

Dated: August 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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.

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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.