TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of Respondents	Number of Responses per Respondent	Total annual responses	Average burden per response	Total hours
Request for reduction of fees collected under section 743 of the FD&C Act	235	1	235	2	470

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

FDA estimates that 510 facilities will be subject to the reinspection and the recall fees under section 743 of the FD&C Act. Of these facilities, we estimate that 46 percent will be small businesses with annual gross sales under $250,000. Therefore, 46 percent of 510 equals to 235 respondents. Each respondent will submit 1 request for reduction of fees. Total annual responses are 235. The average burden is 2 hours, giving a total of 470 hours annual burden.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30471 Filed 11–22–11; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Centers for Disease Control and Prevention

Statement of Delegation of Authority

I hereby delegate to the Administrator, Health Resources and Services Administration (HRSA), and the Director, Centers for Disease Control and Prevention (CDC), with authority to redelegate, the authority vested in the Secretary under Title III, Part P, Section 399T (42 U.S.C. 280g–8), titled ''Support for Patients Receiving a Positive Diagnosis of Down Syndrome or Other Prenatally or Postnatally Diagnosed Conditions,'' of the Public Health Service Act, as amended, insofar as such authority pertains to the functions of HRSA and CDC, respectively. HRSA and CDC will coordinate and collaborate with each other and with the National Institutes of Health, as appropriate, in implementing this authority.

This delegation excludes the authority to issue regulations, to establish advisory committees and councils, and appoint their members, and shall be exercised in accordance with the Department's applicable policies, procedures, and guidelines.

I hereby affirm and ratify any actions taken by the Administrator, HRSA, the Director, CDC, or other HRSA and CDC officials, which involve the exercise of these authorities prior to the effective date of this delegation.

This delegation is effective upon date of signature.

Dated: November 14, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–30411 Filed 11–23–11; 8:45 am]

BILLING CODE 4165–15–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, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency 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 writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* (301) 496–7057; *fax:* (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Genetically Engineered Mouse Model for Use as an Alternative Screening Method for Evaluating P-glycoprotein (P-gp) Substrate Toxicity in Avermectin-sensitive Dogs

Description of Technology: A pitfall to avermectins is central nervous system (CNS) toxicities in herding dogs. As a result, all new avermectins must be tested in a ''Collie Safety Study'' to determine the degree of CNS toxicity. The toxicity is due to a 4 base pair mutation in the ATP-binding cassette, sub-family B member 1 (ABCB1) gene. This gene encodes for the P-glycoprotein (P-gp) that affects absorption, distribution and elimination of certain drugs. Researchers at FDA have developed an alternate animal model that includes two transgenic mouse models, one containing the mutant form of the canine ABCB1 gene (Yancy 1 line) and the other containing the canine wild-type gene (Yancy 2 line). The paired mouse system can be utilized to assess the safety of avermectins and other canine drugs by determining the toxicity to canines with the mutated form of the ABCB1 gene. Ivermectin, a derivative of the avermectin family of heartworm drugs used to treat and control parasitic infections, was used to verify this mouse model. This technology will enhance the population predictions derived from clinical safety data and serve to reduce the use of dogs in avermectin derivative safety studies that are part of the Investigational New Animal Drug (INAD) approval process.

Potential Commercial Applications: Drug screening technology to assess the toxicity of canine drugs to canines with the mutated form of the ABCB1 gene.

Competitive Advantages: Use as an alternative in vivo model to canines for assessment of drug safety in the presence of the ABCB1 mutation.

Development Stage: In vivo data available (animal).

Inventor: Haile F. Yancy (FDA).

Publication: Orzechowski K, *et al.,* in press Am J Vet Res.

Intellectual Property: HHS Reference No. E–292–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Jaime Greene; (301) 435–5559; *greenejaime@mail.nih.gov*.

Collaborative Research Opportunity: The FDA Center for Veterinary Medicine is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or