brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27956 Filed 11–19–09; 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.

Phage Display Plasmids With Improved Expression Properties for Human and Chimeric Nonhuman/Human Fab Libraries

Description of Invention: The Fab molecule was the first generated antibody fragment and still dominates basic research and clinical applications. New phage display vectors were designed to generate and select Fab libraries with human constant domains. These vectors facilitate bacterial expression of human, humanized, and chimeric nonhuman/human Fab antibody fragments. They differ from currently available pComb3H and pComb3X phage display vectors by assembling human and chimeric nonhuman/human Fab libraries in two rather than three PCR steps. As a result, these novel constructs retain the initial variable light and heavy chain sequences and improve the resulting Fab library's complexity in terms of number, diversity, and affinity. These constructs were developed with and without a His tag and yield approximately 100 μg to 2 mg of protein, which can be used for evaluation and characterization of Fab binding properties such as affinity and specificity. Notably, the His tag provides a handle to easily purify Fab.

Applications

- Generation of human, humanized, and chimeric nonhuman/human Fab antibody fragments.
- Research tool to characterize Fab antibody fragments.

Advantages

- Improved Fab library with complexity and number, diversity, and affinity.
- His tag construct allows for simplified purification assays.

Inventor: Christoph Rader (NCI).

Relevant Publications

1. KY Kwong and C Rader. E. coli expression and purification of Fab antibody fragments. Curr Protoc Protein Sci. 2009 Feb;Chapter 6:Unit 6.10.

2. T Hofer *et al.* Chimeric rabbit/human Fab and IgG specific for members of the Nogo-66 receptor family selected for species cross-reactivity with an improved phage display vector. J Immunol Methods. 2007 Jan 10;318(1–2):75–87.

Patent Status: HHS Reference No. E–008–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Potent and Selective Inhibitors of Human Lipoxygenase for Prostate Cancer Therapy

Description of Invention: With more than $2 billion in revenues in the US in 2007, the market for diagnostic and therapeutic products for prostate cancer is substantial. More than 2,000,000 American men currently live with prostate cancer and more than 200,000 new cases are diagnosed each year.

Researchers led by Dr. David Maloney at the National Human Genome Research Institute (NHGRI) have discovered several novel compounds that selectively and potently inhibit lipoxygenase (LOX), an enzyme that metabolizes polyunsaturated fatty acids which has been implicated in the pathogenesis of prostate cancers. These novel compounds are small molecules, and as such have an advantage over antibody-based technologies in this market. As prostate cancer is the most commonly diagnosed malignancy among men in the USA and Europe, the significant need for new therapies suggests that these novel LOX inhibitor compounds have a strong potential of reaching the marketplace.

Applications

- Therapeutics for prostate cancer.
- Therapeutics for several other LOX-associated pathologies including atherosclerosis, asthma, other cancers, glomerulonephritis, osteoporosis, and Alzheimer's disease.

Advantages

- Potent and selective inhibitory activity to reduce negative side effects.
- Compounds are small molecules (less immunogenic than antibodies).

Development Status: Pre-clinical.

Inventors: David Maloney *et al.* (NHGRI).

Relevant Publications

1. V Kenyon *et al.* Novel human lipoxygenase inhibitors discovered using virtual screening with homology models. J Med Chem. 2006 Feb 23;49(4):1356–1363.

2. JD Deschamps *et al.* Baicalein is a potent in vitro inhibitor against both reticulocyte 15-human and platelet 12-human lipoxygenases. Bioorg Med Chem. 2006 Jun 15;14(12):4295–4301.

3. Y Vasquez-Martinez *et al.* Structure-activity relationship studies of flavonoids as potent inhibitors of human platelet 12-hLO, reticulocyte 15-hLO–1, and prostate epithelial 15-hLO–2. Bioorg Med Chem. 2007 Dec 1;15(23):7408–7425.

4. J Inglese *et al.* Quantitative high-throughput screening: a titration-based approach that efficiently identifies biological activities in large chemical libraries. Proc Natl Acad Sci USA. 2006 Aug 1;103(31): 11473–11478.

Patent Status: U.S. Provisional Application No. 61/238,972 filed 01 Sep 2009 (HHS Reference No. E–252–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Patrick P. McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov.*

Collaborative Research Opportunity: The NIH Chemical Genomics Center, NHGRI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please

contact Claire Driscoll at *cdriscol@mail.nih.gov* or 301–594–2235 for more information.

Dated: November 13, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–27925 Filed 11–19–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0614]

Guidance for Industry on Changes to Approved New Animal Drug Applications—New Animal Drug Applications Versus Category II Supplemental New Animal Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #191 entitled ''Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs.'' This guidance is intended to assist sponsors who wish to apply for approval of changes to approved new animal drugs that require FDA to reevaluate safety and/or effectiveness data. The goal of this guidance is to create greater consistency in how such applications are handled by sponsors and by FDA's Center for Veterinary Medicine (CVM).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8105, e-mail: *suzanne.sechen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry #191 entitled ''Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs.'' This guidance is intended to assist sponsors who wish to apply for approval of changes to approved new animal drugs that require FDA to reevaluate safety and/or effectiveness data. The guidance explains how the Office of New Animal Drug Evaluation (ONADE) categorizes possible changes to approved new animal drugs that require reevaluation of safety and/or effectiveness data and explains which administrative vehicle—a new original new animal drug application (NADA) (new NADA) or a Category II supplemental application to the original new animal drug application (Category II supplemental NADA)—a sponsor should use when applying for approval of these changes. The goal of this guidance is to create greater consistency in how such applications are handled by sponsors and by ONADE.

In the **Federal Register** of December 16, 2008 (73 FR 76363), FDA published the notice of availability for a draft guidance entitled ''Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs,'' which gave interested persons until February 17, 2009, to comment on the draft guidance. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition to some of the changes based on the comments received, CVM made a few minor changes to the guidance to add clarity and accuracy. The guidance announced in this notice finalizes the draft guidance dated December 16, 2008.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The 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. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control no. 0910–0032 (expiration date April 30, 2010).

IV. Comments

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/default.htm* or *http://www.regulations.gov*.

Dated: November 13, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27926 Filed 11–19–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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