammatory bowel disease, vitiligo, and multiple sclerosis among others. Immune cells are known to produce primarily two classes of phosphodiesterases (PDE), the PDE4 and the PDE3 classes. Inhibitors of these PDEs have been shown to down-regulate the expression or production of Th1 cytokines and have either no effect or augment the production of Th2 cytokines, therefore making them good candidates for the treatment of Th1-mediated autoimmune diseases.

The NIH announces a new technology wherein PDE-4 and PDE-3 inhibitors are used in combination and a synergistic enhancement of therapeutic activity is achieved. This results in a more potent immunomodulatory effect on the immune cells and could lead to the administration of lower dose rate of the inhibitors. This new form of treatment will alleviate side effects through the use of a lower dose rate for each and will make for a more effective therapy.

Dated: January 17, 2002.

Jack Spiegel,

Director, Division of Technology, Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 02–2029 Filed 1–25–02; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with