

identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2007-D-0369 for “Draft Guidance on Difluprednate.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” will be publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more

information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993-0002, 301-796-5850.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE guidances available to the public on FDA’s Web site at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific BE guidances and to provide a meaningful opportunity for the public to consider and comment on the guidance. This notice announces the availability of revised draft BE recommendations for generic difluprednate emulsion.

FDA initially approved new drug application 022212 for DUREZOL (difluprednate emulsion) in June 2008. In January 2016, FDA issued a draft guidance for industry on BE recommendations for generic difluprednate emulsion. We are now issuing a revised draft guidance for

industry on BE recommendations for difluprednate emulsion (“Draft Guidance on Difluprednate”).

In September 2016, Alcon Pharmaceuticals, Ltd. and its affiliated company, Novartis Pharmaceuticals Corporation, submitted a citizen petition requesting that FDA take several actions with respect to ANDAs for difluprednate emulsion, including regarding the demonstration of BE for any ANDA referencing DUREZOL. FDA has reviewed the issues raised in this citizen petition and is responding to the citizen petition separately in the docket for that citizen petition (Docket No. FDA-2016-P-2781, available at <http://www.regulations.gov>).

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for difluprednate emulsion. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 9, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-02972 Filed 2-14-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing 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.

**FOR FURTHER INFORMATION CONTACT:**

Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**SUPPLEMENTARY INFORMATION:**

Technology description follows.

**Single-Chain Antibodies Directed to Norovirus GI.1 and GII.4 and Their Use**

*Description of Technology:* Vaccines and therapies to prevent and treat Norovirus infections are not available, despite the worldwide prevalence of Norovirus infections. Outbreaks of human gastroenteritis attributable to Norovirus commonly occur in group settings, such as hospitals, nursing homes, schools, dormitories, cruise ships and military barracks. This application claims isolated VHH monoclonal antibodies that specifically bind to a Norovirus polypeptide. Llama-derived single chain antibody fragments (also called VHH) are small, recombinant monoclonal antibodies of 15 kDa ("nanobodies") with several advantages over conventional antibodies. The antibodies that were derived from llamas showed strong neutralizing activity against Norovirus in *in vitro* assays. These nanobodies may have application as immunoprophylaxis to protect individuals from infections or as a possible treatment for infected individuals, or can be used to develop a diagnostic for detection of norovirus infections, and may be potentially utilized in vaccine research.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

*Potential Commercial Applications:*

- Therapeutics
- Diagnostics
- Vaccine research

*Competitive Advantages:*

- Ease of manufacture
- Potent neutralizing activity
- Potential cross-reactivity
- Low-cost therapeutics/immunoprophylaxis

*Development Stage:*

- In vivo data assessment (animal)

*Inventors:* Lisbeth Kim Green (NIAID), Karin Bok (NIAID), Stanislav

Sosnovtsev (NIAID), Marina Bok (EM), Pamela Aguilar (EM), Lorena Garaicoechea (EM), and Viviana Parreno (EM).

*Publications:* Garaicoechea L. et al., "Llama nanoantibodies with therapeutic potential against human norovirus diarrhea," PLoS One. 2015 Aug 12;10(8):e0133665. doi:10.1371/journal.pone.0133665. eCollection 2015. [PMID 26267898].

*Intellectual Property:* HHS Reference No. E-136-2013/0—U.S. Provisional Application No. 61/821,354, filed May 9, 2013; PCT Application No. PCT/US2014/037520, filed May 9, 2014; European Application No. 14727696.8, filed May 9, 2014 (pending); U.S. Application No. 14/889,774, filed November 6, 2015 (pending); and Argentine Application No. 20140101882, filed May 9, 2014 (pending).

*Licensing Contact:* Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

*Collaborative Research Opportunity:* The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a therapeutic, diagnostic or vaccine for Norovirus infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Dated: February 8, 2017.

**Suzanne Frisbie,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

[FR Doc. 2017-03015 Filed 2-14-17; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Neurological Disorders and Stroke, Muscular Dystrophy Coordinating Committee Call for Committee Membership Nominations**

**SUMMARY:** The Office of the Secretary of the Department of Health and Human Services (HHS) is seeking nominations for an individual to serve as a nonfederal public member on the Muscular Dystrophy Coordinating Committee.

**DATES:** Nominations are due by 5 p.m. EST on March 17, 2017.

**ADDRESSES:** Nominations must be sent to Glen Nuckolls, Ph.D., by email to [nuckollg@ninds.nih.gov](mailto:nuckollg@ninds.nih.gov).

**FOR FURTHER INFORMATION CONTACT:** Glen Nuckolls, Ph.D., by email to [nuckollg@ninds.nih.gov](mailto:nuckollg@ninds.nih.gov).

**SUPPLEMENTARY INFORMATION:** The Muscular Dystrophy Coordinating Committee (MDCC) is a federal advisory committee established in accordance with the Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2001 (MD-CARE Act; Pub. L. 107-84). The MD-CARE Act was reauthorized in 2008 by Pub. L. 110-361, and again in 2014 by Pub. L. 113-166. The MD-CARE Act specifies that the committee membership be composed of 2/3 governmental agency representatives and 1/3 public members. We are seeking nominations for four non-federal, public members at this time, due to turnover of committee membership. Nominations will be accepted between February 17 and March 17, 2017.

*Who is Eligible:* Nominations are encouraged for new or reappointment of non-federal public members who can provide the public and/or patient perspectives to discussions of issues considered by the Committee. Self-nominations and nominations of other individuals are both permitted. Only one nomination per individual is required. Multiple nominations for the same individual will not increase likelihood of selection. Non-federal, public members may be selected from the pool of submitted nominations or other sources as needed to meet statutory requirements and to form a balanced committee that represents the diversity within the muscular dystrophy communities. Nominations are especially encouraged from leaders or representatives of muscular dystrophy research, advocacy, or service organizations, individuals with muscular dystrophy or their parents or guardians. In accordance with White House Office of Management and Budget guidelines (FR Doc. 2014-19140), federally-registered lobbyists are not eligible.

*Committee Composition:* The Department strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that the views of all genders, all ethnic and racial groups, and people with disabilities are represented on HHS Federal advisory committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this