

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.fda.gov/regulatoryinformation/dockets/default.htm>.

**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 CPG to the Food and Feed Policy Staff, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

**FOR FURTHER INFORMATION CONTACT:** Spring C. Randolph, Center for Food Safety and Applied Nutrition (HFC-325), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1421.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

We are announcing the availability of the draft CPG entitled "Compliance Policy Guide Sec. 540.750 Use of *The Seafood List* to Determine Acceptable Seafood Names." The draft CPG, if finalized, will update the previously issued "CPG Sec. 540.750—Common or

Usual Names for Seafood in Interstate Commerce." The draft CPG is intended to provide guidance for FDA staff regarding use of *The Seafood List* to determine whether a seafood name is acceptable. The draft CPG explains when we may consider a seafood product to be misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343). The draft CPG also contains information that may be useful to the regulated industry and to the public.

We are issuing this draft CPG consistent with our good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent our current thinking on acceptable names for seafood in interstate commerce. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate 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 CPG from FDA's Office of Regulatory Affairs CPG history page at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 15, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-27843 Filed 11-17-16; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Notice of Joint Meeting by the Urology Interagency Coordinating Committee and the Diabetes Mellitus Interagency Coordinating Committee Meeting**

**SUMMARY:** The Diabetes Mellitus Interagency Coordinating Committee (DMICC) and the Urology Interagency Coordinating Committee (UICC) will hold a joint meeting on December 16, 2016. The subject of the meeting will be "The Urologic Complications of Diabetes." The meeting is open to the public.

**DATES:** The meeting will be held on December 16, 2016; from 9:00 a.m. to 12:00 p.m. Individuals wanting to present oral comments must notify the contact person at least 10 days before the meeting date.

**ADDRESSES:** The meeting will be held in the Democracy 2 Building at 6707 Democracy Blvd., Bethesda, MD, in Conference Room 7050.

**FOR FURTHER INFORMATION CONTACT:** For further information concerning this meeting, see the DMICC Web site, [www.diabetescommittee.gov](http://www.diabetescommittee.gov), or contact Dr. B. Tibor Roberts, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 31 Center Drive, Building 31A, Room 9A19, MSC 2560, Bethesda, MD 20892-2560, telephone: 301-496-6623; FAX: 301-480-6741; email: [dmicc@mail.nih.gov](mailto:dmicc@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The DMICC and the UICC, both chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) comprising members of the Department of Health and Human Services and other federal agencies that support diabetes-related or urologic-related activities respectively, facilitate cooperation, communication, and collaboration on diabetes among government entities. The Committees' meetings, held several times a year, provide an opportunity for their members to learn about and discuss current and relevant future programs in their member organizations and to identify opportunities for collaboration. The December 16, 2016 joint meeting will focus on The Urologic Complications of Diabetes.

Any member of the public interested in presenting oral comments to the Committees should notify the contact person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives or organizations should submit a letter of intent, a brief description of the organization represented, and a written copy of their oral presentation in advance of the meeting. Only one representative of an organization will be allowed to present; oral comments and presentations will be limited to a maximum of 5 minutes. Printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committees by forwarding their statement to the contact person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Because of time constraints for the meeting, oral comments will be allowed on a first-come, first-serve basis.

Members of the public who would like to receive email notification about

future DMICC meetings should register for the listserv available on the DMICC Web site, [www.diabetescommittee.gov](http://www.diabetescommittee.gov).

Dated: November 9, 2016.

**B. Tibor Roberts,**

*Executive Secretary, Office of Scientific Program and Policy Analysis, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.*

[FR Doc. 2016-27825 Filed 11-17-16; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing and/or Co-Development**

**AGENCY:** National Institutes of Health, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. 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 and/or co-development.

**ADDRESSES:** Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702.

**FOR FURTHER INFORMATION CONTACT:** Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email [ncitechtransfer@mail.nih.gov](mailto:ncitechtransfer@mail.nih.gov). A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

**SUPPLEMENTARY INFORMATION:**

Technology description follows.

*Title of invention:* Methods of Making and Using Dopamine D3 Receptor Selective Antagonists/Partial Agonists

*Summary of Technology:* A library of novel compounds that selectively bind the dopamine D<sub>3</sub> receptor have been designed and characterized extensively. *In vivo* rodent studies indicate selected

lead molecules may be useful to treat drug addiction/dependence.

*Description of Technology:* Dopamine is a major neurotransmitter in the central nervous system and among other functions is directly related to the rewarding effects of drugs of abuse. Dopamine signaling is mediated by D<sub>1</sub>, D<sub>2</sub>, D<sub>3</sub>, D<sub>4</sub> and D<sub>5</sub> receptors. The dopamine D<sub>3</sub> receptor is a known target to treat a variety of neuropsychiatric disorders, including substance use disorders (e.g. cocaine and opioid), schizophrenia and depression. Despite extensive efforts, it has proven difficult to identify a lead molecule that selectively binds to D<sub>3</sub> receptors (versus D<sub>2</sub> receptors, for example), with the desired pharmacological and pharmacokinetic profile. For example, metabolic instability or predicted toxicity has precluded successful translation of previously reported D<sub>3</sub>R-selective antagonists to clinical use for cocaine abuse.

The library of compounds is designed to have high affinity and specificity for the dopamine D<sub>3</sub> receptor. Preliminary studies at National Institute of Drug Abuse (NIDA) indicate that selected lead compounds have promising *in vivo* activity in rodents, including reduced acquisition to self-administration of oxycodone, inhibition of reinstatement to oxycodone seeking, and ameliorating naloxone-precipitated withdrawal from oxycodone dependence.

This invention is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S., in accordance with 35 U.S.C. 209 and 37 CFR part 404, 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 and/or co-development.

*Potential Commercial Applications:*

- Treatment of Opioid Use Disorders
- Treatment of Schizophrenia
- Treatment of Bipolar Disorder
- Treatment of cannabis (Tetrahydrocannabinol, THC) dependence

*Value Proposition:* Despite extensive efforts to develop D<sub>3</sub> receptor-selective compounds, it has proven difficult to identify a ligand with the desired pharmacological and pharmacokinetic profile for translation to the clinic. The D<sub>3</sub> receptor ligands described herein may be useful to treat a variety of diseases, including opioid use disorders and schizophrenia.

*Development Stage:* Pre-clinical (in vivo validation).

*Inventor(s):* Amy Newman and Vivek Kumar (NIDA).

*Intellectual Property:* E-053-2016 United States Provisional Patent Application No. 62/307,600, filed March 14, 2016, titled "Dopamine D3 Receptor Selective Antagonists/Partial Agonists; Methods of Making and Use Thereof".

*Publications:* *J Med Chem.* 2016 Aug 25;59(16):7634-50. doi: 10.1021/acs.jmedchem.6b00860. Epub 2016 Aug 10.

*Collaboration Opportunity:* Researchers at the NIDA seek licensing and/or co-development research collaborations for development of Dopamine D3 ligands to treat opioid use disorders.

*Contact Information:* Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

Dated: November 10, 2016.

**John D. Hewes,**

*Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2016-27770 Filed 11-17-16; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request: A National Survey of Nurse Coaches (NIH Clinical Center)**

**AGENCY:** National Institutes of Health.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 22, 2016, pages 56668-9 (81 FR 56668) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received by December 19, 2016.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be