## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2006D–0066]**

### Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry and FDA Staff: Whole Grain Label Statements.'' The draft guidance is intended to provide guidance to industry about what the agency considers to be ''whole grain'' and to assist manufacturers in labeling their products.

**DATES:** Submit written or electronic comments concerning the draft guidance by April 18, 2006, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance, to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1491, e-mail: *shellee.anderson@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Through the years, the Federal Government has worked to provide consistent and scientifically sound recommendations to consumers about healthy eating patterns and wise food choices. Such advice originated with the ''Basic Four'' and has progressed through today's ''Dietary Guidelines for Americans'' (developed jointly by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture). ''Dietary Guidelines for Americans, 2005'' (2005 DG) recommends that Americans, among other things, ''consume 3 or more ounce-equivalents of whole grain products per day, with the rest of the recommended grains coming from enriched or whole-grain products'' and that ''in general at least half the grains should come from whole grains'' (Ref. 1).

Manufacturers may make factual statements about whole grains on the label of their products, such as ''100% whole grain'' (as percentage labeling under 21 CFR 102.5(b)) or ''10 grams of whole grains'' (21 CFR 101.13(i) (3)) provided that the statements are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(a)) and do not imply a particular level of the ingredient, i.e., ''high'' or ''excellent source.'' In addition, manufacturers may use health claims relating whole grains to a reduced risk of coronary heart disease and certain cancers on their product labels for qualifying foods based on notifications FDA received under section 403(r) (3) (C) of the act (21 U.S.C. 343(r)(3)(C)) (health claims based on an authoritative statement of a scientific body) (see *http://www.cfsan.fda.gov/~dms/labfdama.html*). To assist manufacturers in labeling their products, the agency has reviewed various industry and scientific definitions of ''whole grains'' and developed guidance to industry about what the agency considers to be ''whole grain.''

The agency has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance is being issued as a Level 1 guidance document consistent with the GGPs. The draft guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

#### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at: *http://www.cfsan.fda.gov/guidance.html*.

#### IV. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture, ''Dietary Guidelines for Americans, 2005,'' *http://www.healthierus.gov/dietaryguidelines*, 2005.

Dated: February 14, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 06–1509 Filed 2–15–06; 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, 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.

**Anti-Viral Griffithsin Compounds, Compositions, and Methods of Use**

Barry R. O'Keefe *et al.* (NCI)
U.S. Provisional Application No. 60/741,403 filed 01 Dec 2005 (HHS Reference No. E–025–2006/0–US–01).
*Licensing Contact:* Sally H. Hu, Ph.D., M.B.A.; 301/435–5606; *hus@mail.nih.gov.*

The invention provides for a composition of an anti-viral polypeptide, Griffithsin, glycosylation-resistant Griffithsin, and related conjugates, compositions, nucleic acids, vectors, host cells, antibodies and methods of production and use. More specifically, Griffithsin inhibits viral binding, fusion and entry into the host cells by binding to viral envelope gp120. Thus, subject invention can be developed as an inhibitor therapeutically or prophylactically against retroviral infections including HIV–1 and HIV–2 as well as FIV, SIV, MLV, BLV, equine infectious virus, avian sarcoma viruses, and HTLV. Subject invention also can be developed as an inhibitor against non-retroviruses infectious such as influenza virus, including H5N1, SARS, Hepatitis C, and Ebola, measles, varicella, human herpes viruses and others. In addition, Griffithsin can be used in combination with other anti-viral agents to treat patients who have drug-resistant virus.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

**Discovery of Tropolone Inhibitors of HIV–1 Integrase That Can Be Used for the Treatment of Retroviral Infection, Including AIDS**

Yves Pommier, Christophe Marchand, Elena Semenova, Allison Johnson (NCI).
U.S. Provisional Application No. 60/741,769 filed 01 Dec 2005 (HHS Reference No. E–308–2005/0–US–01).
*Licensing Contact:* Sally H. Hu, Ph.D., M.B.A.; 301/435–5606; *hus@mail.nih.gov.*

This invention provides pharmaceutical compositions comprising one or more HIV–1 integrase inhibitor compounds, as well as methods for treatment or prevention of HIV infection. These compounds are alpha-hydroxytropolone or its salt, solvate or hydrate, and they have been shown to inhibit the integrase by interfering with the enzyme catalytic site by chelating magnesium ions, and have been shown to inhibit the strand transfer reaction. Integrase is an important target for AIDS therapy since it is critical for viral replication, and does not have cellular counterparts, which can potentially reduce toxic side effects. Thus, the compounds of this invention can be developed as novel anti-viral agents that can be used in combinational therapy, especially since they might be less toxic than other anti-viral agents.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Dated: February 10, 2006.

**Steven M. Ferguson,**

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

[FR Doc. E6–2357 Filed 2–16–06; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Initial Review Group, Subcommittee H—Clinical Groups.

*Date:* March 6–8, 2006.

*Time:* 6 p.m. to 9:30 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Providence Biltmore, 11 Dorrance Street, Providence, RI 02903.

*Contact Person:* Timothy C. Meeker, MD, Ph.D., Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8088, Bethesda, MD 20892. (301) 594–1279, *meekert@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 10, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06–1467 Filed 2–16–06; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; SBIR Topic 217, ''Nanoparticle Biosensors for Recognition of Exposure and Risk Analysis in Cancer''.

*Date:* March 16, 2006.

*Time:* 12 p.m. to 4 p.m.

*Agenda:* To review and evaluate contract applications.

*Place:* National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

*Contact Person:* C. Michael Kerwin PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of