DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Oral Treatment of Hemophilia

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.


DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before October 21, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments and other materials relating to the contemplated Exclusive Patent License should be directed to: Vince Contreras, Ph.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4711; Facsimile: (301) 402–0220; Email: vince.contreras@nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This technology relates to therapeutic methods of arresting bleeding episodes in a subject having hemophilia A or B, by orally administering an effective amount of the appropriate clotting factor, sufficient to induce oral tolerance and supply exogenous clotting factor to the subject. Roughly 20,000 people in the U.S. have hemophilia with over 200 new patients born every year. Currently there is no cure for hemophilia and treatment generally involves intravenous infusion of missing clotting factors derived from concentrated preparations of donated blood plasma which can be expensive and result in generating inhibitory antibodies. The current technology provides a rapid, inexpensive oral treatment for individuals suffering from hemophilia A or B by utilizing a high quantity source of clotting factors produced in milk. The prospective worldwide Exclusive Patent License will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. 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 part 404. Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the contemplated Exclusive Patent 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.


Richard U. Rodriguez,

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

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BILLING CODE 4140–01–P
nominated substances to propose for formal evaluation for the RoC. 

20 Substances Nominated to the RoC*

- Aloe vera whole leaf extract (Aloe barbadensis Miller)
- 2-Butoxyethanol (CAS No. 111–76–2)
- Chlorothalonil (2,4,5,6-tetrachloroisopthalonitrile) (CAS No. 1897–45–6)
- Coconut diethanolamide (CAS No. 68603–42–9)
- Cobalt (metal) (CAS No. 7440–48–4)
- Docosan (CAS No. 91–17–8)
- Ginkgo biloba extract
- Goldenseal root powder (Hydrastis canadensis)
- Kava kava extract
- 2-Methylimidazole (CAS No. 693–98–1)
- 4-Methylimidazole (CAS No. 822–36–6)
- Methyl isobutyl ketone (CAS No. 108–10–1)
- Nickel nanoparticles
- Nitro polycyclic aromatic hydrocarbons (PAH) as a class
- Perfluorooctanoic acids (PFOA) (CAS No. 335–67–1)
- Polyacrylates
- Pulegone (CAS No. 89–82–7)
- Tetralin (CAS No. 119–64–2)
- Tris-(1,3-dichloro-2-propyl) phosphate (chlorinated Tris, TDCPP) (CAS No. 13674–87–8)
- Wood smoke

* Nominations to the RoC may seek to reclassify the listing status of a listed substance.

Background Information on the RoC:
The RoC is a congressionally mandated, science-based, public health report that identifies agents, substances, mixtures, or exposures (collectively called “substances”) in our environment that pose a cancer hazard for people in the United States. The NTP prepares the RoC on behalf of the Secretary of Health and Human Services. The NTP follows an established, four-part process for preparation of the RoC (http://ntp.niehs.nih.gov/go/rocprocess). Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. The 12th RoC, the latest edition, was published on June 10, 2011 (available at http://ntp.niehs.nih.gov/go/roc12). The 13th RoC is under development.

John R. Bucher,
Associate Director, National Toxicology Program.

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–NEW; Form I–407]

Agency Information Collection Activities: Record of Abandonment of Lawful Permanent Resident Status; Existing Collection in Use Without an OMB Control Number

ACTION: 60-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment on this proposed collection in use without an OMB Control Number. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the Federal Register to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e. the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until November 19, 2013.

ADDRESSES: All submissions received must include the OMB Control Number 1615–NEW in the subject box, the agency name and Docket ID USCIS–2013–0005. To avoid duplicate submissions, please use only one of the following methods to submit comments:

2. Email. Submit comments to USCISFRComment@uscis.dhs.gov;

SUPPLEMENTARY INFORMATION:

Comments

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at http://www.regulations.gov, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of http://www.regulations.gov.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check “My Case Status” online at: https://egov.uscis.gov/cris/Dashboard.do, or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who