(HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing the availability of its report of scientific and medical literature and information concerning the use of non-standardized allergenic extracts in the diagnosis and treatment of allergic disease. FDA is making this report available to provide information and obtain comment on the report from public and private stakeholders. FDA will also seek input on the report from APAC at a meeting to be held on October 25, 2011. A separate notice of the APAC meeting is published elsewhere in this issue of the **Federal Register**. This process will assist FDA in its continued oversight of regulated products.

II. Discussion

In 2004, FDA formed an internal committee to review available scientific and medical data on the safety and effectiveness of non-standardized allergenic extracts. FDA formed this committee to consider the previous evaluations performed by the external allergenics advisory review panels under 21 CFR 601.25 (Panel I or ''Original Panel'') and under 21 CFR 601.26 (Panel II or ''Reclassification Panel''). Reports of the Original and Reclassification Panels are available at *http://www.fda.gov/BiologicsBloodVaccines/Allergenics/ucm272115.htm.* The internal committee designed a data file to use in its review and to archive supporting data. The data file includes a report of information for each product, including a discussion of each product reviewed, and a list of reviewed literature associated with each product. FDA's approach to creating this data file was presented to APAC on April 7, 2005, and discussed again at the APAC meeting on September 13, 2006.

After receiving favorable feedback from the APAC on FDA's proposed methodology, FDA proceeded to collect the following information in order to facilitate its assessment of safety and effectiveness of non-standardized allergenic products.

A. Literature Reviewed by the Allergenics Advisory Review Panels

This includes literature reviewed by the Original Panel as part of its final report in 1981 and literature reviewed by the Reclassification Panel as part of its final report in 1983.

B. Data Concerning the Effectiveness and Safety of Non-Standardized Allergenic Products That Have Become Available Since 1972

This includes published literature, available manufacturer data, and data from other external sources. FDA accumulated these data from the following sources:

1. Published Literature From 1972 to the Present

This literature was acquired by searching for articles using a PubMed and/or Institute for Scientific Information (ISI) search engine (English-language literature articles only).

2. Publicly Available Manufacturer Data

These data were obtained by reviewing information published in the literature.

3. Medwatch Data Collected for Years 1987 to 2010

These data were evaluated for safety related product trends.

4. Data From Other External Sources

These data were obtained by performing a broad Internet search (*e.g.,* Google) to check for any additional safety or effectiveness data not captured in published articles found via PubMed or ISI.

FDA collected information from published scientific and medical literature and other data sources for each extract in order to identify those studies that used acceptable alternative testing methods. FDA also collected information from studies that:

- *Provided identifiable, specific and valid nomenclature for the source materials used in the preparation of the allergenic extracts in the studies.*
- *Were performed using aqueous based extracts prepared from specifically identified source materials with correct nomenclature.*
- *Described identifiable, specific, and valid study methods.*
- *Provided objective and evaluable data.*
- *For skin test data in the studies:*

Obtained positive skin tests in index cases by either skin prick or intradermal methods, demonstrated by:

- Wheal or erythema;
- Where appropriate, comparison to positive and negative control data in same study subjects.
- *For studies with cross reactivity data, demonstrated cross reactivity by:*
  - ELISA or RAST inhibition;
  - Western immunoblot; or
  - Other valid immunochemical data.

In reviewing evidence of efficacy, FDA did not consider to be adequate ''random experience,'' or reports that lacked sufficient scientific detail for proper evaluation (such as imprecise nomenclature). FDA also did not consider to be adequate ''isolated case reports'' unless corroborated by the following: (1) Other case reports from independent authors, (2) well-described allergen challenge data, or (3) valid cross-reactivity data.

FDA is providing its report of the collected literature and other data in a data file that is currently available in PDF format on FDA's Web site at *http://www.fda.gov/downloads/BiologicsBloodVaccines/Allergenics/UCM271330.pdf.* FDA welcomes comments on the scientific and medical literature and information presented in the data file.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the data file at *http://www.fda.gov/downloads/BiologicsBloodVaccines/Allergenics/UCM271330.pdf* or *http://www.regulations.gov.*

Dated: September 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24598 Filed 9–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0013]

Statement of Organizations, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has reorganized the Center for Drug Evaluation and Research (CDER) by establishing two offices and their substructures under the Office of Medical Policy: Office of Prescription Drug Promotion (OPDP) and Office of Medical Policy Initiatives (OMPI). OPDP will consist of the Division of Direct-to-Consumer Promotion and the Division of Professional Promotion. OMPI will consist of the Division of Medical Policy Development and Division of Medical Policy Programs.

FOR FURTHER INFORMATION CONTACT: Karen Koenick, Center for Drug Evaluation and Research (HFD–063), Food and Drug Administration, 11919 Rockville Pike, rm. 324, Rockville, MD 20852, 301–796–4422.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Statement of Organization, Functions, and Delegations of Authority for CDER (35 FR 3685, February 25, 1970; 60 FR 56605, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; 76 FR 19376, April 7, 2011; and 76 FR 51039, August 17, 2011) is amended to reflect the restructuring of CDER that was approved by the Secretary of Health and Human Services on May 25, 2011, as follows:

II. Organization

CDER is headed by the Director and includes the following organizational units:

Office of Medical Policy

1. Provides Center oversight and leadership in the development of medical policy procedures and policy initiatives pertaining to drug development, drug approval, bioresearch monitoring, human subject protection, and postmarket surveillance.

2. Provides scientific and regulatory leadership in ensuring accurate and effective communication of medical information to health care professionals and patients and compliance with applicable regulations.

3. Fosters an interdisciplinary approach to medical policy development, implementation, and coordination through collaboration with other disciplines, program areas, and FDA Centers in a manner that enhances integration of evolving science and policy into drug development, regulatory review, and postmarket surveillance processes.

Office of Prescription Drug Promotion

1. Formulates and establishes policy for the regulation of prescription drug promotion, including advertisements and promotion labeling, and other promotional activities.

2. Plans and supervises research studies to evaluate the impact of health communication and prescription drug promotion directed to health care professionals and consumers.

Division of Direct-To-Consumer Promotion

1. Reviews draft Direct-to-Consumer Promotion (DTCP) promotional materials and provides detailed written advisory comments to industry sponsors. Examples of draft materials include television ads, magazine ads, Internet Web sites, and patient brochures.

2. Develops and issues enforcement actions against false and misleading DTCP materials and activities for prescription drugs.

3. Reviews draft patient labeling for inappropriate promotional content.

Division of Professional Promotion

1. Reviews draft promotional materials directed to health care professionals and provides detailed written advisory comments to industry sponsors. Examples of draft materials include journal ads, Internet Web sites, commercial exhibit hall materials, sales aids, and broadcast advertisements.

2. Develops and issues enforcement actions against false and misleading prescription drug promotional materials and activities directed to health care professionals.

3. Reviews draft professional labeling for inappropriate promotional content.

Office of Medical Policy Initiatives

1. Provides oversight and direction for development of medical policies and procedures pertaining to drug development and drug approval and postmarket surveillance processes.

2. Provides oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas, including initiatives to develop active safety monitoring of marketed products, improve the science and efficiency of clinical trials, regulate biosimilars (or follow-on biologics), and enhance consumer-directed drug information.

Division of Medical Policy Development

1. Responsible for the development of medical policy pertaining to drug development, drug approval, bioresearch monitoring, human subject protection, and postmarket surveillance processes in collaboration with appropriate program areas and coordinating committees. Develops issue papers, guidances, regulations, and operating procedures.

2. Provides advice and assistance to FDA staff and external constituents concerning implementation or application of new and existing medical policies and procedures.

3. Collaborates with the Office of Regulatory Policy to ensure timely and efficient clearance and dissemination of new and revised policy documents.

Division of Medical Policy Programs

1. Implements the Sentinel Initiative, an innovative safety monitoring program for marketed medical products that employs active surveillance of automated health care databases.

2. Coordinates with FDA Centers, external partners, and stakeholders to ensure efficient implementation of quality science and technology, and effective privacy and security strategies.

3. Manages and coordinates policy development related to biosimilars legislation and resulting programs.

4. Manages and coordinates clinical trial modernization policy and programs, including coordinating public-private partnerships dedicated to removing barriers to clinical trials participation, enhancing evidence derived from clinical trials, and optimizing the use of clinical trial resources.

5. Manages and coordinates policy and program initiatives to improve quality and utility, and broaden dissemination, of consumer-directed medical information.

6. Manages and coordinates efforts to ensure that professional labeling is compliant with applicable regulations and is optimized as a tool for communicating about the safety and efficacy of drugs.

7. Coordinates and collaborates with relevant program areas to ensure optimal FDA scientific and technical input for ongoing policy initiatives.

8. Develops and manages new science and technology policy initiatives pertaining to drug development, drug approval, and postmarket surveillance processes.

III. Delegation of Authority

Pending further delegation, directives or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided

they are consistent with this reorganization.

Dated: September 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24583 Filed 9–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Cultural and Linguistic Competency and Health Literacy Data Collection Checklist (OMB No. 0915–xxxx)—[New]

The vision of the Health Resources and Services Administration (HRSA) is ''Healthy Communities, Healthy People.'' In addition, the HRSA mission statement is ''To improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.'' This is the framework that supports a health care system that assures access to comprehensive, culturally competent, quality care.

Performance measures have been helpful for HRSA to assess the progress of each grantee. The measure used will be the degree to which HRSA-funded programs have incorporated cultural and linguistic competence and health literacy elements into their policies, guidelines, contracts and training. HRSA Bureaus/Offices shall be encouraged to incorporate this performance measure or a modified version of this measure into their funding opportunity announcements either as a stand-alone or integrated measure.

Using a scale of 0–3, the grantee may use the Cultural and Linguistic Competency and Health Literacy Data Collection Checklist to assess if specified cultural/linguistic competence and health literacy elements have been incorporated into their policies, guidelines, contracts and training. Each HRSA program may add data sources and year of data used for scoring to provide a rationale for determining a score, and/or applicability of elements to a specific program.

The goal of this checklist is to increase the number of HRSA-funded programs that have integrated both cultural and linguistic competence, as well as health literacy, into their policies, guidelines, contracts and training. In addition, variations of the proposed tool have proven useful for grantees' self-assessment. This proposed tool can also offer insights into technical assistance challenges and opportunities.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Data Collection Checklist	900	1	900	1	900
Total	900	1	900	1	900

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 20, 2011.

Reva Harris,

Acting Director, Division of Policy Information and Coordination.

[FR Doc. 2011–24561 Filed 9–23–11; 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.

A Novel Method To Predict Kidney Tumor Growth

Description of Technology: The invention pertains to a computerized method of predicting kidney tumor growth for early stage treatment planning. The method utilizes a finite