* 4. Proposed labeling for oxycodone HCl IR capsules, PMRS, NDA 209155 (Dec. 2017).
* 5. Complete Response letter, NDA 209155 (November 16, 2017).
* 6. ''Filing Communication Responses,'' PMRS, NDA 209155.
* 7. ''Request for Priority Review Designation,'' PMRS, NDA 209155.
* 8. ''Memorandum of Meeting Minutes'' for Type B, Pre-NDA, July 11, 2016 teleconference (August, 8, 2016).
* 9. ''NDA 209155 CMC Information Request 5–25–17,'' PMRS, NDA 209155.
* 10. Centers for Disease Control, ''Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance From the CDC and the U.S. Department of Health and Human Services,'' *Morbidity and Mortality Weekly Report,* vol. 61, pp. 1–40, 2012.
* 11. National Institute on Drug Abuse, ''What is heroin and how is it used?'', available at *https://www.drugabuse.gov/publications/research-reports/heroin/what-heroin* (accessed June 13, 2018).
* 12. FDA News Release, ''FDA requests removal of Opana ER for risks related to abuse'' (June 8, 2017), available at *https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.*
13. Hunt, R. et al., ''A Mechanistic Investigation of Thrombotic Microangiopathy Associated with IV Abuse of Opana ER,'' *Blood,* Feb. 16, 2017.
* 14. FDA Guidance for Industry ''Abuse-Deterrent Opioids—Evaluation and Labeling,'' available at *https://www.fda.gov/downloads/Drugs/Guidances/UCM334743.pdf.*

Dated: October 25, 2018.

Denise Hinton,

Chief Scientist.

[FR Doc. 2018–23710 Filed 10–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Nurse Education and Practice

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Advisory Council on Nurse Education and Practice (NACNEP or the Council) has scheduled a public meeting. Information about NACNEP and the agenda for this meeting can be found on the NACNEP website at *https://www.hrsa.gov/advisory-committees/nursing/index.html.*

DATES: November 19, 2018, 8:30 a.m.–4:15 p.m. ET.

ADDRESSES: This meeting will be held by teleconference and webinar. The conference call-in number is 1–888–455–0640; passcode: HRSA COUNCIL. The webinar link is *https://hrsa.connectsolutions.com/nacnep/.*

FOR FURTHER INFORMATION CONTACT: Tracy L. Gray, MBA, MS, RN, Division of Nursing and Public Health, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, 11N112, Rockville, Maryland 20857; 301–443–3346; or *DScott1@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACNEP provides advice and recommendations to the Secretary of Health and Human Services (Secretary) and the U.S. Congress on policy matters arising in the administration of Title VIII of the Public Health Service (PHS) Act, as amended, including the range of issues relating to nurse supply, education, and practice improvements. NACNEP provides an annual report to the Secretary and Congress describing the activities of NACNEP, including findings and recommendations made by NACNEP concerning the activities under this title.

During the November 19, 2018, meeting, NACNEP will continue discussing areas where nursing can take the lead in the transition of the health care system to value-based care through improvements to nurse education and practice, to advance the development of its 15th Report. In addition, the members will discuss strategic priorities and future directions for the Council and discuss possible topics for its 16th Report. Agenda items are subject to change as priorities dictate. Refer to the NACNEP website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written statements to NACNEP should be sent to Ms. Tracy L. Gray, Designated Federal Official, using the contact information above at least 3 business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–23685 Filed 10–29–18; 8:45 am]

BILLING CODE 4165–15–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 jointly owned by an agency of the U.S. Government with Pontificia Universidad Catolica de Chile 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 U.S. patent application listed below may be obtained by communicating with Ami Gadhia, JD, LL.M., CLP, Technology Transfer and Patenting Specialist, National Center for Advancing Translational Sciences, NIH, 9800 Medical Center Drive, Rockville, MD 20850, Phone: 301–217–6098, or email *ami.gadhia@nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

c-Abl Tyrosine Kinase Inhibitory Compounds and Methods of Manufacture and Use

Description of Technology

The invention includes compounds that inhibit c-Abl tyrosine kinase, and methods of making them which include administering (i) a therapeutically effective amount of the compound or a stereoisomer, tautomer, pharmaceutically acceptable salt, solvate, or prodrug thereof; or (ii) a therapeutically effective amount of the pharmaceutical compositions to a patient with the disease which involves c-Abl tyrosine kinase, including the overexpression of it. In some embodiments, the compound inhibits c-Abl tyrosine kinase by binding to an allosteric site of the c-Abl tyrosine kinase. In some embodiments, the compound binds to a myristate pocket of the c-Abl tyrosine kinase.

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