availability of a draft guidance entitled ''Pharmacogenomic Data Submissions—Companion Guidance.'' The guidance is intended as a companion to the guidance of the same name, which was issued in 2005 (70 FR 14698; March 23, 2005). It reflects experience gained since the issuance of that guidance with voluntary genomic data submissions as well as with review by FDA of numerous protocols and data submitted under investigational new drug (IND) applications, new drug applications (NDAs), and biologics license applications (BLAs). The recommendations are intended to facilitate scientific progress in the field of pharmacogenomics and to facilitate the use of pharmacogenomic data in drug development.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 27, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Federico Goodsaid, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3663, Silver Spring, MD 20903–0002, 301–796–1535.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance, which is intended to be used as a companion to the guidance issued in March 2005 entitled ''Pharmacogenomic Data Submissions.'' This draft guidance entitled ''Pharmacogenomic Data Submissions—Companion Guidance'' is based on FDA's experience with voluntary genomic data submissions as well as with its review of numerous protocols and data submitted under IND applications, NDAs, and BLAs during the last 2 years. FDA believes that the recommendations in the draft guidance will benefit sponsors considering the submission of either voluntary genomic data or marketing submissions containing genomics data. As technology changes and more experience is gained, these recommendations may be updated.

Specifically, this draft guidance contains recommendations on gene expression data from microarrays, genotyping, genomic data in clinical study reports, genomic data from nonclinical toxicology studies, and data submission formats. Each of the sections in the guidance make recommendations on technical steps or describes report contents or formats that will facilitate the submission of genomic data to FDA. A concept paper containing the contents of this draft guidance was made available on the Genomics Web site of FDA (*http://www.fda.gov/cder/genomics/conceptpaper_20061107.pdf*) on November 2006. The concept paper was discussed at the FDA/Drug Information Association/Pharmaceutical Research and Manufacturers of America Foundation/Biotechnology Industry Organization workshop on Best Practices and Development of Standards for the Submission of Genomic Data to FDA held in Washington, DC on November 27 and 28, 2006. This draft companion guidance reflects feedback received at and since the workshop.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on recommendations for the submission and review of genomic data. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–17103 Filed 8–28–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0125]

Draft Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of July 9, 2007 (72 FR 37246). The document announced the availability for public comment of a draft guidance entitled ''Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims.'' The document was published with an incorrect Internet address for submitting electronic comments and an incorrect telephone number. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Paula Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2579.

SUPPLEMENTARY INFORMATION: In FR Doc. E7–13274, appearing on page 37246 in the **Federal Register** of Monday, July 9, 2007, the following corrections are made:

1. On page 37246, in the second column, in the **ADDRESSES** section, the phrase ''*http://www/fda/gov/dockets/ecomments*'' is corrected to read ''*http://www.fda.gov/dockets/ecomments*''.

2. On page 37246, in the second column, in the **FOR FURTHER INFORMATION CONTACT** section, the telephone number ''310–436–2579'' is corrected to read ''301–436–2579''.

Dated: August 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–17038 Filed 8–28–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Policy Documents for Comment

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: This is a Notice of Availability and request for comments on draft Agency Guidance (''Policy Information Notices'' (PINs)) to describe the policy and processes pertaining to requests from federally-funded health centers to change the scope of their Federal project. The PINs, ''Defining Scope of Project and Policy for Requesting Changes,'' ''Change in Scope Requests: Policy for Adding a New Target Population,'' and ''Specialty Services and Health Centers' Scope of Project,'' are available on the Internet at *http://bphc.hrsa.gov.*

DATES: Comments must be received by September 28, 2007.

ADDRESSES: Please send your comments to the following e-mail address: *DPDgeneral@hrsa.gov.*

SUMMARY: HRSA believes that community input is valuable to the development of policies and policy documents related to the implementation of HRSA programs, including the Health Center Program. Therefore, we are requesting comments on the PINs referenced above. After review and consideration of all comments received, the PINs may be amended to incorporate recommendations from the public. Once the PINs are finalized, they will be made available on HRSA's Web site, along with the Agency's ''Response to Public Comments.'' The ''Response to Public Comments'' will summarize the major comments received and describe the Agency's response, including any corresponding changes made to the PINs. Where comments do not result in a revision to the PINs, explanations will be provided.

Background: HRSA administers the Health Center Program, which supports more than 3,800 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers. Health centers serve clients that are primarily low-income and minorities, and deliver preventive and primary care services to patients regardless of their ability to pay. Charges for health care services are set according to income. The purpose of the recently published draft PINs is to describe the policy and processes pertaining to requests from federally-funded health centers to change the scope of their Federal project, including requests to include new specialty services and/or a new target population within the scope of the Federal project.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at 301–594–4300.

Dated: August 21, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–17092 Filed 8–28–07; 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.

Collagen-Induced Platelet Aggregation Inhibitor From Mosquito Salivary Glands

Description of Technology: Exposed collagen in injured blood vessels provides a substrate for platelets to adhere and aggregate initiating the first step in thrombosis, the formation of blood clots inside a blood vessel. Despite the essential role of platelets in vascular injury, excessive platelet aggregation may also result in thrombotic diseases such as stroke and heart attack.

Available for licensing is a collagen binding protein, named aegyptin, which selectively inhibits collagen-platelet aggregation, but not platelet aggregation induced by other agonists. Collagen initiates recruitment of circulating platelets and triggers platelet activation. Collagen also plays a critical role in angiogenesis. Aegyptin blocks the interaction of collagen with its major ligands, von Willebrand factor, glycoprotein VI (GPVI), and integrin $\alpha 2\beta 1$. These three ligands are of particular importance because von Willebrand factor plays a critical role in tethering platelets to collagen, GPVI is the major signaling platelet receptor, and integrin $\alpha 2\beta 1$ mediates platelet adhesion and contributes to activation. Since these ligands play a critical role in the early stages of thrombus formation, aegyptin represents a potentially highly effective therapeutic that can prevent and treat patients with thrombotic disease. Alternatively, aegyptin is potentially useful in conditions where collagen plays a critical role in angiogenesis or in conditions where excessive deposition of collagen plays a pathological role (e.g. pancreatic carcinoma).

Applications:

Adjuvant to ''Clot busting'' therapeutics.

Method to prevent and/or treat cardiovascular/thrombotic disease.

Method to treat patients undergoing invasive cardiovascular procedures (e.g. angioplasty).

Model to study collagen-dependent platelet aggregation or collagen-mediated angiogenesis.

Advantages:

Highly effective therapeutics can negatively modulate thrombosis in its early stages by preventing collagen interaction with three major ligands involved in thrombus/clot formation.

Aegyptin's potential use as a prototype for drug delivery as an oral therapeutic, which can reduce the need for invasive surgeries that dilate blood vessels such as stents or catheters.

Market:

Thrombolytic/antithrombotic therapies are worth billions of dollars, common therapeutics include heparin, warfarin, and plasminogen activators.

Anticancer and antiangiogenic therapies.