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