

TABLE 1.—LIST OF REGULATIONS—Continued

| 21 CFR Section | FCC Edition and/or Supplement Currently Referenced | Name of Additive | Current FCC Reference |
|----------------|----------------------------------------------------|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 173.165(d) | 3d Ed. | <i>Candida lipolytica</i> | Citric acid produced must conform to FCC specifications (under "Citric acid"). |
| 173.228(a) | 4th Ed. | Ethyl acetate | Meets FCC specifications. |
| 173.280(c) | 3d Ed. | Solvent extraction process for citric acid | Meets FCC specifications. |
| 173.310(c) | 4th Ed. | Boiler water additives; Sodium carboxymethylcellulose | Contains not less than 95% sodium carboxymethylcellulose on a dry-weight basis, with maximum substitution of 0.9 carboxymethylcellulose groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2% by weight aqueous determined by the method cited in FCC. |
| 173.310(c) | 4th Ed. | Boiler water additives; Sorbitol anhydride esters | Meets FCC specifications. |
| 173.368(c) | 4th Ed. | Ozone | Meets FCC specifications. |
| 178.1005(c) | 3d Ed. | Hydrogen peroxide solution | Meets FCC specifications. |
| 180.25(b) | 3d Ed. | Mannitol | Meets FCC specifications. |
| 180.30(a) | 3d Ed. | Brominated vegetable oil | Meets FCC specifications. |
| 180.37(b) | 3d Ed. | Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin | Meets FCC specifications. |

The agency has determined under 21 CFR 25.30(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 4, 2010.

Catherine L. Copp,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2010-19722 Filed 8-9-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, September 7, 2010, 8:30 a.m. to September 8, 2010, 12 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892, which was published in the

Federal Register on July 22, 2010, 75 FR42758.

This amendment has been processed to change the start and end times of the NCAB meeting. The meeting will now start at 4 p.m. and end at 5:45 p.m. on September 7, 2010. On September 8, 2010, the closed session will be held from 8:30 a.m. to 10 a.m. The open session will start at 10:15 a.m. and end at 5 p.m.

Dated: August 4, 2010.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-19681 Filed 8-9-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Griffithsin, Glycosylation-Resistant Griffithsin, and Related Conjugates as Biotherapeutics for the Treatment of HIV and HCV Infections

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive license to practice the inventions embodied in:

1. U.S. Provisional Patent Application Serial No. 60/576,056, filed on June 1, 2004, entitled "Griffithsin, Glycosylation-Resistant Griffithsin, and Related Conjugates, Compositions, Nucleic Acids, Vectors, Host Cells, Methods of Production And Methods of Use", converted to PCT/US2005/18778, filed May 27, 2005, and entered national stage in U.S. (patent application serial number 11/569,813), Canada (patent application serial number 2,567,728), Australia (patent application serial number 2005250429), Europe (patent application serial number 05804849.7), Japan (patent application serial number 2007-515398), Israel (patent application serial number 179236), New Zealand (patent number 2006/09573), and South Africa (patent application serial number 2006/09573) (HHS reference E-106-2003/0) from Dr. Barry O'Keefe *et al.* (NCI).

2. U.S. Provisional Patent Application Serial No. 60/741.403, filed on

December 1, 2005, entitled "Antiviral Activity Of Griffithsin Against SARS And HCV", converted to PCT/US2006/045930, filed December 1, 2006, and entered national stage in U.S. (patent application serial number 12/095,697), and Europe (patent application serial number 06838737.2) (HHS reference E-025-2006/0) from Dr. Barry O'Keefe *et al.* (NCI).

To Rodos Biotarget GmbH (Rodos here after) having a place of business in Germany. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before September 9, 2010 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Sally Hu, PhD, M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; *E-mail:* hus@od.nih.gov; *Telephone:* (301) 435-5606; *Facsimile:* (301) 402-0220.

SUPPLEMENTARY INFORMATION:

The first invention, E-106-2003, provides for isolated and purified Griffithsin protein and antibodies, plus related purified nucleic acids. Griffithsin is a novel, potent anti-HIV protein isolated from an aqueous extract of the red algae Griffithsia and Griffithsin inhibits viral binding, fusion and entry into the host cells by binding to viral envelope gp120. In addition, E-106-2003 also provides the methods of producing Griffithsin and methods of inhibiting a viral infection (incl. HIV), as well as vaccine development, and screening assays.

The second invention, E-025-2006, follows its predecessor patent application (E-106-2003) and claims new indications in particular for severe acute respiratory syndrome (SARS) and Hepatitis C. More specifically, the subject 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.

Based on the above two inventions, Griffithsin can be developed as an HIV entry inhibitor therapeutically or prophylactically against retroviral infections and 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.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 30 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The prospective exclusive license will enter an agreement with University of Canterbury in Christchurch of New Zealand complying with the U.S. Government's policy of the U.N. CBD for sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic researches with the "Source Country" providing such resources (U.N. CBD; Article 15.7: <http://www.cbd.int/convention/convention.shtml>).

The field of use may be limited to the development of non-encapsulated and encapsulated Griffithsin for use in treating human viral infections where those viral infections are human immunodeficiency virus (HIV) or hepatitis C virus (HCV).

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 3, 2010 .

Richard U. Rodriguez,

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

[FR Doc. 2010-19680 Filed 8-9-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0364]

Advancing the Development of Medical Products Used In the Prevention, Diagnosis, and Treatment of Neglected Tropical Diseases; Public Hearing; Change of Hearing Date and Location

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a change in date and location for the upcoming public hearing entitled "Advancing the Development of Medical Products Used in the Prevention, Diagnosis, and Treatment of Neglected Tropical Diseases." A new date and address are given for those attending the public hearing.

DATES: The public hearing will be held on September 23, 2010, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or it may end early.

ADDRESSES: The public hearing will be held at the National Labor College, 10000 New Hampshire Ave., Silver Spring, MD 20903. Persons attending the public hearing are advised that FDA is not responsible for providing access to electrical outlets.

FOR FURTHER INFORMATION CONTACT: Ann M. Staten, Office of Critical Path Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 32, rm. 4106, Silver Spring, MD 20993-0002, 301-796-8504, Ann.Staten@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 20, 2010 (75 FR 42103), FDA published a notice announcing a public hearing that is intended to solicit general views and information from interested persons on issues related to advancing the development of medical products (drugs, biological products, and medical devices) used in the prevention, diagnosis, and treatment of neglected tropical diseases. The registration dates from the July 20, 2010, notice have not changed. Individuals interested in making an oral presentation should submit a notice of participation by September 1, 2010. All others attending the public hearing are requested to register by September 17, 2010.

Because of a scheduling conflict with the published date, FDA is announcing in this notice a new date and location for the public hearing.

II. New Date and Location for the Public Hearing

The new date will be September 23, 2010 (see **DATES**). The new location will be the National Labor College (see **ADDRESSES**). Directions and information on parking, accommodations, and transportation options can be found at <http://www.nlc.edu/about/maps-and-directions>.