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

Date and Time: The meeting will be held on December 4, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Shalini Jain, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, e-mail: *jains@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up to date information on this meeting. Background materials for this meeting, when available, will be posted on the Web site 1 business day before the meeting at: *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*.

Agenda: The committee will discuss current screening methods to assess sound alike and look alike proprietary drug names, in order to reduce the incidence of medication errors resulting from look alike and sound alike names. This advisory committee meeting is in followup to the FDA, Institute for Safe Medication Practices, and the Pharmaceutical Research and Manufacturers of America public meeting on the same subject, held on June 26, 2003.

Procedure: 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 November 24, 2003. 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 November 24, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shalini Jain at least 7 days in advance of the meeting.

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

Dated: November 10, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–28685 Filed 11–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food 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). The meeting will be open to the public.

Name of Committee: Food Advisory Committee.

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

Date and Time: The meeting will be held on December 10, 2003, from 9:30 a.m. until 4:30 p.m. and on December 11, 2003, from 8:30 a.m. to 4 p.m.

Location: Hotel Washington, Pennsylvania Ave. at 15th St. NW., Washington, DC 20004–1099.

Contact Person: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 301–436–2397, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The purpose of the meeting is to review reports of the Dietary Supplements, Additives and Ingredients, Food Biotechnology, Contaminants and Natural Toxicants, and Infant Formula Subcommittees and to provide a status report and response to the Food Advisory Committee's recommendations on methyl mercury in fish and shellfish.

Procedure: 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 November 26, 2003. Oral presentations from the public on the subcommittee reports will be scheduled between approximately 11:30 a.m. and 12 noon on December 10, 2003, and from 9:15 a.m. and 12:15 p.m. on December 11, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 26, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Catherine DeRoever at least 7 days in advance of the meeting.

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

Dated: November 10, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–28684 Filed 11–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs 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). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on December 16, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776 or e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) General issues on clinical trial design and endpoints; and (2) non-small cell lung cancer endpoints as a follow-up to issues discussed at an April 15, 2003, FDA workshop.

Procedure: 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 December 9, 2003. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., and between approximately 2:30 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 9, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Trevelin Prysock at 301–827–7001 at least 7 days in advance of the meeting.

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

Dated: November 10, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–28687 Filed 11–17–03; 8:45 am]

BILLING CODE 4160–01–S

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 invention listed below is owned by an agency of the U.S. Government and is 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 application 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 application.

Methods of Diagnosis of Colorectal Cancer, Compositions and Methods of Screening for Modulators of Colorectal Cancer

Thomas Ried and Madhvi Upender (NCI).

U.S. Provisional Application No. 60/340,124 filed 13 Dec 2001 (DHHS Reference No. E–206–2003/0–US–01); U.S. Patent Application No. 10/318,578 filed 12 Dec 2002 (DHHS Reference No. E–206–2003/0–US–02).

Licensing Contact: Catherine Joyce; (301) 435–5031; *joycec@mail.nih.gov.*

Oncogene activation by gene amplification is a major pathogenetic mechanism in human cancer. Comparative genomic hybridization and DNA microarray expression profiling was used to examine the expression of over 2000 genes that were identified as residing on chromosome arms that were amplified in metastatic colon cancer cancers *i.e.* 7p, 8q, 13q, and 20q. The results indicated that amplified genes that also demonstrate increased expression levels are quite rare. However, the results also identified 93 genes, which reside on the chromosome arms in question, which showed an increased expression level concomitant with amplification. Some of these genes could provide targets for therapy.

As a result of the above findings, the inventors contemplate methods of diagnosing colon cancer through detection of the increased expression of one or more of the identified 93 genes. Aspects of this work have been published as follows: Platzer *et al.*, 2002, Silence of Chromosomal Amplifications in Colon Cancer, *Cancer Research* 62:1134–1138.

This technology is available for licensing on an exclusive or a non-exclusive basis.

Compositions and Methods for Detecting Abnormal Cell Proliferation

Lance Liotta *et al.* (NCI).

U.S. Provisional Application No. 60/466,154 filed 28 Apr 2003 (DHHS Reference No. E–253–2002/0–US–01).

Licensing Contact: Catherine Joyce; (301) 435–5031; *joycec@mail.nih.gov.*

The invention relates to the discovery that class 5 semaphorins are linked to cancer. A *Drosophila* model system was used to identify genes that functionally alter tumorigenicity or metastasis. Deletion of *Drosophila* lethal giant larvae (l(2)gl) leads to highly invasive and widely metastatic tumors on transplantation into adult flies. Random homozygous P element insertions were screened for the ability to modulate the l(2)gl phenotype. Analysis of metastasis patterns of the lines containing P element insertions and lacking wild-type l(2)gl expression identified Semaphorin 5c (Sema 5c) as being required for tumorigenicity.

Semaphorin 5c, is a transmembrane protein with a large extracellular domain that contains seven thrombospondin type I (Tsp I) repeats. The semaphorin 5c gene belongs to the class 5 group of semaphorins, which are transmembrane proteins with short cytoplasmic (C-terminal) tails and extracellular domains containing seven thrombospondin type I repeats, a plexin domain, and a semaphorin domain sequences. Class 3 semaphorins, previously linked to cancer, are structurally different from class 5, lacking the thrombospondin repeats present in the transmembrane class 5 semaphorins.

The invention is a screening method using *Drosophila* to (a) screen for functional important genes associated with cancer growth, invasion and metastasis, and (b) screen for the effects of an anti-cancer targeted therapy by administering the therapy to the drosophila host bearing the tumor. In addition the invention covers a specific gene Semaphorin 5c which is a potential therapeutic target acting in the TGFbeta pathway.