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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License:** Avian influenza vaccines for domesticated poultry/wild birds to be provided to the National Veterinary Stockpile program and avian influenza vaccines to be sold as Veterinary Biological Products.

**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, is contemplating the grant of an exclusive license to practice the inventions embodied in Patent Applications USSN 61/021,596, filed Jan 16, 2008; 61/023,341, filed Jan 24, 2008; PCT/US2009/031329, filed Jan 16, 2009; and USSN 12/838,292, filed Jul 16, 2010; entitled "Influenza DNA Vaccination and Methods of Use Thereof", by Rao et al (NIAID/VRC) (E-050-2008/0,1,2,3), to ANQUAGEN, LLC having a place of business at 2329 N. Career Avenue, Suite 306, Sioux Falls, SD 57107. The patent rights in this invention have been assigned to the United States of America.

**DATE:** Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Cristina Thalhammer-Reyero, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: ThalhamC@mail.nih.gov; Telephone: 301-435-4507; Facsimile: 301-402-0220.

**SUPPLEMENTARY INFORMATION:**

The prospective worldwide 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 fifteen (15) 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 invention relates to compositions and methods of use as Veterinary Influenza Vaccines. Sustained outbreaks of highly pathogenic influenza in animals increase the risk of reassortment and adaption to humans. This technology describes DNA vaccines against influenza serotypes H5N1, H1N1, H3N2, and H3N8 for poultry, swine and equine. Particularly one vaccine, a trivalent combination of H5N1 immunogens, effectively protects against homologous and heterologous challenges. These vaccines can be delivered intramuscularly or through needle-free delivery mechanism. These veterinary influenza vaccines are specifically designed for poultry, swine and equine recipients, with the following advantages: a) More efficient and versatile than the conventional inactivated whole-virus vaccines; b) Can be precisely tailored to target one or more strains of avian, swine or equine outbreaks; c) Adaptable to large scale immunization; e) Shorter production time than the current egg-based technology; f) Noninfectious and safe to manipulate and handle; g) Needle-free device delivery elicits robust cellular immune response; and h) Because they do not contain other viral proteins, a diagnostic test will enable vaccinated animals to be differentiated from naturally infected animals, key if

governments mandate vaccination and a vital consideration for the international industry. Data are available for mice, chickens, pigs, and horses.

The field of use may be limited to "Avian influenza vaccines for domesticated poultry/wild birds to be provided to the National Veterinary Stockpile program and avian influenza vaccines to be sold as Veterinary Biological Products".

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.

December 15, 2011
Date

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

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