completely. Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings. Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

In the **Federal Register** of August 19, 2010 (75 FR 51271), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments from two individuals and one trade association. FDA acknowledges one request for additional details on the necessity and purpose of the information to be collected, but notes that comments were invited on FDA's request for a generic clearance related to the formative testing of communications about veterinary products and products for animals. Under this generic clearance, details of individual studies (research questions, target audiences, methodologies, and consultants) will be tailored to specific communications-related questions. For each study FDA requests under this clearance, FDA will provide OMB with these details on the information collection. The communication development process will inform the purpose of the data collection and the means by which the data will be collected. For very early message development, qualitative research such as in-depth interviews or focus groups will be appropriate. At later communication development stages, more quantitative data collection would be more useful. FDA plans to use the data collected under this generic clearance to inform its communications campaigns. The data will not be used for the purposes of making policy or regulatory decisions.

Audience targets are also informed by the specific research question. Nonetheless, FDA provided more information by specifying some of the groups more likely to be targeted in tasks under this generic clearance, including: Consumers, pet owners, large animal producers, veterinarians, animal distributors, pet shop owners, stockyards staff and owners, abattoir owners or staff, grocery meat purchasers, agricultural extension agents, and professors of food science and related fields.

Furthermore, comments related to ways to enhance the data collection and to assess FDA's estimate of burden indicated that FDA should not limit itself to in-house expertise. FDA acknowledges that assistance may be requested from experts in other Government agencies. Depending on the specific research question to be addressed, FDA may consult experts in the United States Department of Agriculture and the United States Environmental Protection Agency.

FDA received a comment relating to the cruelty and sadism of animal testing. In response to this comment, FDA notes that its notice was for public comment on data collection related to communication studies. No animal testing is involved.

FDA received a comment that made a series of complaints against the Agency unrelated to its notice for public comment. Accordingly, those comments are not addressed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. 393(d)(2)(D)	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Individual in-depth interviews	360	1	360	.75	270
General public focus group interviews	288	1	288	1.50	432
Intercept interviews: Central location	200	1	200	.25	50
Intercept interviews: Telephone [2]	2,000	1	2,000	.08	160
Self-administered surveys	2,400	1	2,400	.25	600
Gatekeeper reviews	300	1	300	.50	150
Omnibus surveys	1,200	1	1,200	.17	204
Total (general public)					1,866
Veterinarian/scientific expert focus group interviews	288	1	288	1.50	432
Total (overall)					2,298

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] These are brief interviews with callers to test message concepts and strategies following their call-in request to an FDA Center 1–800 number.

Dated: December 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31891 Filed 12–17–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Defense Advanced Research Projects Agency and Food and Drug Administration Expanding In Vivo Biomarker Detection Devices Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop cosponsored with the Defense Advanced Research Projects Agency (DARPA): Expanding In Vivo Biomarker Detection Devices Workshop.

The DARPA Defense Sciences Office and the FDA Center for Devices and Radiological Health (CDRH) are hosting a workshop to discuss current state-of-the-art and innovative research opportunities in the area of in vivo analytical devices capable of measuring biomarkers that characterize normal biological processes, pathologic

processes, and pharmacologic responses. In particular, this workshop will focus on the technical challenges for developing implanted or continuously applied devices capable of measuring and monitoring clinically relevant molecular biomarkers (small molecules, proteins, peptides, and nucleic acids) to alert the user of the need for clinical attention and/or to inform the clinician with regard to appropriate action.

Date and Time: The workshop will be held on February 9, 2011, from 7:30 a.m. to 5 p.m.

Location: The workshop will be held at the Executive Conference Center at Liberty Center, 4075 Wilson Blvd., suite 350, Arlington, VA 22203.

Contact: Jonathan Sackner-Bernstein, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5410, Silver Spring, MD 20903, 301–796–5420, e-mail: *jonathan.sackner-bernstein@fda.hhs.gov;* or Daniel Wattendorf, Defense Advanced Research Projects Agency, 3701 North Fairfax Dr., Arlington, VA 22203, 703–526–6630. Administrative questions about the workshop should be directed to the attention of Ms. Jenifer Schimmenti (*jschimmenti@sainc.com*).

Registration and Requests for Presentations: Registration logistics will be managed by DARPA according to instructions posted on their Web site at *http://www.sa-meetings.com/DARPA_FDA_Workshop* (login: DARPAFDA, password: arlington), including instructions for registration and presentation of previous or potential research and development capabilities consistent with the workshop goals in order to facilitate discussions. The deadline to submit abstracts and requests for poster presentations is listed on the DARPA Web site. After the deadline posted, no submissions will be considered.

If you need special accommodations due to a disability, please contact Jenifer Schimmenti (*see Contact*) at least 7 days in advance.

Transcripts: There will not be a transcription of this workshop.

SUPPLEMENTARY INFORMATION:

Currently available glucose monitoring systems provide the most developed approach to continuous monitoring of a biomarker in real-time. Despite FDA approval for human use and extensive research and development, these monitoring systems exhibit several important limitations including accuracy/precision, durability, adaptability, and reliability. For example, many of these technologies are limited to detecting one biomarker (glucose) in real-time and the approach cannot be used for the detection of other classes of biomarkers (*e.g.,* nucleic acids), nor do they have the capabilities for being multiplexed. Additionally, these technologies also require frequent secondary testing of blood glucose levels to assure the performance and accuracy of the device. Such technical challenges limit the ability to conveniently monitor health status in real-time settings outside of the patient-physician encounter. These challenges are not isolated to implantable/applied technologies. Available in vitro tools are primarily developed for intermittent measurements, typically within a clinical environment, and do not account for biologic dynamics or responses to environmental stimuli.

With accelerating advances in genomics, epigenomics, transcriptomics, proteomics, and microbiomics, innumerable biomarkers could be informative for the health/disease of individuals and/or populations, particularly when considering potential exposure to allergens, infections, and toxins. Owing to the typical paradigm for development of diagnostic devices, these next generation class of biomarkers that function either as a surrogate endpoint for efficacy or an adverse response do not have their clinical utility qualified in the real-world setting. Without a device to accurately measure predictive biomarkers either continuously or at an acceptable interval, clinical utility may be difficult to establish and translation to accepted screening or diagnostic testing may be impaired. Qualification of biomarkers that inform an individual to seek medical attention or guide a medical provider toward an intervention or clinical decision, within the context of an implanted/applied technology, is a priority.

DARPA and CDRH are seeking to understand challenges and develop technological advancements necessary to enable in vivo medical devices for biomarker detection. While glucose is a critical biomarker, workshop interest will focus broadly on technologies for detection of next-generation biomarkers including chemical biomarkers, proteins, peptides, and nucleic acids. The workshop will address the challenges for developing in vivo devices to clinically validate biomarkers for disease screening, surveillance, prediction of therapeutic response, or prognosis, as well as the potential for using an in vivo approach to measure biomarkers for safety and effectiveness of a therapy (metabolites, toxicity, or surrogate endpoints) as part of a real-time Phase 4 postmarketing surveillance.

The workshop will not focus on the discovery or identification of relevant biomarkers or potential surrogates. Instead, the workshop will focus on critical topic areas and specific technical challenges related to the development of in vivo technologies capable of biomarker detection.

We encourage you to address the following specific technical challenges related to development of in vivo devices:

- *Novel materials:* Materials and chemistries that can be safely applied for continuous in vivo detection of biomarkers, and do not induce/stimulate a biological response (e.g., inflammation).
- *Device design for analytical validation:* Methods for maximizing and verifying accuracy, sensitivity, specificity, reproducibility, and reliability of in vivo biomarker detection methods.
- *Minimal invasiveness:* Device delivery methods and device size reduction, to include issues related to on-board versus external power, communication, and processing.
- *Maximum duration:* Operational lifetime of the implanted device to include overcoming bio-fouling, enhanced biocompatibility, and continuous versus periodic measurements.
- Capacity to measure multiple biomarkers simultaneously.
- Capacity to be rapidly adapted to measure an emerging biomarker of concern.
- Potential for using an in vivo approach to clinically validate biomarkers for disease screening, surveillance, prediction of therapeutic response, or prognosis.

Ideally, these challenges are within the context of the following, as summarized in the Institute of Medicine (IOM) *Evaluation of Biomarker and Surrogate Endpoints in Chronic Disease 2010 Consensus Report (http://books.nap.edu/openbook.php?record_id=12869*):

1. Analytical validation to assure biomarker tests are reliable, reproducible, and adequately sensitive and specific.

2. Qualification to assure the measurement methods can be correlated to a clinical outcome of concern.

3. Utilization analysis to determine that the biomarker used to develop the technology is appropriate.

The goals of this workshop are to define the current state-of-the-art and innovative research opportunities and challenges in developing such devices.

Participants are asked to submit an abstract of no more than 250 words to explain their research efforts and how they specifically pertain to the objectives of the Expanding In Vivo Biomarker Detection Devices Workshop. A workshop representative will contact participants after abstract submission.

Dated: December 14, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–31811 Filed 12–17–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0030]

Determination of Regulatory Review Period for Purposes of Patent Extension; FOLOTYN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FOLOTYN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product FOLOTYN (pralatrexate). FOLOTYN is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for FOLOTYN (U.S. Patent No. 6,028,071) from Southern Research Institute, Sloan-Kettering Institute for Cancer Research, and SRI International, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 3, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FOLOTYN represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for FOLOTYN is 4,591 days. Of this time, 4,406 days occurred during the testing phase of the regulatory review period, while 185 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* March 2, 1997. The applicant claims January 31, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 2, 1997, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 24, 2009. The applicant claims March 23, 2009, as the date the new drug application (NDA) for Folotyn (NDA 22–468) was initially submitted. However, FDA records indicate that NDA 22–468 was submitted on March 24, 2009.

3. *The date the application was approved:* September 24, 2009. FDA has verified the applicant's claim that NDA 22–468 was approved on September 24, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments and ask for a redetermination by February 18, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 20, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (*See* H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.