administered WELLBUTRIN and ZYBAN (bupropion) that have market exclusivity. The studies described in the written request were for the indications of depression and smoking cessation in the pediatric population. GlaxoSmithKline declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of WELLBUTRIN and ZYBAN (bupropion) in the pediatric population.

On July 3, 2002, FDA issued a written request for pediatric studies to GelTex Pharmaceuticals, the holder of approved applications for RENAGEL (sevelamer) that have market exclusivity. The studies described in the written request were for the indication of hyperphosphatemia in the pediatric population. GelTex Pharmaceuticals declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of RENAGEL (sevelamer) in the pediatric population.

Consistent with the provisions of the BPCA, on November 14, 2003, FDA referred to the Foundation the written requests for the conduct of the pediatric studies for ZONEGRAN (zonisamide), WELLBUTRIN and ZYBAN (bupropion), and RENAGEL (sevelamer).

Dated: April 7, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8514 Filed 4–14–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8006]

Memorandum of Understanding Between the Department of Health and Human Services of the United States Through the Food and Drug Administration and the Ministry of Maritime Affairs and Fisheries of the Republic of Korea Covering the Safety and Quality of Fresh and Frozen Aquacultured Molluscan Shellfish Exported From the Republic of Korea to the United States of America

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Department of Health and Human Services of the United States of America through the Food and Drug Administration (FDA) and the Ministry of Maritime Affairs and Fisheries of the Republic of Korea. This understanding is in keeping with the beneficial and cooperative work conducted under the terms of a 1988 MOU concerning the safety and quality of molluscan shellfish exported to the United States from the Republic of Korea. The purpose of the MOU is to establish the set of guidelines to be implemented for assuring that molluscan shellfish exported from the Republic of Korea and offered for import into the United States of America are safe for human consumption and are harvested, processed, transported, and labeled in accordance with the provision of the U.S. National Shellfish Sanitation Program and the applicable requirements of the U.S. Federal Food and Drug and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, and title 21 of the U.S. Code of Federal Regulations.

DATES: The agreement became effective October 28, 2003.

FOR FURTHER INFORMATION CONTACT: Paul W. Distefano, Center for Food Safety and Applied Nutrition (HFS–417), Food and Drug Administration, College Park, MD 20740, 301–436–1410.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: March 24, 2004.

Jeffrey Shuren,

Assistant Commissioneer for Policy.

BILLING CODE 4160–01–S

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

MINISTRY OF MARITIME AFFAIRS AND FISHERIES OF THE REPUBLIC OF KOREA

AND THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA THROUGH THE FOOD AND DRUG ADMINISTRATION

COVERING THE SAFETY AND QUALITY OF FRESH AND FRESH FROZEN MOLLUSCAN SHELLFISH EXPORTED FROM THE REPUBLIC OF KOREA TO THE UNITED STATES OF AMERICA

The Ministry of Maritime Affairs and Fisheries (MOMAF) of the Republic of Korea and the Department of Health and Human Services of the United States of America, through the Food and Drug Administration (FDA), hereinafter referred as "The Participants,"

Desiring to safeguard public health and to ensure the safety and quality of fresh and fresh frozen molluscan shellfish that are or may be exported into the United States of America;

Wishing to maintain the long standing cooperation begun on November 24, 1972 when the Government of the United States of America signed a Shellfish Sanitation Agreement with the Government of the Republic of Korea in which both governments agreed to cooperate in seeking to assure that molluscan shellfish are safe and wholesome;

In keeping with the beneficial and cooperative work conducted under the terms of a 1998 Memorandum of Understanding concerning the safety and quality of molluscan shellfish exported to the United States of America from the Republic of Korea;

Recognizing that the Participants have held technical consultations leading to the successful development and implementation of an effective molluscan shellfish sanitation program in the Republic of Korea for molluscan shellfish;

Recognizing that nothing in this Memorandum of Understanding (MOU) will in any way abrogate the responsibility or authority of the FDA under section 801 of the Federal Food, Drug, and Cosmetic Act to examine, and, where appropriate, refuse admission of, any food product being offered for entry into the United States of America or to comply with and enforce any other law administered by the FDA; and

Acknowledging that the FDA recognizes the Korean Shellfish Sanitation Program (KSSP) and finds that the KSSP adequately meets U.S. National Shellfish Sanitation Program (NSSP) guidelines, and that MOMAF retains the overall responsibility for the KSSP and coordinates participation of the Korean Government in the Molluscan Shellfish Program

Have hereby reached the following understanding:

ARTICLE I
Purpose

The purpose of this MOU is to establish the set of guidelines to be implemented for assuring that molluscan shellfish exported from the Republic of Korea and offered for import into the United States of America are safe for human consumption and are harvested, processed, transported, and labeled in accordance with the provisions of the NSSP Model Ordinance and the applicable requirements of the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, and Title 21 of the U.S. Code of Federal Regulations.

ARTICLE II
Definitions

For the purpose of this MOU the words listed below will have the following meaning:

1. Approved means the classification used to identify a growing area where the harvest of molluscan shellfish for direct marketing is allowed.

2. Central file means the single location where MOMAF maintains a copy of all information, data, reports, and maps associated with the KSSP.

3. Lot of shellstock means a collection of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area harvested by one or more harvesters.

4. Lot of shucked molluscan shellfish means a collection of containers of shucked molluscan shellfish of no more than one day's harvest from a single defined growing area, produced under conditions as nearly uniform as possible, and designated by a common container code or marking.

5. Marine biotoxins means any poisonous compound produced by marine microorganisms and accumulated by shellstock.

6. Korean Shellfish Sanitation Program (KSSP) means the regulatory control program in the Republic of Korea designed to ensure the safety of molluscan shellfish intended for export

to the United States of America through the implementation of control measures set forth in the NSSP.

7. Molluscan Shellfish, means all edible species of oysters, clams, mussels, and whole or roe on scallops; either shucked or in the shell, fresh or fresh frozen, whole or in part.

8. National Shellfish Sanitation Program (NSSP) means the cooperative state (domestic and foreign)-FDA-industry program to ensure the safety and quality of molluscan shellfish intended for human consumption. Guidelines for ensuring the safety and quality of molluscan shellfish are set forth in the NSSP Model Ordinance.

9. Patrol means the active control of molluscan shellfish harvesting to ensure that only molluscan shellfish from approved areas are harvested, processed, and shipped.

10. Relay means the transfer of shellstock from unapproved areas to approved areas for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

11. Sanitary Survey Report means the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on the water quality in a molluscan shellfish growing area.

12. Shellstock means live molluscan shellfish in the shell.

ARTICLE III
Obligations of the Participants

A. RESPONSIBILITIES OF MOMAF

1. MOMAF assumes the commitment of overall responsibility for the coordination and implementation of the KSSP.

2. MOMAF intends to:

   a. Maintain legal, administrative, safety, quality, and sanitary controls over molluscan shellfish intended for export to the United States of America by certified Korean processors.

   b. Ensure that the KSSP conforms to the NSSP, including, but not limited to:

      i. classifying molluscan shellfish growing waters;

      ii. preparing sanitary survey reports and maintaining sanitary survey reports and all related data in the central file;

iii. updating sanitary survey reports annually and triennially for the purpose of ensuring the proper classification of each molluscan shellfish growing area;

iv. approving and supervising harvesting and relaying operations and ensuring proper labeling and identification of molluscan shellfish in accordance with the NSSP;

v. restricting the harvest of molluscan shellfish from unapproved growing areas, controlling the harvest of molluscan shellfish from unapproved growing areas, and taking enforcement action against persons or firms harvesting from unapproved growing areas;

vi. prohibiting the harvest of molluscan shellfish from growing areas in response to contamination emergencies and for rescinding such prohibitions when water quality data or marine biotoxin analyses demonstrate that the area meets NSSP approved area criteria;

vii. recalling unsafe molluscan shellfish when the responsible processor fails to carry out the necessary product recall;

viii. maintaining NSSP conforming laboratories certified to participate in the KSSP;

ix. inspecting processors that process fresh or fresh frozen molluscan shellfish for export to the United States of America to ensure compliance with NSSP controls;

x. certifying processors exporting fresh or fresh frozen molluscan shellfish to the United States of America in accordance with the NSSP for listing on FDA's Interstate Certified Shellfish Shippers List (ICSSL);

xi. notifying FDA of the name, location and certification number of KSSP certified processors exporting to the United States of America on Form FD-3038, "Shellfish Dealer Certification";

xii. canceling the certification of any processor that:

- operates out of compliance with the NSSP;
- ships molluscan shellfish from unapproved growing areas; or
- ships molluscan shellfish that otherwise do not conform to the requirements of the U.S. Federal Food, Drug, and Cosmetic Act,

the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, or Title 21 of the U.S. Code of Federal Regulations.

- fails to recall molluscan shellfish determined to be unsafe for human consumption;

xiii. ensuring that each container in a lot of molluscan shellfish certified for export to the United States of America is properly labeled in accordance with the NSSP;

xiv. maintaining a central file of all KSSP records, including an English version of all sanitary survey reports, patrol reports, and laboratory evaluation reports and make them available to FDA upon request;

xv. providing FDA evaluation reports, interpretations, laboratory quality assurance program information, and other molluscan shellfish program information from FDA to federal government agencies having responsibility for the KSSP;

xvi. reviewing, at least annually, the level of conformity with the NSSP and summarizing the findings in a written report and providing an English translation of the report to FDA annually;

xvii. providing FDA with information concerning current or potential public health problems affecting molluscan shellfish intended for export to the United States of America; and

xviii. making travel arrangements in the Republic of Korea for, and conducting joint inspections with, FDA evaluation officers at FDA's request. Providing transportation for FDA officials while in the Republic of Korea.

c. Permit the harvesting of molluscan shellfish for processing by KSSP certified processors and shipment to the United States of America only from growing areas approved by MOMAF with concurrence from the FDA.

d. Within 30 days of written notification from FDA of NSSP deficiencies, develop a written Corrective Action Plan, and submit it to FDA for review and concurrence. If a Plan is not developed within 30 days, FDA will remove Korean processors from the ICSSL and/or take other appropriate action to prevent molluscan shellfish from the Republic of Korea from entering the United States of America. In case of a serious public health threat, this 30 day period may be reduced or eliminated. Such action should remain in effect until all KSSP deficiencies have been corrected and FDA has determined that the KSSP is in compliance with the NSSP.

3. MOMAF may designate a KSSP laboratory evaluation officer to:

   a. certify laboratories participating in the KSSP;

   b. periodically evaluate certified KSSP laboratories to verify compliance with the NSSP and maintain laboratory quality assurance procedures;

   c. maintain a marine biotoxin monitoring program for growing areas where molluscan shellfish are harvested for export to the United States of America;

   d. maintain a split-sample program among KSSP laboratories for evaluating uniform microbiological laboratory practices;

   e. notify FDA of laboratories not in compliance with the NSSP; and

   f. prevent KSSP laboratories not in compliance with the NSSP from participating in the KSSP.

4. MOMAF should update the KSSP Model Ordinance to be consistent with published NSSP Model Ordinance revisions. MOMAF should provide an English version of all updates to FDA for review and concurrence.

5. Any change in responsibility from MOMAF to another authority must be reported to FDA within 30 days of such change. A change from MOMAF to a new authority may require re-evaluation of the KSSP by FDA.

B. RESPONSIBILITIES OF THE FDA

FDA intends to:

1. Accept the Republic of Korea as a participant in the NSSP and the Interstate Shellfish Sanitation Conference (ISSC), cooperative research programs, seminars, training courses, and other NSSP activities and have MOMAF certify Korean processors for inclusion in FDA's ICSSL.

2. Publish the names, locations, and certification numbers of Korean firms certified by MOMAF in the ICSSL upon receipt of Form FD-3038.

3. Provide training and technical assistance to MOMAF, subject to the availability of funds and personnel for such purposes.

4. Inform MOMAF of the reasons for any detention of certified molluscan shellfish shipments from the Republic of Korea.

5. Participate with MOMAF in joint evaluations of the KSSP. Joint evaluations will be conducted to ascertain the level of conformity with the requirements of the NSSP and with the responsibilities specified in this MOU. FDA should pay round trip transportation expenses between the United States of America and the Republic of Korea and the per diem of the members of the FDA evaluation team while in the Republic of Korea.

6. Notify MOMAF of NSSP deficiencies and request that MOMAF submit, within 30 days, a written Corrective Action Plan to FDA for review and concurrence. If a Plan is not developed within 30 days or if the deficiencies are not corrected in accordance with the Plan, FDA will remove Korean processors from the ICSSL and/or take other appropriate action to prevent Korean molluscan shellfish from entering the United States of America. In case of a serious public health threat, this 30-day period may be reduced or eliminated. Such action should remain in effect until all NSSP deficiencies have been corrected and FDA has determined that the KSSP is in compliance with the NSSP.

7. Remove individual Korean processors from the ICSSL when it is determined by FDA or MOMAF that a processor is not in compliance with the NSSP or when an imminent health hazard exists with a processor's product.

8. Report any change in responsibility from FDA to another federal authority to MOMAF within 30 days of such change.

ARTICLE IV
Technical Information Exchange

The working language for documents exchanged under this MOU should be English. The Participants plan to share expertise, provide assistance, and exchange information. Such mutual cooperation may include, but is not be limited to:

1. Exchanging information concerning proposed and final changes in KSSP operations and procedures including, but not limited to:

a. methods and procedures for sampling;

b. methods of analysis;

c. methods of confirmation;

d. administrative guidelines, tolerances, specification standards, and nomenclature;

e. reference standards; and

f. inspection procedures.

2. Providing written notification to the other Participant within 30 days of changes in liaison officers. Changing liaison officers does not otherwise constitute a change in the provisions of this MOU.

3. Facilitating the exchange of information between MOMAF and U.S. Federal and State agencies concerned with the introduction and proliferation of exotic organisms that might be carried by Korean molluscan shellfish.

ARTICLE V
Liaison Officers

In order to obtain an adequate follow up of the cooperation activities derived from this MOU, the liaison officers will be

A. For MOMAF:

Director, Fisheries Policy Bureau
Ministry of Maritime Affairs and Fisheries (MOMAF)
50 Chungjeong-no, Seodaemun-gu
120-715, Seoul, Korea
Telephone: 82 2 3148-6800

First Secretary for Maritime Affairs and Fisheries
Embassy of the Republic of Korea
2450 Massachusetts Avenue
Washington, D.C. 20008
The United States of America
Telephone: 01 202 939-5676

B. For the Food and Drug Administration:

Director, Office of Seafood
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
5100 Paint Branch Parkway (HFS-400)
College Park, MD 20740
The United States of America
Telephone: 01 301 436-2300

ARTICLE VI

Final Dispositions

Activities under this MOU commence upon signature by both Participants and continue for five (5) years. It may be extended with written consent of both Participants.

The Participants intend to evaluate the MOU during the five-year period. It may be amended by written consent of both Participants, specifying the date in which the activities will commence.

All activities undertaken pursuant to this MOU are to be conducted in accordance with the laws and regulations of the United States of America and the Republic of Korea and are subject to the availability of personnel, resources, and appropriated funds.

This MOU is not intended to create any obligations under international or other law.

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective Government agencies, have signed this Memorandum of Understanding.

Signed at Washington, D.C. and Rockville, Maryland on this twenty-eighth day of October 2003 in duplicate in the English language.

FOR THE MINISTRY OF MARITIME AFFAIRS AND FISHERIES OF THE REPUBLIC OF KOREA

On behalf of the Ambassador,
Jong Hwa Choe
Economic Minister

HAN SUNG-JOO

Ambassador to the United States
Embassy of the Republic of Korea

FOR THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA

On behalf of the Commissioner
Murray M. Lumpkin
Principal Associate
Commissioner

MARK B. McCLELLAN, M.D., Ph.D.

Commissioner of Food and Drugs

[FR Doc. 04–8443 Filed 4–14–04; 8:45 am]
BILLING CODE 4160–01–C

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 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.

Therapeutic Administration of the Scrambled Anti-Angiogenic Peptide C16Y

K.E. Csaky (NEI), M.L. Ponce (NEI), H. Kleinman (NIDCR)

PCT Application No. PCT/US04/04142 filed 12 Feb 2004 (DHHS Reference No. E–008–2004/0–PCT–01)

Licensing Contact: Susan Rucker; 301/435–4478; *ruckersu@mail.nih.gov.*

This application relates to the field of anti-angiogenesis. In particular, the application describes and claims compositions and methods useful for treating diseases associated with angiogenesis such as macular degeneration (AMD), diabetic retinopathy, neovascular glaucoma and cancers associated with solid tumors particularly, breast cancer. The compositions and methods offer alternatives to other ocular anti-angiogenic agents currently in development due to their ease of manufacture and mode of action on an integrin pathway.

The compositions and methods utilize a synthetic peptide of between 8 and 12 amino acid residues derived from a region of the γ1 chain of laminin-1 that binds to endothelial cell integrins αvβ3 and α5β1. The preferred embodiment, designated C16Y, is 12 amino acids in length and is easily prepared by conventional peptide synthesis. The anti-angiogenic properties of the C16Y peptide have been demonstrated in an *in vitro* model of choroidal neovascularization and in tumor-bearing mice.

This work has been published, in part at ML Ponce et al., Cancer Research 63(16): 5060 (Aug 15, 2003).

Hybrid Adeno-Retroviral Vector for the Transformation of Cells

Changyu Zheng, Brian C. O'Connell, Bruce J. Baum (NIDCR)

U.S. Provisional Application No. 60/179,327 filed 31 Jan 2000 (DHHS Reference No. E–258–1998/0–US–01); PCT Application No. PCT/US01/03026 filed 30 Jan 2001 (DHHS Reference No. E–258–1998/0–PCT–02); U.S. Patent Application No. 10/182,644 filed 30 Jul 2002 (DHHS Reference No. E–258–1998/0–US–03)

Licensing Contact: Jesse Kindra; 301/435–5559; *kindraj@mail.nih.gov.*

The invention described and claimed in this patent application provides for novel hybrid vectors which may be used for cell transformation, either *in vivo* or *in vitro.* The hybrid vectors have an adenoviral backbone with retroviral long terminal repeats (LTRs). Such vectors are capable of transforming dividing or non-dividing cells and integrate stably into the chromosome providing a means of efficient, reliable, long-term gene expression. The vector was packaged as a recombinant adenovirus and delivered to the target cell. Unlike other chimeric or hybrid vector systems, only a single vector is required to deliver a transgene of interest, and retroviral structural proteins are not required.

This work has been published, in part, in: Zheng *et al.,* Nature Biotechnol. (2000 Feb) 18(2):176–180; Zheng *et al.,* Biochem. Biophys. Res. Commun. (2002 Feb 15) 291(1):34–40; Zheng *et al.,* Biochem. Biophys. Res. Commun. (2003 Jan 3) 300(1):115–20; Zheng *et al.,* Virology (2003 Sep 1) 313(2):460–72.

Antitumor Macrocyclic Lactones

Michael R. Boyd (NCI)

U.S. Patent No. 6,353,019 issued 05 Mar 2002 (DHHS Reference No. E–244–1997/0–US–07) and related foreign patent applications; and

Vacuolar-Type (H+)-ATPase-Inhibiting Compounds and Uses Thereof

Michael R. Boyd (NCI)

U.S. Patent Application No. 09/914,708 filed 31 Aug 2001 (DHHS Reference No. E–244–1997/3–US–06) and related foreign patent applications

Licensing Contact: George Pipia; 301/435–5560; *pipiag@mail.nih.gov.*

This technology covers a broad composition of matter which includes the salicylihalamides, lobatamides, and numerous other structurally related small molecules which have been shown to inhibit mammalian vacuolar ATPase at low nanomolar concentrations. The compounds are also potent inhibitors of cancer cell growth, with particular specificity for melanoma, osteosarcoma and selected lung, colon and CNS tumor cell lines. Experimental tumor and pharmacokinetic studies are underway to select the most effective analogs for further development. The potential of these compounds to inhibit invasion and metastasis to bone sites is also under investigation.

Dated: April 7, 2004.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–8493 Filed 4–14–04; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting; Interagency Autism Coordinating Committee

The National Institutes of Health (NIH) hereby announces a meeting of the Interagency Autism Coordinating Committee (IACC) to be held on May 11, 2004, on the NIH campus in Bethesda, Maryland.

The Children's Health Act of 2000 (Pub. L. 106–310), Title I, Section 104, mandated the establishment of an Interagency Autism Coordinating Committee (IACC) to coordinate autism research and other efforts within the Department of Health and Human Services (DHHS). In April 2001, Secretary Tommy Thompson delegated the authority to establish the IACC to the NIH. The National Institute of Mental Health (NIMH) at the NIH has been designated the lead for this activity.

The IACC meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such