of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–13029 Filed 5–29–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0432]

Draft Guidance for Industry on Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint To Support Accelerated Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval.'' FDA's accelerated approval regulations permit approval of a new drug to treat a serious disease on the basis of an effect on a surrogate endpoint reasonably likely to predict the clinical benefit of the drug. This draft guidance is intended to assist applicants in designing trials to support marketing approval of drugs to treat breast cancer in the neoadjuvant (preoperative) setting using pathologic complete response (pCR) as a surrogate endpoint that could support approval under the accelerated approval regulations. Despite advances in systemic therapy of early-stage breast cancer over the past few decades, there remains a significant unmet medical need for certain high-risk or poor prognosis populations of early-stage breast cancer patients. This guidance is intended to encourage industry innovation and expedite the development of breakthrough therapies to treat high-risk early-stage breast cancer.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 30, 2012.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tatiana Prowell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5249, Silver Spring, MD 20993–0002, 301–796–2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval.'' Under the accelerated approval regulations (21 CFR part 314, subpart H, and 21 CFR part 601, subpart E), FDA may grant marketing approval for a new drug on the basis of adequate and well-controlled trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit (e.g., an effect on survival or irreversible morbidity), provided that the applicant conducts additional trials after approval to verify and describe the predicted clinical benefit. This draft guidance is intended to assist applicants in designing trials to support marketing approval of drugs to treat breast cancer in the neoadjuvant (preoperative) setting using pCR as a surrogate endpoint that could support approval under the accelerated approval regulations. The guidance proposes a uniform definition of pCR for regulatory purposes. The guidance also advises on appropriate patient populations for inclusion and on the trial designs intended to verify the predicted clinical benefit associated with pCR to support conversion to full approval.

FDA recognizes that despite advances in adjuvant systemic therapy of breast cancer over the past few decades, there remains a significant unmet medical need for certain high-risk or poor prognosis populations of early-stage breast cancer patients. Developing highly effective new drugs for these populations is an FDA priority. In providing guidance on the use of pCR as a surrogate endpoint that could support accelerated approval in the neoadjuvant setting, FDA hopes to encourage industry innovation and expedite the development of breakthrough therapies to treat high-risk early-stage breast cancer.

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 Agency's current thinking on the use of pCR in neoadjuvant treatment of high-risk early-stage breast cancer as an endpoint to support accelerated approval. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information for special protocol assessments have been approved under OMB control number 0910–0470.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: May 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–12928 Filed 5–29–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, 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. 207 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.

Rabbit Polyclonal Antibody To Detect a Pro-Peptide Fragment of NSAID-Activated Gene (NAG–1)/GDF15, a Protein Associated With Cancer

Description of Technology: Chronic inflammation is clearly associated with an increase in the risk of cancer. Non-steroidal anti-inflammatory drugs (NSAIDs) are well documented as agents that inhibit tumor growth and with long-term use can prevent tumor development. NSAID-activated gene (NAG–1), a unique member of the TGF-beta superfamily, is highly induced by NSAIDs and numerous drugs and chemicals with anti-tumorigenic activities.

The protein product of NAG–1 is first formed into an immature peptide dimer that must be cut at a specific site before it can be secreted as a mature protein. Currently available antibodies can only detect either the immature form of NAG–1 or the secreted mature protein, but do not recognize the peptide fragment that remains when the immature dimer is cut to form the mature protein. Now available for the first time, the present new antibody recognizes this NAG–1 pro-peptide fragment.

Potential Commercial Applications: As a research tool to detect expression of the NAG–1/GDF15 cleavage fragment in cells and media from cultured cells.

Competitive Advantages: No other antibody is currently available to detect the NAG–1/GDF15 pro-peptide fragment.

Development Stage: In vitro data available

Inventor: Thomas Eling (NIEHS)

Intellectual Property: HHS Reference No. E–177–2012/0—Research Tool. Patent protection is not being pursued for this technology.

Related Technology: HHS Reference No. E–093–2011/0—Transgenic mice expressing human GDF15/Nag-1/Mic-1

Licensing Contact: Patrick McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov.*

Collaborative Research Opportunity: The NIEHS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this antibody. For collaboration opportunities, please contact Elizabeth M. Denholm, Ph.D. at *denholme@niehs.nih.gov.*

Software for Automated Determination of Macromolecular Structure Using Cryo-Electron Microscopy

Description of Technology: Available for licensing is software for automated generation of density maps of macromolecular structures from series of 2D digital micrographs of frozen hydrated specimens collected using an electron microscope equipped with an ultra-cooled computerized stage. Series of images of biological specimens collected at different tilt angles relative to the electron beam are aligned to compensate for mechanical errors of the stage and combined to obtain 3D images (tomograms). Sub volumes containing a single macromolecular complex can be extracted from the 3D image of a protein solution, or suspension of viruses or cells. These individual sub-volumes of identical structures are aligned and averaged together to generate a density map of the macromolecular complex of interest.

Potential Commercial Applications:

- Macromolecular imaging
- Molecular interaction
- Molecular structure and reactivity

Competitive Advantages:

- Noise processing
- Algorithmic averaging

Development Stage: Prototype

Inventors: Mario Juan Borgnia, Alberto Bartesaghi, Sriram Subramaniam (all of NCI)

Publications:

1. Amat F, et al. Markov random field based automatic image alignment for electron tomography. J Struct Biol. 2008 Mar;161(3):260–75. [PMID 17855124]

2. Kremer JR, et al. Computer visualization of three-dimensional image data using IMOD. J Struct Biol. 1996 Jan–Feb;116(1):71–76. [PMID 8742726]

3. Mastronarde DN. Dual-axis tomography: an approach with alignment methods that preserve resolution. J Struct Biol. 1997 Dec;120(3):343–52. [PMID 9441937]

4. Bartesaghi A, et al. An energy-based three-dimensional segmentation approach for the quantitative interpretation of electron tomograms. IEEE Trans Image Process. 2005 Sep;14(9):1314–23. [PMID 16190467]

Intellectual Property: HHS Reference No. E–162–2012/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301–435–5019; *mish@codon.nih.gov.*

Collaborative Research Opportunity: The NCI Laboratory of Cell Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Chimeric Antigen Receptors That Recognize Mesothelin for Cancer Immunotherapy

Description of Technology: Scientists at the National Institutes of Health (NIH) have developed chimeric antigen receptors (CARs) with high affinity for mesothelin to use as a promising immunotherapy to treat cancers, such as pancreatic cancer, ovarian cancer, and mesothelioma. Mesothelin is a protein cancer antigen with limited expression on normal cells that is overexpressed by