

related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs. Among these measures, FDA agreed to publish guidance on the contents of a complete submission package for a proposed proprietary name for a drug/biological product. FDA also agreed to performance goals for review of proprietary names submitted during the investigational new drug application (IND) phase or with a new drug application (NDA) or biologics license application (BLA); the goals stipulate that a complete submission is required to begin the review clock. (See section IX.A of the goals letter at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm>).

This proprietary names submission guidance is intended to promote prevention of medication errors by assisting industry in the submission of complete product information that will help FDA to evaluate the safety of proposed proprietary drug and biological product names, taking into account other factors that, in association with the name, can contribute to medication errors. In addition, FDA intends to use this information in the assessment of promotional aspects of proposed proprietary names.

This proprietary names submission guidance applies to prescription drug products, including biologics, that are the subject of an IND, NDA, abbreviated new drug application (ANDA), or BLA; and nonprescription drug products that are the subject of an IND, NDA, or ANDA.

The proprietary names submission guidance does not address other performance goals under PDUFA IV, including developing FDA internal policies and procedures to ensure that proprietary name review goals are met; developing guidance on best practices for naming, labeling, and packaging drugs and biologics to reduce medication errors; developing guidance on proprietary name evaluation best practices; and developing and implementing a pilot program for evaluating proposed proprietary names. These performance goals are or will be addressed elsewhere.

In the **Federal Register** of November 24, 2008 (73 FR 71009), FDA announced the availability of a draft guidance for industry entitled "Contents of a Complete Submission for the Evaluation of Proprietary Names" and invited comments. Many comments discussed topics that were beyond the scope of the proprietary names submission guidance,

including other performance goals under PDUFA IV that are addressed in other public dockets. These comments concerned the contents of any industry-sponsored reviews and data for submission to FDA under the pilot program described in the FDA concept paper entitled "PDUFA Pilot Project Proprietary Name Review" (concept paper) (73 FR 58604, October 7, 2008). FDA acknowledges that information in the proprietary names submission guidance could be useful to participants in the voluntary pilot program for proprietary name review. However, the proprietary names submission guidance does not describe the information needed by FDA to evaluate proposed proprietary names under the pilot program. Rather, the purpose is limited to informing industry about what information is needed by FDA to evaluate proposed proprietary names within PDUFA IV goal dates under the traditional review process. We welcome submission of comments about the tools and methods FDA uses for its analysis of proposed proprietary names under the pilot program to docket number FDA-2008-N-0281.

After considering comments on the draft guidance, FDA has issued the proprietary names submission guidance. Changes made to the guidance were editorial and primarily clarifying in response to comments. The revisions included: (1) Clarifying that the purpose of this guidance is to provide industry with a complete listing of the information FDA needs to evaluate a proposed proprietary name under the traditional review process; (2) adding the respective PDUFA IV review performance timeframes for complete submissions of a proposed proprietary name submitted during the IND phase or with an NDA, BLA, or supplement; and (3) referencing the concept paper<sup>1</sup> for a complete discussion of the tools and methods used for FDA's safety evaluation that are mentioned in the proprietary names submission guidance.

This 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 contents of a complete submission for the evaluation of proprietary names. 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.

<sup>1</sup> Available on the Internet at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072229.pdf>.

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

## 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 in 21 CFR part 312 and FDA Form 1571 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 and FDA Form 356h have been approved under OMB control number 0910–0338.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: February 3, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Exclusive License: Purified Inactivated Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in the 3'-UTR of Dengue Types 1,2,3, and 4**

**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 following invention as embodied in the following patent applications:

(1) E-120-2001/0, Whitehead *et al.*, "Development of Mutations Useful for Attenuating Dengue Viruses and Chimeric Dengue Viruses"—European Patent Application Number 02739358.6, filed May 22, 2002; United States Patent Application Number 10/719,547, filed November 21, 2003, now U.S. Patent Number 7,226,602, issued June 5, 2007; Canadian Patent Application Number 2448329, filed May 22, 2002; Australian Patent Application Number 2002312011, filed May 22, 2002, now Australian Patent Number 2002312011, issued August 8, 2007; Brazilian Patent Application Number PI0209943.8, filed May 22, 2002; Indian Patent Application Number 2184/DELNP/2003, filed May 22, 2002, now Indian Patent Number 218306, issued March 31, 2007; Indian Patent Application Number 165/DELNP/2008, filed May 22, 2002; United States Patent Application Number 11/446,050, filed June 2, 2006, now U.S. Patent Number 7,560,118, issued July 14, 2009; Australian Patent Application Number 2008203275, filed May 22, 2002; Indian Patent Application Number 204/DELNP/2005, filed May 22, 2002; and United States Patent Application Number 12/396,376, filed March 2, 2009

(2) E-089-2002/0,1, Whitehead *et al.*, "Dengue Tetraivalent Vaccine Containing a Common 30 Nucleotide Deletion in the 3'-UTR of Dengue Types 1,2,3, and 4, or Antigenic Chimeric Dengue Viruses 1,2,3, and 4"—United States Patent Application Number 10/970,640, filed October 21, 2004, now United States Patent Number 7,517,531, issued April 14, 2009; Canadian Patent Application Number 2483653, filed April 25, 2003; European Patent Application Number 03724319.3, filed April 25, 2003; Japanese Patent Application Number 2004-50077, filed April 25, 2003; Indian Patent Application Number 3450/DELNP/2004, filed April 25, 2003, now Indian Patent Number 3450/DELNP, issued May 29, 2006; Australian Patent Application 2003231185, filed April 25, 2003, now Australian Patent Number 2003231185, issued January 10, 2008; United States Patent Application Number 12/398,043, filed March 4, 2009; and Brazilian Patent Application PI0309631-9, filed April 25, 2003

(3) E-139-2006/0, Whitehead *et al.*, "Development of Dengue Vaccine Components"—Australian Patent Application 2007285929, filed August 15, 2007; Canadian Patent Application Number 2661296, filed August 15, 2007; Chinese Patent Application Number 200780031489.4, filed August 15, 2007; European Patent Application Number 07840969.5, filed August 15, 2007; Indian Patent Application Number 1608/DELNP/2009, filed August 15, 2007; United States Patent Application Number 12/376,756, filed February 6, 2009; and Brazilian Patent Application TBA, filed August 15, 2007 to GlaxoSmithKline Biologicals, having a place of business in Rixensart, Belgium. The patent rights in this invention 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 March 10, 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: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; E-mail: [ps193c@nih.gov](mailto:ps193c@nih.gov); Telephone: (301) 435-4646; Facsimile: (301) 402-0220.

**SUPPLEMENTARY INFORMATION:** The global prevalence of dengue has grown dramatically in recent decades. The disease is now endemic in more than 100 countries in Africa, North and South America, the Eastern Mediterranean, Southeast Asia and the Western Pacific. Southeast Asia and the Western Pacific are most seriously affected. Before 1970 only nine countries had experienced Dengue Hemorrhagic Fever (DHF) epidemics, a number that had increased more than four-fold by 1995. WHO currently estimates there may be 50 million cases of dengue infection worldwide every year.

The methods and compositions of this invention provide a means for prevention of dengue infection and dengue hemorrhagic fever (DHF) by immunization with attenuated, immunogenic viral vaccines against dengue. The vaccine is further described in Blaney JE *et al.*, "Mutations which enhance the replication of dengue virus type 4 and an antigenic chimeric dengue virus type 2/4 vaccine candidate in Vero cells." *Vaccine*. 2003 Oct 1;21(27-30):4317-27 and Whitehead SS *et al.*, "A live, attenuated dengue virus type 1 vaccine candidate with a 30-nucleotide

deletion in the 3' untranslated region is highly attenuated and immunogenic in monkeys." *J. Virol.* 2003 Jan;77(2):1653-7.

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 thirty (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 field of use may be limited to purified inactivated vaccines against dengue infections in humans.

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: January 28, 2010.

**Richard U. Rodriguez,**

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

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

#### Agency Information Collection Activities: Form I-129, Revision of an Existing Information Collection; Comment Request

**ACTION:** 60-Day Notice of Information Collection Under Review: Form I-129, Petition for Nonimmigrant Worker; OMB Control Number 1615-0009.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for 60 days until April 9, 2010.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated