TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN YEAR 2[1]—Continued

| Questionnaire | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Month 9 Questionnaire | 1,875 | 1 | 1,875 | .25 | 469 |
| Month 10 Questionnaire | 2,250 | 1 | 2,250 | .42 | 945 |
| Month 12 Questionnaire | 2,250 | 1 | 2,250 | .42 | 945 |
| Total | | | 8,625 | | 3,304 |

[1]There are no capital costs or operating and maintenance costs associated with the collection of information.

The burden estimate is based on FDA's experience with the 1993 to 1994 survey mentioned in the previous paragraph and information available for the Diet History Questionnaire.

Dated: September 22, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–22052 Filed 9–30–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Preparation for the International Conference on Harmonization Meetings in Yokohama, Japan: Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH meetings in Yokohama, Japan'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Yokohama, Japan. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Experts Working Groups meetings in Yokohama, Japan on November 15 through 18, 2004, at which discussion of the topics underway and the future of ICH will continue.

*Date and Time*: The meeting will be held on October 19, 2004, from 1:30 to 3 p.m.

*Location*: The meeting will be held at 5600 Fishers Lane, 3rd floor, Chesapeake Conference Room, Rockville, MD. For security reasons, all attendees are asked to arrive no later than 1:15 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to the Chesapeake Conference Room.

*Contact Person*: Sema Hashemi, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3050, FAX 301–480–0716, e-mail: *Sema.Hashemi@fda.hhs.gov*.

*Registration and Requests for Oral Presentations*: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by October 15, 2004.

If you need special accommodations due to a disability, please contact Sema Hashemi at least 7 days in advance.

*Transcripts*: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

**SUPPLEMENTARY INFORMATION:** The ICH of Technical Requirements for the Registration of Pharmaceuticals for Human Use was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area, and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org.*

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 2:30 and 3 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by October 15, 2004, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on October 8, 2004, on the Internet at *http://www.fda.gov/cder/meeting/ICH_10192004.htm*.

Dated: September 23, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–22053 Filed 9–30–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Program Exclusions; Correction

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions; correction.

**SUMMARY:** The HHS Office of Inspector GeneralPublished a document in the **Federal Register** of September 15, 2003, imposed exclusions. The document contained an incorrect exclusion type.

**FOR FURTHER INFORMATION CONTACT:** Jacqueline Freeman, (410) 786–5197.

**Correction**

In the **Federal Register** of September 15, 2004, in FR Doc. 20710, on page 55641, correct the exclusion date to read:

| | |
|---|---|
| LABONTE, MARY ..... SCOTTSDALE, AZ | 9/20/2004 |

Dated: September 21, 2004.

**Katherine B. Petrowski,**

*Director, Exclusions Staff, Office of Inspector General.*

[FR Doc. 04–22046 Filed 9–30–04; 8:45 am]

**BILLING CODE 4150–04–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.

**Cytonectin, Cytonectin Gene and Cytonectin Inhibitors and Binding Ligands and Their Use in the Diagnosis and Treatment of Disease**

*Soni J. Anderson et al. (NCI)*

U.S. Provisional Application No. 60/553,977 Filed 18 Mar 2004 (DHHS Reference No. E–128–2004/0–US–01); U.S. Provisional Application No. 60/578,068 Filed 09 Jun 2004 (DHHS Reference No. E–128–2004/1–US–01)

Licensing Contact: Fatima Sayyid; (301) 435–4521; *sayyidf@mail.nih.gov*.

Cytonectin is a 35K molecular weight protein that displays ion-independent adherence properties, is expressed in a variety of organs and tissues and is evolutionarily conserved from human to rodent and avian species. Within the body it is thought to serve the function of ''super glue'' contributing to cell-cell interactions and 3-dimensional tissue structure and a physiologic ''do not attack'' signal molecule that prevents tissue destruction by cells of monocyte lineage including odontoclasts in secondary teeth. It also plays an important role in the pathology associated with cancer, arthritis, Alzheimer's and Parkinson's disease.

The present invention relates to cytonectin, to polynucleotides that encode cytonectin, to inhibitors and antibodies that bind to cytonectin and to the use of compositions in the diagnosis and treatment of cytonectin-related diseases and conditions.

**Genetic Fingerprint of Acute Stroke**

*Alison E. Baird (NINDS)*

U.S. Provisional Application No. 60/575,279 Filed 27 May 2004 (DHHS Reference No. E–306–2003/0–US–01)

Licensing Contact: Fatima Sayyid; (301) 435–4521; *sayyidf@mail.nih.gov*.

Stroke is the third leading cause of death and the leading cause of adult disability in developed countries. Despite the prevalence and burden of this disease, stroke precipitants and pathophysiological mechanisms in individual patients are often unknown. It is also difficult to accurately predict whether a stroke will lead to only minor neurological sequelae or more serious medical consequences. Although animal experiments in focally ischemic brain tissue have indicated that there are alterations in gene expression following a stroke, gene expression profiling has not yet been applied to clinical human stroke, primarily because brain tissue samples are inaccessible and rarely justified.

The present provisional patent application discloses methods of determining whether a subject had an ischemic stroke, methods of determining the prognosis of a subject who had an ischemic stroke, as well as methods of determining an appropriate treatment regimen for a subject who had an ischemic stroke.

**Inhibition of Smad3 To Prevent Fibrosis and Improve Wound Healing**

*Anita B. Roberts et al. (NCI)*

U.S. Patent Application No. 10/299,886 Filed 18 Nov 2002 (DHHS Reference No. E–070–2000/0–US–06), claiming priority to PCT Application No. PCT/US00/13725 Filed 19 May 2000 (DHHS Reference No. E–070–2000/0–PCT–01)

Licensing Contact: Marlene Shinn-Astor; (301) 435–4426; *shinnm@mail.nih.gov*.

Millions of dollars are spent each year to heal chronic non-healing wounds and in the treatment of severe burn patients. The NIH announces a new technology that may lead to improved approaches to treatment of burn patients and the reduction of scarring and more rapid closure of both acute (surgical) and chronic wounds (*e.g.,* diabetic, decubitus, and venus statis ulcers).

Smad2 and Smad3 are highly homologous cytoplasmic proteins which function to transduce signals from Transforming Growth Factor–beta (TGF–beta) and activin receptors to promoters of target genes found in the nucleus. This new technology indicates that interference with specific signaling pathways downstream of TGF–beta may be more selective and have a better outcome than approaches aimed at blocking all effects of this pleiotropic cytokine.

Specifically, it is proposed that elimination or inhibition of Smad3 may interfere with fibrogenic mechanisms and reduce the accumulation of scar tissue associated with high dose radiation and wound healing, while increasing the rate of re-epithelialization of wounds.