Dr. Bartsch has entered into a Voluntary Exclusion Agreement (Agreement) in which she neither admits nor denies ORI's finding of scientific misconduct; the settlement is not an admission of liability on the part of the respondent. In accordance with the terms of the Agreement, she has voluntarily agreed, beginning on April 15, 2008:

(1) To exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as ''covered transactions'' pursuant to HHS' Implementation (2 CFR Part 376 *et seq.*) of OMB Guidelines to Agencies on Government-wide Debarment and Suspension (2 CFR Part 180) for a period of two (2) years; and

(2) To exclude herself permanently from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant or contractor to PHS for a period of three (3) years.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852 (240) 453–8800.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. E8–9858 Filed 5–5–08; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegation of Authority

Notice is hereby given that I have delegated to the Principal Deputy Assistant Secretary, Deputy Assistant Secretaries, Program Directors, Program Commissioners, Deputy Director/Commissioner, Office of Child Support Enforcement, and Staff Office Directors the following authority vested in me by the Secretary of Health and Human Services in the memorandum dated August 20, 1991, Delegations of Authority for Social Security Act Programs; 31 U.S.C. 1535; and HHS General Administrative Manual, Chapter 8–77.

(a) *Authorities Delegated.*

1. Authority to administer approved cooperative research, experimental, pilot or demonstration projects under the provisions of sections 1110 and 1115 of the Social Security Act.

2. Authority to approve interagency agreements to procure, provide or exchange services, supplies or equipment.

(b) *Limitations.*

1. The authority listed in #1 above shall be exercised under the condition that projects may be approved and administered by the Office of Planning, Research and Evaluation (OPRE), by the program/staff office or jointly by OPRE with the program/staff office.

2. Where all or any part of an experimental, pilot, demonstration, or other project is wholly financed with Federal funds made available under sections 1110 or 1115 of the Social Security Act, without any State, local or other non-Federal financial participation, that project must be approved by the Secretary of Health and Human Services.

3. This delegation of authority does not include the authority to approve/disapprove projects under section 1115 of the Social Security Act or approve/disapprove waivers of State Plan requirements or costs that would not otherwise be included as expenditures under the provisions of sections 1115(a)(1) and (2) of the Social Security Act.

4. The authority to approve interagency agreements to procure, provide, or exchange services, supplies, or equipment requires the concurrence of the ACF Chief Financial Officer if it exceeds $250,000 (including amendments) within a fiscal year or if it requires the signature of the Assistant Secretary, ACF, or the Secretary of HHS.

(c) *Effective Date.*

This delegation is effective upon the date of signature.

(d) *Effect on Existing Delegations.*

As related to this delegation of authority, this delegation supersedes all previous delegations of authority involving the administration of the cross-program authorities delegated herein.

I hereby ratify and affirm any actions taken by the Principal Deputy Assistant Secretary, Deputy Assistant Secretaries, Program Directors, Program Commissioners, Deputy Director/Commissioner, Office of Child Support Enforcement, and Staff Office Directors, which involved the exercise of the authority delegated herein prior to the effective date of this delegation.

Dated: April 22, 2008.

Daniel C. Schneider,

Assistant Secretary for Children and Families.

[FR Doc. E8–9898 Filed 5–5–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0259]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review

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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed collection of information concerning requests by sponsors of investigational new drugs and applicants for new drug approvals or biologics licenses for fast track designation as provided in the guidance for industry on fast track drug development programs.

DATES: Submit written or electronic comments on the collection of information by July 7, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Elizabeth Berbakos, Office of the Chief Information Officer (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, 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 set forth in this document.

With respect to the following collection of information, FDA invites comment on these topics: (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.

Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review (OMB Control Number 0910–0389)—Extension

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506 (21 U.S.C. 356). The section authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to address an unmet medical need. Under FDAMA section 112(b), FDA issued guidance to industry on fast track policies and procedures outlined in section 506 of the act. The guidance discusses collections of information that are specified under section 506 of the act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving collection of information: (1) Fast track designation requests, (2) premeeting packages, and (3) requests to submit portions of an application. Of these, fast track designation requests and premeeting packages, in support of receiving a fast track program benefit, provide for additional collections of information not covered elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the agency, may, in some cases, be incorporated into the request by referring to the information rather than resubmitting it.

Under section 506(a)(1) of the act, an applicant who seeks fast track designation is required to submit a request to the agency showing that the product: (1) Is intended for a serious or life-threatening condition; and (2) the product has the potential to address an unmet medical need. Mostly, the agency expects that information to support a designation request will have been gathered under existing provisions of the act, the PHS Act, or the implementing regulations. If such information has already been submitted to the agency, the information may be summarized in the fast track designation request. The guidance recommends that a designation request include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After the agency makes a fast track designation, a sponsor or applicant may submit a premeeting package which may include additional information supporting a request to participate in certain fast track programs. The premeeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for fast track designation, the agency expects that most sponsors or applicants will have gathered such information to meet existing requirements under the act, the PHS Act, or implementing regulations. These may include descriptions of clinical safety and efficacy trials not conducted under an investigational new drug application (i.e., foreign studies), and information to support a request for accelerated approval. If such information has already been submitted to FDA, the information may be summarized in the premeeting package. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

Under section 506(c) of the act, a sponsor must submit sufficient clinical data for the agency to determine, after preliminary evaluation, that a fast track product may be effective. Section 506(c) also requires that an applicant provide a schedule for the submission of information necessary to make the application complete before FDA can commence its review. The guidance does not provide for any new collection of information regarding the submission of portions of an application that is not required under section 506(c) of the act or any other provision of the act. All forms referred to in the guidance have a current OMB approval: FDA Forms 1571 (OMB Control No. 0910–0014); 356h (OMB Control No. 0910–0338); and 3397 (OMB Control No. 0910–0297).

Respondents to this information collection are sponsors and applicants who seek fast track designation under section 506 of the act. The agency estimates the total annual number of respondents submitting requests for fast track designation to the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research is approximately 64, and the number of requests received is approximately 77 annually. FDA estimates that the number of hours needed to prepare a request for fast track designation is approximately 60 hours per request.

Not all requests for fast track designation may meet the statutory standard. Of the requests for fast track designation made per year, the agency granted 60 from 54 respondents, and for each of these granted requests a premeeting package was submitted to the agency. FDA estimates that the preparation hours are approximately 100 hours per premeeting package.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation Request	64	1.28	77	60	4,620
Premeeting Packages	54	1.11	60	100	6,000
Total					10,620

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: April 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9882 Filed 5–5–08; 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, 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.

Human Papillomavirus microRNA Diagnostics and Therapeutics

Description of Technology: Available for licensing and commercial development are patent rights that cover the uses of a p53 specific microRNA (miRNA). It has been reported that the tumor suppressive mRNA miR–34a (a downstream target of p53) is downregulated in HPV-infected primary keratinocytes. miR–34a arrests the cell cycle at G2 phase and promotes apoptosis. Therapeutic restoration of normal expression levels of miR–34a and/or simultaneous stabilization of p53 (inhibited by HPV E6) induces miR–34a accumulation in G0/G1 phase and can arrest tumor growth. Neoplasia and cancer cell progression has also been associated with p18Ink4c overexpression which can be regulated with the introduction of a therapeutic amount of miR–34a. Tumor reduction/suppression by down regulating p18Ink4c is also a therapeutic benefit provided by this invention.

Applications: Cervical cancer; Human papillomavirus; Therapeutics.

Inventors: Zhi-Ming Zheng and Xiaohong Wang (NCI).

Publications:

1. WO Lui *et al.* Patterns of known and novel small RNAs in human cervical cancer. Cancer Res. 2007 Jul 1;67(13):6031–6043.

2. I Martinez *et al.* Human papillomavirus type 16 reduces the expression of microRNA–218 in cervical carcinoma cells. Oncogene 2007 Nov 12; Advance online publication, doi:10.1038/sj.onc.1210919.

Patent Status:

U.S. Provisional Application No. 60/983,368 filed 29 Oct 2007 (HHS Reference No. E–029–2008/0–US–01).

U.S. Provisional Application No. 61/041,842 filed 02 Apr 2008 (HHS Reference No. E–029–2008/1–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute HIV and AIDS Malignancy Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HPV-induced aberrant expression of microRNAs for cervical cancer diagnostics and therapeutics. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Microarray Binding Sensors Using Carbon Nanotube Transistors

Description of Technology: Available for licensing and commercial development are: (a) An apparatus containing microarray binding sensors having biological probe materials and carbon nanotube transistors (CNTs) and (b) various methods of using the highly sensitive CNTs for the electronic detection of nucleic acid hybridization for performing microarray gene expression experiments and detection of DNA–DNA, DNA–RNA, Peptide Nucleic Acid (PNA) –DNA, PNA–RNA, DNA-protein or PNA-protein binding. By analogy to the microarray concept, each transistor is associated with a distinct probe oligonucleotide. Each transistor is operated as a field effect transistor (FET) and the transconductance between the source and drain electrodes is measured before and after a hybridization event. The expected advantages are, besides higher sensitivity and ease of use, the elimination of chemical labeling and enzymatic manipulation and the further miniaturization. The unique distinction of this design over other CNT-based biomolecular sensing schemes is the complete isolation of the CNTs from chemical reactions concomitant with probe immobilization and target capture, and the CNTs functioning only as charge sensors. In contrast, current methods rely on enzymatic amplification of nucleic acids, fluorescent labeled targets, hybridization, amplification of signal and detection by optical scanners, which are time consuming and have limited sensitivity.

Applications: The apparatus and method can be used for numerous applications, among them: High-throughput monitoring of genome-wide