FDA has determined that the applicable regulatory review period for LASTACAFT is 2,189 days. Of this time, 1,886 days occurred during the testing phase of the regulatory review period, while 303 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:* August 1, 2004. The applicant claims July 31, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 1, 2004, 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:* September 29, 2009. The applicant claims September 28, 2009, as the date the new drug application (NDA) for LASTACAFT (NDA 22–134) was initially submitted. However, FDA records indicate that NDA 22–134 was submitted on September 29, 2009.

3. *The date the application was approved:* July 28, 2010. FDA has verified the applicant's claim that NDA 22–134 was approved on July 28, 2010.

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 1,246 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 July 2, 2012. 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 October 30, 2012. 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. 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 *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 2012.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. 2012–10694 Filed 5–2–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0408]**

### Risk Evaluation and Mitigation Strategy Assessments: Social Science Methodologies to Assess Goals Related to Knowledge; Public Workshop; Issue Paper

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Risk Evaluation and Mitigation Strategy Assessments: Social Science Methodologies to Assess Goals Related to Knowledge.'' The purpose of the public workshop is to initiate constructive dialogue and information-sharing among regulators, researchers, the pharmaceutical industry, health care organizations, health care providers, and others from the general public about survey methodologies and instruments that can be used to evaluate patients' and health care providers' knowledge about the risks of drugs marketed with an approved Risk Evaluation and Mitigation Strategy (REMS). The input from this workshop will be used to develop guidance for industry describing the best practices for conducting an assessment of a REMS goal regarding patient and/or health care provider knowledge about a drug's risk(s). To assist in the workshop discussion and the ultimate development of the guidance, FDA is making available an issue paper that discusses our experience with knowledge assessments for REMS and contains specific questions we hope to receive input on. FDA is also opening a public docket to receive written comments.

*Date and Time:* The public workshop will be held on June 7, 2012, from 8 a.m. to 5 p.m.

*Location:* The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* Participants are encouraged to arrive early to ensure time for parking and security screening before the workshop.

*Contact Person:* Colleen O'Malley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4305, Silver Spring, MD 20993–0002, 301–796–1786, FAX: 301–796–9832, email: *colleen.omalley@fda.hhs.gov.*

*Registration and Requests for Oral Presentations:* There is no fee to attend the workshop, and attendees who do not wish to make a formal presentation do not need to register. Seating will be on a first-come, first-served basis. Individuals who wish to make a presentation at the public workshop must register and provide an abstract of your presentation by 5 p.m. on May 21, 2012.

Submit electronic registration requests to make a presentation to *KnowledgeAssessmentWorkshop@fda.hhs.gov.* Submit written registration requests to make a presentation to Colleen O'Malley (see *Contact Person*). Please provide your name, title, business affiliation (if applicable), address, telephone, FAX number, and email address. Identify the Panel number(s) for the question(s) you will discuss in your presentation (see section IV of this document).

FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make a formal presentation should check in before the workshop. Time will be allowed during the scheduled agenda for attendees to ask questions of the panelists. In addition, we strongly

encourage electronic or written comments to the docket.

FDA has developed an issue paper entitled ''Risk Evaluation and Mitigation Strategy Assessments: Social Science Methodologies to Assess Goals Related to Knowledge'' that discusses our experience with knowledge assessments for REMS. The issue paper also contains a number of specific questions that we hope to receive input on. The issue paper can be found on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm292337.htm.*

Background information on the public workshop, registration information, the agenda, and other relevant information will be posted on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* as it becomes available.

If you need special accommodations due to a disability, please contact Colleen O'Malley (see *Contact Person*) at least 7 days before the workshop.

*Comments:* FDA is opening a docket to allow for public comments to be submitted to the Agency on the issues and questions presented in the issue paper or at the workshop. Regardless of attendance at the public workshop, interested persons may submit to the Division of Dockets Management either electronic or written comments by July 7, 2012, to receive consideration. Submit electronic comments 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. 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.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Title IX, Subtitle A, section 901 of the Food and Drug Administration Amendments Act (FDAAA) (Pub. L. 110–85) [1] created new section 505–1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355–1), which authorizes FDA to require persons submitting new drug applications (NDAs) or abbreviated new drug applications (ANDAs) for prescription products, or biologics license applications (BLAs), to submit and implement a REMS if FDA determines that a REMS is necessary to ensure the benefits of a drug outweigh the risks of the drug. To require a REMS for an already approved drug, FDA must have become aware of new safety information as defined in the statute. Elements for REMS approved for NDAs and BLAs may include a Medication Guide, a communication plan, and/or elements to assure safe use (ETASU), and an implementation system, if specific statutory criteria are met. All approved REMS for products approved under an NDA or BLA must include a timetable for submission of assessments of the REMS. FDAAA contains provisions that are specifically directed to REMS for ANDAs, and these REMS may include only a Medication Guide and/or ETASU and an implementation system.

Because most REMS include a goal related to knowledge, such as to inform or educate patients and/or health care providers about the serious risks associated with and safe use of a drug, assessments for a drug subject to a REMS frequently include assessments of patients' and providers' knowledge. To conduct this assessment, most applicants have undertaken cross-sectional surveys of patients who have taken the drug and health care providers who have prescribed or dispensed the drug.

As a result of FDA's review of the surveys that are included as components of a REMS assessment, the Agency has identified certain challenges to conducting these types of studies. FDA has specific questions about the methodology for obtaining survey data and presenting the results, including about appropriate sample size; methods to ensure representativeness; how to determine endpoints; questionnaire design and analyses; and presentation of survey results.

To date, FDA has worked with individual applicants to attempt to introduce and sustain some measure of consistency in methods and expectations. Although absolute uniformity is not possible, the Agency seeks to solicit information and feedback about valid survey methods that can improve the quality and consistency of REMS assessment surveys. In addition, FDA seeks feedback on whether methodologies other than surveys could be used to obtain this information. Finally, FDA seeks to solicit information about using surveys other than knowledge assessment surveys as a tool to assess whether the elements of a REMS are meeting its goals including: (1) Changes in behavior for both patients and prescribers such as whether a drug is used to a large degree in patients at higher risk of an adverse reaction; (2) burden on the health care system, which could include the time required to accomplish REMS-related activities; and (3) adverse effects on patient access to the drug, such as substantial delays between the time of presentation of a prescription and the time of drug dispensing or prescribers choosing not to prescribe the drug anymore.

## II. Why are we holding this public workshop?

FDA is soliciting information and feedback to optimize the assessment of REMS goals related to knowledge. Because we have received only surveys that assess knowledge, the workshop will invest considerable time in identifying best methodological practices for conducting REMS assessment surveys. However, FDA is also encouraging discussion of alternatives to surveys, given the issues we have observed, as discussed in the issue paper. Feedback received in the docket and resulting from this workshop will assist the Agency in developing guidance for industry.

The workshop objectives are as follows: (1) Initiate constructive dialogue and information-sharing about survey methodologies and instruments used to evaluate patients' and healthcare providers' knowledge about drugs' risks; (2) share current FDA experience regarding social science assessments of surveys as a component of REMS Assessment Plans; (3) obtain information that will be used to develop standardized survey methodologies for evaluating patient and health care provider knowledge under a REMS; (4) discuss alternative methodologies to surveys to assess knowledge; and (5) discuss the use of surveys as a tool to assess patient and prescriber behavior changes, burden on the health care system, and patient access to the drug under a REMS.

## III. Who is the target audience and who should attend this public workshop?

Although the workshop is open to all interested parties, the target audience includes social science professionals; statisticians; regulators; researchers; and representatives from academia, the pharmaceutical industry, and the scientific community who may be interested in improving the quality and consistency of methodology for evaluating REMS goals related to knowledge.

## IV. What are the topics we intend to discuss at the public workshop?

The workshop will include panel discussions and individual and/or joint presentations. The key issues to be addressed are: (1) How should

[1] See *http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf.*

assessments of knowledge be structured to achieve valid, reliable, and informative results; (2) how can surveys be used to assess changes in patient and prescriber behavior, burden to the health care system, and patient access to the drug; and (3) what are appropriate alternatives to surveys to assess educational components of REMS? Two panel discussions will focus on areas in which the Agency requests specific input.

- *Panel 1* will focus on using surveys to assess knowledge. Topics will include, but are not limited to, recruiting a representative sample, sample size, question design, process, and endpoints.
- *Panel 2* will focus on alternatives to surveys and the use of surveys to assess patient and prescriber behavior changes, burden on the health care system, and patient access to the drug. Topics will include, but are not limited to, recruiting a representative sample, question design, interpretation of results, and specific pros and cons of the alternatives.

**V. Transcripts**

Please be advised that as soon as a transcript of the workshop is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: April 27, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–10646 Filed 5–2–12; 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:** 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.

**Mouse Monoclonal Antibody Targeting Human NOX1, a Target for Cancer and Inflammation**

*Description of Technology:* Available for licensing is a mouse monoclonal antibodies targeting human nicotinamide adenine dinucleotide phosphate-oxidase (NAPH) oxidase 1 (NOX1) enzyme. NOX mediates the homeostasis of reactive oxygen species, which play a critical regulatory role in cancer cell signal transduction and tumor cell differentiation. NOX1-generated hydrogen peroxide can trigger an ''angiogenic switch'' that includes the induction of angiogenic factors that promote tumor cell vascularization. Additionally, NOX1 may play a role in inflammation.

Investigators at the National Cancer Institute found NOX1 is significantly expressed more in colon and gastric cancers compared with adjacent normal bowel and gastric mucosa respectively. To the best of NIH's knowledge, this is the only monoclonal antibody that can be used to detect human NOX1. This antibody detects endogenous levels of the NOX1 protein and could potentially be used in biochemical laboratory studies as well as diagnostic tests that involve the functional significance of NOX1 in human physiology and pathophysiology, particularly its role in cancer and inflammation.

Potential Commercial Applications:

- Research tool to study cancer and inflammation
- Method to diagnose colon and gastric cancer
- Treatment for cancer and inflammation

*Competitive Advantages:* To the best of NIH's knowledge, this is the only available monoclonal antibody to detect human NOX1.

Development Stage:

- Early-stage
- In vitro data available

*Inventors:* James Doroshaw, Krishnendu Roy, Guojian Jiang, Jiamo Lu, and Smitha Antony (all of NCI).

*Intellectual Property:* HHS Reference No. E–097–2012/0—Research Tool. Patent protection is not being pursued for this technology.

*Licensing Contact:* Sabarni K. Chatterjee, Ph.D.; 301–435–5587; *chatterjeesa@mail.nih.gov.*

**A Non-Invasive Post-Treatment Strategy for Stroke by Intranasal Delivery of Cocaine- and Amphetamine-Regulated Transcript (CART)**

*Description of Technology:* Cocaine and amphetamine-regulated transcript (CART) is a neuropeptide known to protect against ischemic brain injury when administered before the onset of stroke in mice, both in vivo and in vitro. Utilizing a classic stroke model in rodents, middle cerebral artery occlusion (MCAo), inventors at NIDA discovered a novel post-stroke therapeutic approach involving the intranasal administration of CART. This new non-invasive treatment strategy for stroke patients is effective when initiated three days after stroke, providing a longer treatment window. Nasal delivery of CART improved behavioral recovery and reduced neurological scores in stroke animals. CART, given after stroke, modifies endogenous neural repair in stroke brain by facilitating neuroprogenitor cell proliferation and migration, enhancing reinnervation, and improving the functional recovery.

*Potential Commercial Applications:* Method of treating stroke

Competitive Advantages:

- New treatment strategy for stroke patients
- Non-invasive (nasal spray)
- Longer treatment window (3 days post-stroke)
- Current strategies aim to protect lesion site from damage, whereas this method helps brain repair

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available
- In vivo data available (animal)

*Inventors:* Yun Wang, Hui Shen, Seong Jin Yu, Yihong Yang (all of NIDA).

*Publications:* Manuscript in preparation.

*Intellectual Property:* HHS Reference No. E–058–2012/0—U.S. Provisional Application No. 61/592,761 filed 31 Jan 2012.

*Licensing Contact:* Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov.*