

be kept in an active file for two years. New hire information will then be stored for an additional three years before being destroyed.

Tax refund and administrative offset information will be maintained for six years in an active master file for purposes of collection and adjustment. After this time, records of cases for which there was no collection will be destroyed. Records of cases with a collection will be stored on-line in an inactive master file.

Records pertaining to passport denial will be updated and/or deleted as obligors meet satisfactory restitution or other State approved arrangements.

Records of information provided by the FPLS to authorized users will be maintained only long enough to communicate the information to the appropriate State or Federal agent. Thereafter, the information provided will be destroyed. However, records pertaining to the disclosures, which include information provided by States, Federal agencies contacted, and an indication of the type(s) of information returned, will be stored on a history tape and in hard copy for five years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Program Operations Office of Child Support Enforcement Administration for Children and Families 370 L'Enfant Promenade, SW., 4th Floor East Washington, DC. 20447.

NOTIFICATION PROCEDURES:

To determine if a record exists, write to the System Manager listed above. The requester must provide his or her full name and address. Additional information, such as your Social Security Number, date of birth or mother's maiden name, may be requested by the system manager in order to distinguish between individuals having the same or similar names.

RECORD ACCESS PROCEDURES:

Write to the System Manager specified above to attain access to records. Requesters should also reasonably specify the record contents they are seeking.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under system manager above, and reasonably identify the record and specify the information to be contested and corrective action sought with supporting justification to show how the record is inaccurate, incomplete, untimely or irrelevant.

RECORD SOURCE CATEGORIES:

Information is obtained from departments, agencies, or instrumentalities of the United States or any State.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 97-26049 Filed 10-1-97; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on October 24, 1997, 9:30 a.m. to 6 p.m.

Location: Gaithersburg Marriott Washingtonian Center, Salons C and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8243, ext. 157, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee is being asked to provide input to the agency regarding the design of clinical trials to support premarket approval applications for devices intended to treat atrial septal defects, patent foramen ovale, and patent ductus arteriosus. Of particular concern are the following issues: What are the appropriate controls to be used in such trials? What are the appropriate safety and efficacy measures? When should assessments of these measures be made?

Procedure: On October 24, 1997, from 12:30 p.m. to 6 p.m., the meeting is

open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 14, 1997. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 14, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On October 24, 1997, from 9:30 a.m. to 12:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). FDA staff will present trade secret and/or confidential information regarding pending and future circulatory system device submissions.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 25, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-26113 Filed 10-1-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-382]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated

burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* ESRD Beneficiary Selection and Supporting Regulations Contained in 42 CFR 414.330; *Form No.:* HCFA-382 (OMB# 0938-0372); *Use:* ESRD facilities have each new home dialysis patient select one of two methods to handle Medicare reimbursement. The intermediaries pay for the beneficiaries selecting Method I and the carriers pay for the beneficiaries selecting Method II. This system was developed to avoid duplicate billing by both intermediaries and carriers. *Frequency:* Other (One time only); *Affected Public:* Individuals or Households, Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 3,100; *Total Annual Responses:* 3,100; *Total Annual Hours:* 259.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 24, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.
[FR Doc. 97-26158 Filed 10-1-97; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the United States 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 U.S. 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 24, 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.

Genes for Niemann-Pick Type C Disease

DA Tagle, ED Carstea, JA Morris, PG Pentchev, WJ Pavan, MA Rosenfeld, SK Loftus (NINDS/NHGRI)
Serial No. 60/051,682 filed 03 Jul 97
Licensing Contact: Leopold J. Luberecki, Jr., 301/496-7735 ext. 223

Niemann-Pick disease is a class of inherited lipid storage diseases. Niemann-Pick Type C disease is an autosomal recessive neurovisceral lipid storage disorder which leads to systemic and neurological abnormalities including ataxia, seizures, and loss of speech. Patients with the disease typically die as children. The biochemical hallmark of Niemann-Pick Type C cells is the abnormal accumulation of unesterified cholesterol in lysosomes, which results in the delayed homeostatic regulation of both uptake and esterification of low density lipoprotein (LDL) cholesterol. Niemann-Pick Type C is characterized by phenotypic variability. The disease appears at random in families that have no history of the disorder, making diagnosis problematic. This invention provides the human gene for Niemann-Pick Type C disease and the nucleic acid sequences corresponding to the human gene for Niemann-Pick Type C disease. Also provided is the mouse homolog of the human gene. The invention could lead to improved diagnosis and the design of therapies for the disease and improved means of detection of carriers of the gene. In addition, this invention may contribute to the understanding and development of treatments for atherosclerosis, a more common disorder associated with

cholesterol buildup that involves the accumulation of fatty tissue inside arteries that blocks blood flow, leading to heart disease and stroke. The invention may also lead to additional discoveries concerning how cholesterol is processed in the body.

AIB-1, A Steroid Receptor Co-Activator Amplified in Breast and Ovarian Cancer

PS Meltzer, JM Trent (NHGRI)
OTT Reference No. E-018-97/0 filed 17 Jun 97
Licensing Contact: Ken Hemby, 301/496-7735 ext. 265

Breast cancer is the number one cancer in U.S. women, with over 185,000 cases in 1996 and an estimated 44,560 deaths in the past year. Breast cancer arises from estrogen-responsive breast epithelial cells. Estrogen activity is thought to promote the development of breast cancer, and many breast cancers are initially dependent on estrogen at the time of diagnosis. Anti-estrogen compositions have therefore been used to treat breast cancer.

AIB-1 (Amplified in Breast Cancer-1) is a novel gene that is pivotal to a crucial metabolic pathway linked to the growth and progression of human breast cancer. In many cancers, especially breast cancer, tumor cells have amplified copies of genes that can give the cancer a growth advantage. AIB-1, located on the long arm of chromosome 20, is one such amplified gene. High-level AIB-1 amplification and overexpression have been observed in several estrogen receptor (ER) positive breast and ovarian cancer cell lines, as well as in uncultured breast cancer specimens. AIB-1 has also been found to be expressed in prostate epithelial cells.

AIB-1 is the most recently identified member of a gene family known as SRC-1 (steroid receptor coactivator), all of which interact with genes for steroid hormone receptors, ultimately enhancing tumor cell growth.

This invention provides the gene for AIB-1, a novel steroid receptor co-activator which is overexpressed in breast cancer cells. It also encompasses diagnostic assays for steroid hormone-responsive cancers and screening assays to identify compounds which inhibit interactions of the co-activator with steroid hormone receptors and other proteins in this pathway.

Methods and Compositions for Inhibiting Inflammation and Angiogenesis

K Kelly (NCI)
Serial No. 60/027,871 filed 25 Oct 96