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
860.123	6	1	6	500	3,000

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

Based on current trends and actual reclassification petitions received, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff that are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Dated: September 7, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18221 Filed 9–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0251]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 7, 2005 (70 FR 33179), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0569. The approval expires on August 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 7, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18222 Filed 9–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0186]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 14, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910–0275)—Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

In the **Federal Register** of June 20, 2005 (70 FR 35446), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments.

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
100.2(d)	1	1	1	10	10

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

The reporting burden for § 100.2(d) is insignificant because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any enforcement notifications. Since the enactment of section 403A(b) of the act (21 U.S.C. 343–1(b)) as part of the Nutrition Labeling and Education Act of 1990, FDA has received only a few enforcement notifications. Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the act against a particular food located in the State.

Dated: September 7, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18223 Filed 9–13–05; 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 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.

Soluble Fragments of the IGF1R Ectodomain

Dimiter S. Dimitrov et al. (NCI)
HHS Reference No. E–144–2005/0—Research Tool
Licensing Contact: Michelle A. Booden; 301/451–7337; *boodenm@mail.nih.gov.*

The type 1 insulin-like growth factor (IGF) receptor (IGF1R) is over-expressed by many tumors and mediates proliferation, motility, and protection from apoptosis. Agents that inhibit IGF1R expression or function can potentially block tumor growth and metastasis.

The present invention relates to the identification of soluble fragments of the IGF1R ectodomain, where these fragments bind IGF-I, IGF-II, or the various other ligands of IFG1R. The identified fragment may be useful for identifying agents that block IGF1R and may act as a strong dominant negative inhibitor of tumor growth by blocking the IGF1R pathway. The invention also encompasses other IGF1R fragments or derivatives of the original fragments, methods of identifying IGF1R fragments or other similar fragments in the IGF1R ectodomain, methods of using said fragments to block binding of ligands, and methods of producing antibodies against the IGF1R fragments.

The technology is available for licensing under a biological material license. In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Polymer-Linked Pseudomonas Exotoxin Immunotoxin

Ira Pastan (NCI) et al.
U.S. Provisional Application No. 60/636,007 filed 12 Dec 2004 (HHS Reference No. E–121–2005/0-US–01)
Licensing Contact: Jesse Kindra; 301/435–5559; *kindraj@mail.nih.gov.*

Molecules based on monoclonal antibodies hold the promise of highly selective therapeutics. However, their efficacy can be limited by poor tissue penetration, rapid renal clearance and an immune response to the antibody. The present technology provides an immunotoxin that is modified to overcome such limitations.

The technology relates to polymer-conjugated immunotoxins targeted to the mesothelin tumor cell antigen. These polymer-immunotoxin conjugates possess an enhanced therapeutic index and may provide improved methods of treating tumors and cancers expressing the mesothelin antigen.

Tumor Suppressor Gene Caliban

Mark A. Mortin et al. (NICHD)
U.S. Provisional Application filed 06 Jun 2005 (DHHS Reference No. E–118–2005/0-US–01)
Licensing Contact: Jesse S. Kindra; 301/435–5559; *kindraj@mail.nih.gov.*

This invention relates to the identification of a tumor suppressor gene named Caliban from Drosophila melanogaster. The inventors have demonstrated that Caliban is very similar to the corresponding human gene and they have shown that the human gene is inactive in human lung cancer cells but active in normal lung cells. For the first time, it has been shown that when full length Caliban is expressed in human lung cancer cells they lose many of their tumorigenic properties. Hence, using gene therapy to replace the inactive gene with full length Caliban may treat cancer. Details of this were published in Bi *et al.*, ''Drosophila caliban, a nuclear export mediator, can function as a tumor suppressor in human lung cancer cells,'' Oncogene advance online publication, August 15, 2005; doi:10.1038/sj.onc.1208962.

This invention also provides a biomarker assay that can be used to determine if the fly or human tumor suppressor Caliban gene product is functioning in cells. This assay uses a peptide from the fly gene Prospero, named HDA, which when fused to a reporter such as green fluorescent protein, is exported from the nucleus when Caliban is working.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.