ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Survey development field tests, respondent debriefing questionnaires, cognitive interviews, split sample experiments, focus groups	5100	1700	1	.75	3,825	1,275

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Karl Koerper, Reports

Clearance Officer.

[FR Doc. 2014–21918 Filed 9–12–14; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0649]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: External Pacemaker Pulse Generator; Withdrawal of Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the draft guidance entitled ''Class II Special Controls Guidance Document: External Pacemaker Pulse Generator,'' dated October 2011, in response to the requirements of the Food and Drug Administration Safety and Innovation Act (FDASIA) and new input received during a panel meeting.

DATES: The withdrawal is effective September 15, 2014.

FOR FURTHER INFORMATION CONTACT: Hina Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1652, Silver Spring, MD 20993, 301–796–6351.

SUPPLEMENTARY INFORMATION:

In a notice published in the **Federal Register** of October 17, 2011 (76 FR 64228), FDA announced the availability of a draft special controls guidance document that, if finalized, would serve as a special control if FDA reclassified these devices. FDA believed that the special controls described in the draft guidance entitled, ''Class II Special Controls Guidance Document: External Pacemaker Pulse Generator'' would be sufficient to mitigate the risks to health associated with the external pacemaker pulse generator (EPPG) (Ref. 1).

On July 9, 2012, FDASIA (Pub. L. 112–144) was enacted. Section 608(a) of FDASIA amended section 513(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(a)) changing the process for reclassifying a device from rulemaking to an administrative order. Subsequent to the publication of the proposed rule, FDASIA's amendments to section 513 of the FD&C Act required FDA to hold a classification panel (an FDA advisory committee) meeting to discuss the classification of this device type. On September 11, 2013, a meeting of the Circulatory System Devices Panel (the Panel) was held to discuss whether EPPG devices should be reclassified or remain as class III devices (Ref. 2). The Panel recommended that EPPG devices be reclassified to class II with special controls when intended for cardiac rate control or prophylactic arrhythmia prevention.

FDA provided an opportunity for interested parties to comment on the special control guidance on EPPG. FDA did not receive any comments to the docket. As a result of the Panel recommendation and the amendment to section 513(e) of the FD&C Act, FDA will now include the special controls for EPPG devices in a proposed order published elsewhere in this issue of the **Federal Register** and withdraw the draft guidance through this notice.

References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Class II Special Controls Draft Guidance Document: External Pacemaker Pulse Generator, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM275703.pdf.*

2. The transcript and other meeting materials for the September 11, 2013, Circulatory System Devices Panel are available on FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/*

MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm342357.htm.

Dated: September 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21815 Filed 9–12–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Evaluation License: Development of Antibody-Drug Conjugates Comprising Topoisomerase Inhibitors for the Treatment of Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Provisional Patent Application No. 60/844,027 entitled, ''Azonafide derived tumor and cancer targeting compounds,'' filed September 12, 2006 [HHS Ref. No. E–160–2006/0–US–01], PCT Application No. PCT/US2007/078233 entitled, ''Azonafide derived tumor and cancer targeting compounds,'' filed September 12, 2007 [HHS Ref. No. E–160–2006/0–PCT–02], European Patent Application No. 7842310.0 entitled, ''Azonafide derived tumor and cancer targeting compounds,'' filed September 12, 2007 [HHS Ref. No. E–160–2006/0–EP–03], and U.S. Patent Application No. 12/441,029 entitled, ''Azonafide derived tumor and cancer targeting compounds,'' filed March 12, 2009 now US Patent No. 8,008,316 issued August 30, 2011 [HHS Ref. No. E–160–2006/0–US–04], and all related continuing and foreign patents/patent applications for the technology family, to Oncolinx, Inc. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to the development and use of the licensed patent rights as a component of an antibody-drug conjugate for the treatment of human cancers. Upon expiration or termination of the exclusive evaluation option license, Oncolinx will have the right to execute an exclusive patent commercialization license which will supersede and replace the exclusive evaluation option license with no broader territory than granted in the exclusive evaluation option license and the field of use will be commensurate with the commercial development plan at the time of conversion.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before September 30, 2014 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Jennifer Wong, M.S., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4633; Facsimile: (301) 402–0220; Email: *wongje@od.nih.gov.*

SUPPLEMENTARY INFORMATION: The present technology provides compound formulation and method of use of improved derivatives of 2-[2′-(2-aminoethyl)-2-methyl-ethyl]-l,2-dihydro-6-methoxy-3H-dibenz-[de,h]isoquinoline-l,3-dione (herein referred to as azonafides), anthracene-based DNA intercalcators that inhibit tumor growth. The synthesized azonafides can be attached to a ligand or antibody to recognize specific receptors on cancer cells and delivered as a targeted cytotoxic payload. The azonafides have been developed to allow for easy modification with different peptide linkers and antibodies, but also allow for rapid release once cleaved in lysosomes after delivery to the cancer cell enabling highly targeted attack of cancer cells. The azonafides have reduced toxicity and lower development of drug resistance.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive patent commercialization license, may be granted unless within fifteen (15) days from the date of this published notice, the 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.

Any additional, properly filed, and complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted 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.

Dated: September 9, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–21855 Filed 9–12–14; 8:45 am]

BILLING CODE 4140–01–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 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.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

A Novel Fusion Protein for Inhibiting HIV Budding

Description of Technology: Ubiquitin plays a critical role in HIV–1 budding. Vectors containing deubiquitin enzymes (DUbs) were constructed to deliver DUbs to HIV–1 production sites in living cells. The DUbs vectors comprise DUb cDNAs and cDNA expressing either HIV–1 gag, or the ESCRT protein TSG101.