finalized. FDA made changes to provide additional clarification, including adding information regarding in-use labeling language that we recommend for multi-dose animal drug products (mostly food animal drugs) for which less than the theoretical maximum number of punctures are used for the in-use stability study; providing examples of adverse trending that may lead us to recommend the use of aged product for in-use stability studies; and clarifying that if changes are made to the storage temperature or expiry period that would impact a current in-use statement on an approved animal drugs, that we recommend sponsors reassess the in-use statement and submit revised labeling for review.

This final guidance reflects the Agency's current thinking on how to formulate in-use statements, as well as how to design and carry out in-use stability studies to support these in-use statements, for multiple-dose injectable drug products intended for use in animals. This current thinking pertains to both generic drug products and pioneer drug products regardless of whether the pioneer RLNAD currently has an in-use statement on the labeling.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.'' 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. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; and the collections of information in sections 512(b) and 512(n) of the Federal Food, Drug, and Cosmetic Act have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: November 20, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26183 Filed 11–25–20; 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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by communicating with Betty B. Tong, Ph.D., National Institute of Diabetes and Digestive and Kidney Diseases, Technology Advancement Office, 12A South Drive Suite 3011, Bethesda, MD 20892; telephone: 301–451–7836; email: *tongb@mail.nih.gov.* A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

P2Y14 Receptor Antagonists Containing A Biaryl Core

The technology discloses composition of compounds that fully antagonize the human P2Y14 receptor, with moderate affinity with insignificant antagonism of other P2Y receptors. Therefore, they are highly selective P2Y14 receptor antagonists. Even though there is no P2Y14 receptor modulators in clinical use currently, selective P2Y14 receptor antagonists are sought as potential therapeutic treatments for asthma, cystic fibrosis, inflammation and possibly diabetes and neurodegeneration.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications

Development of P2Y14 receptor antagonist for treatment of disorders, such as:

- Inflammation
- diabetes
- cystic fibrosis
- asthma
- neurodegeneration

Development Stage:

- Early stage

Inventors: Kenneth A. Jacobson (NIDDK), Jinha Yu (NIDDK), Antonella Ciancetta (NIDDK), Zhiwei Wen (NIDDK), Young-Hwan Jung (NIDDK)

Publications: Yu J, Ciancetta A, Dudas S, *et al.,* Structure-guided modification of heterocyclic antagonists of the P2Y14 receptor. J. Med. Chem., 2018, 61: 4860–4882, Jung YH, Yu J, Wen Z, *et al.,* Exploration of alternative scaffolds for P2Y14 receptor antagonists containing a biaryl core. J. Med. Chem., 2020, 63:9563–9589.

Intellectual Property: HHS Reference No. E–028–2018–0/1, US Provisional Patent Application 62/628,699 filed 09 Feb 2018, International Patent Application PCT/US2019/17422, filed 11 Feb 2019.

Licensing Contact: Betty B. Tong, Ph.D.; 301–451–7836; *tongb@mail.nih.gov. This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.*

Dated: November 19, 2020.

Bei Tong,

Senior Licensing and Patenting Manager, National Institute of Diabetes and Digestive and Kidney Diseases, Technology Advancement Office.

[FR Doc. 2020–26168 Filed 11–25–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the National Toxicology Program Board of Scientific Counselors was renewed for an additional two-year period on November 14, 2020.

It is determined that the National Toxicology Program Board of Scientific Counselors is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed