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 submitted by States requesting the agency take enforcement action under the act against a particular food. Over 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 obligation of a State to notify FDA of an enforcement action under the provisions of section 310(b) of the act.

Dated: August 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–21853 Filed 8–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiological Safety of Drug Residues in Food; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) will sponsor a workshop entitled ''Microbiological Safety of Drug Residues in Food.'' The workshop will discuss the use of model systems to establish acceptable daily intakes (ADI's) for antimicrobial drug residues in food. The workshop will focus on human consumption of new animal drug residues in food and their direct effects on human intestinal microflora.

The document entitled ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food–Producing Animals'' (the ''framework'' document) will not be discussed at this workshop. Information about workshops on the framework document will be announced in a future **Federal Register** notice, CVM update(s), and on CVM's Internet home page, at ''http://www.fda.gov/cvm/fda/mappgs/antitoc.html''.

Date and Time: The workshop will be held on Monday and Tuesday, September 20 to 21, 1999, from 8 a.m to 6 p.m. on Monday and from 8 a.m. to 2 p.m. on Tuesday.

Location: The workshop will be held at The DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD, 20852, 301–468–1100.

Contact: Lynda W. Cowatch, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5281.

Registration: The registration for the workshop is free. However, registration is required. For additional information and a registration form, please contact Lynda W. Cowatch at the above address. A registration form is also available on the CVM home page at ''http://www.fda.gov/cvm/fda/mappqs/registration.html''.

If you need special accommodations for a disability, please contact the DoubleTree Hotel at least 7 days in advance.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 1996 (61 FR 3043), CVM published a notice of availability of a guidance document entitled ''Microbiological Testing of Antimicrobial Drug Residues in Food.'' This guidance document defines when antimicrobial drugs would be exempt from additional microbiological testing and when additional testing may be necessary to establish the safety of antimicrobial drug residues in food. The document also establishes 1.5 milligrams/person/day as the ADI of microbiologically active residues that would be allowed in food without additional microbiological testing. CVM also expressed the intention of validating model systems that could be used to evaluate the effect of low levels of antimicrobial drugs on the human intestinal microflora.

In 1995 and 1996, CVM initiated research to validate an in vitro and an in vivo model system that could be used to set ADI's for antimicrobial drug residues in food based on perturbations of the human intestinal microflora. The results of this research will be presented at the September workshop. In addition, other methods for determining ADI's for antimicrobial residues used internationally and in Europe will be presented and discussed.

Based on the information presented and discussed at the workshop, CVM intends to reevaluate its guidance document for testing microbiological effects of antimicrobial residues on the human intestinal microflora.

Dated: August 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–21854 Filed 8–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1076–N]

Medicare Program; September 16, 1999, Meeting of the Competitive Pricing Advisory Committee

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Competitive Pricing Advisory Committee (the CPAC) on September 16, 1999. The Balanced Budget Act of 1997 (BBA) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. The BBA requires the Secretary to create the CPAC to make recommendations on demonstration area designation and appropriate research designs for the project. The CPAC meetings are open to the public.

DATES: The CPAC is scheduled to meet on September 16, 1999, from 9 a.m. until 4 p.m., e.d.s.t.

ADDRESSES: The meeting will be held at the Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT: Sharon Arnold, Ph.D., Executive Director, Competitive Pricing Advisory Committee, Health Care Financing Administration, 7500 Security Boulevard, C4–14–17, Baltimore, MD 21244–1850, (410) 786–6451.

SUPPLEMENTARY INFORMATION:

Section 4011 of the Balanced Budget Act of 1997 (BBA) (Public Law 105–33), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. Section 4012(a) of the BBA requires the Secretary to appoint a Competitive Pricing Advisory Committee (the CPAC) to meet periodically and make recommendations to the Secretary concerning the designation of areas for inclusion in the project and appropriate research designs for implementing the project. The CPAC has previously met on May 7, 1998, June 24 and 25, 1998, September 23 and 24, 1998, October 28, 1998, January 6, 1999, May 13, 1999, and July 22, 1999.

The CPAC consists of 15 individuals who are independent actuaries, experts in competitive pricing and the administration of the Federal Employees Health Benefit Program, and representatives of health plans, insurers, employers, unions, and beneficiaries. The CPAC members are: James Cubbin, Executive Director, General Motors Health Care Initiative; Robert Berenson, M.D., Director, Center for Health Plans and Providers, Health Care Financing Administration; John Bertko, Actuary Principal, Reden & Anders, Ltd.; Dave Durenberger, Vice President, Public Policy Partners; Gary Goldstein, M.D., former CEO, The Oschner Clinic; Samuel Havens, Healthcare Consultant and Chairman of Health Scope/United; Margaret Jordan, President and CEO, The Margaret Jordan Group; Chip Kahn, President, The Health Insurance Association of America; Cleve Killingsworth, President, Health Alliance Plan; Nancy Kichak, Director, Office of Actuaries, Office of Personnel Management; Len Nichols, Principal Research Associate, The Urban Institute; Robert Reischauer, Senior Fellow, The Brookings Institution; John Rother, Director, Legislation and Public Policy, American Association of Retired Persons; Andrew Stern, President, Service Employees International Union, AFL–CIO; and Jay Wolfson, Director, Florida Health Information Center, University of South Florida. The chairperson of the CPAC is James Cubbin and the co-chairperson is Robert Berenson, M.D. In accordance with section 4012(a)(5) of the BBA, the CPAC will terminate on December 31, 2004.

The agenda for the September 16, 1999, meeting will include the following:

- A review of the competitive pricing demonstration design.
- A discussion on how to minimize disruption for beneficiaries in the demonstration sites.
- A discussion on the process for review of plan bids.
- A revision of the implementation timeline for the Kansas City, MO Metropolitan Area and Maricopa County, AZ demonstration sites.

Individuals or organizations that wish to make 5-minute oral presentations on the CPAC agenda issues should contact Sharon Arnold, CPAC Executive Director, by 12 noon, September 9, 1999, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director no later than 12 noon, September 9, 1999. Anyone who is not scheduled to speak may submit written comments to the Executive Director, by 12 noon, September 13, 1999.

This meeting is open to the public, but attendance is limited to the space available.

(Sec. 4012 of the Balanced Budget Act of 1997, Pub. L. 105–33 (42 U.S.C. 1395w–23 note) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 18, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

[FR Doc. 99–21859 Filed 8–23–99; 8:45 am]

BILLING CODE 4120–01–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, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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 contacting Richard U. Rodriguez, M.B.A., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 287; fax: 301/402–0220; e-mail: rr154z@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Peptides and Their Utility in Modulation of Behavior of Cells Expressing $\alpha 3\beta 1$ Integrins

David D. Roberts, Henry C. Krutzsch (NCI)

DHHS Reference No. E–169–99/0 filed 15 Jul 1999

The present invention relates generally to peptides that bind to or are recognized by $\alpha 3\beta 1$ integrins and in particular, to pharmaceutical compositions containing and methods of using said peptides to inhibit or promote various functions of cells that express $\alpha 3\beta 1$ integrins.

Integrins are transmembrane α, $\beta 1$-heterodimer receptors expressed on a wide variety of cells which are involved in extracellular matrix (ECM) interactions. Experimental data has shown that the ECM can affect gene expression and that this altered gene expression can change the composition of the ECM. A bi-directional exchange of information between cells and their surrounding matrix is therefore taking place and because of this communication, integrins can control cell growth, motility, differentiation and survival. Defects in the regulation of these processes can result in many disease states, such as inheritable developmental disorders, defective wound repair, hemotological disorders, cardiovascular diseases, immunological disorders, neurodegenerative diseases and cancer initiation, invasion and metastasis. The disclosed peptides have been shown to inhibit angiogenesis, cell adhesion and proliferation and wound repair when administered in a soluble