discretion, alters any person's liability or obligations in any other enforcement action, or precludes the Agency from initiating or proceeding with enforcement action in connection with any other alleged violation of the FD&C Act, whether or not related to a drug product covered by this notice. Similarly, a person who is or becomes enjoined from marketing unapproved or misbranded drugs may not resume marketing of such products based on FDA's exercise of enforcement discretion as described in this notice.

Drug manufacturers and distributors should be aware that the Agency is exercising its enforcement discretion as described previously only in regard to drug products covered by this notice that are marketed under an NDC number listed with the Agency in full compliance with section 510 of the FD&C Act before July 5, 2012. As previously stated, drug products covered by this notice that are currently marketed but not listed with the Agency on the date of this notice must, as of the effective date of this notice, have approved applications before their shipment in interstate commerce. Moreover, any person or firm that has submitted or submits an application but has yet to receive approval for such products is still responsible for full compliance with this notice.

V. Discontinued Products

Some firms may have previously discontinued manufacturing or distributing products covered by this notice without removing them from the listing of their products under section 510(j) of the FD&C Act. Other firms may discontinue manufacturing or distributing listed products in response to this notice. Firms that wish to notify the Agency of product discontinuation should send a letter signed by the firm's chief executive officer and fully identifying the discontinued product(s), including the product NDC number(s), and stating that the manufacturing and/or distribution of the product(s) has (have) been discontinued. The letter should be sent electronically to Astrid Lopez-Goldberg (see **ADDRESSES**). Firms should also electronically update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of unapproved products covered by this notice. FDA plans to rely on its existing records, including its drug listing records, the results of any subsequent inspections, or other available information when it targets violations for enforcement action.

VI. Reformulated Products

In addition, FDA cautions firms against reformulating their products into unapproved new drugs without oxycodone and marketing them under the same name or substantially the same name (including a new name that contains the old name) in anticipation of an enforcement action based on this notice. As stated in the Marketed Unapproved Drugs CPG, FDA intends to give higher priority to enforcement actions involving unapproved drugs that are reformulated to evade an anticipated FDA enforcement action. In addition, reformulated products marketed under a name previously identified with a different active ingredient have the potential to confuse health care practitioners and harm patients.

Dated: June 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–16475 Filed 7–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0603]

Assessment of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act V; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the statement of work for an assessment of the Program for Enhanced Review Transparency and Communication for New Molecular Entity (NME) New Drug Applications (NDAs) and Original Biologics License Applications (BLAs) (the Program). The Program is part of the FDA performance commitments under the proposed fifth authorization of the Prescription Drug User Fee Act (PDUFA), which, if enacted into law, will allow FDA to collect user fees for the review of human drug and biologics applications for fiscal years (FYs) 2013–2017. The Program is described in detail in section II.B of the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017.'' [1] The Program will be evaluated by an independent contractor in an interim and final assessment. As part of the FDA performance commitment, FDA is providing a period of 30 days for public comment on the statement of work before letting the contract for the assessment.

DATES: Submit electronic or written comments by August 6, 2012.

ADDRESSES: 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Andrea Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1173, Silver Spring, MD 20993–0002, 301–796–7641, *Andrea.Tan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The timely review of the safety and effectiveness of new drugs and biologics is central to FDA's mission to protect and promote the public health. Before the enactment of PDUFA in 1992, FDA's drug review process was relatively slow and not very predictable compared to other countries. As a result of concerns expressed by industry, patients, and other stakeholders at the time, Congress enacted PDUFA, which provided the added funds through user fees that enabled FDA to hire additional reviewers and support staff and upgrade its information technology systems. In return for these additional resources, FDA agreed to certain review performance goals, such as completing reviews of NDAs and BLAs and taking regulatory actions on them in predictable timeframes. These changes revolutionized the drug approval process in the United States and enabled FDA to speed the application review process for new drugs and biologics without compromising the Agency's high standards for demonstration of safety, efficacy, and quality of new drugs and biologics prior to approval.

PDUFA provides FDA with a source of stable, consistent funding that has made possible our efforts to focus on

[1] The ''*PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017*'' is available on the Internet at *http://www.fda.gov/downloads/For Industry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.*

promoting innovative therapies and helping to bring to market critical products for patients. When PDUFA was originally authorized in 1992, it had a 5-year term. The PDUFA program has been reauthorized every 5 years, with the most recent reauthorization occurring in 2007 for FYs 2008–2012. As directed by Congress in preparing for reauthorization of PDUFA for a new 5-year period, FDA conducted negotiations with regulated industry and conducted regular consultations with public stakeholders, including patient advocates, consumer advocates, and health care professionals between July 2010 and May 2011. Following these discussions, related public meetings, and Agency requests for public comment, FDA transmitted proposed PDUFA V recommendations to Congress for FYs 2013–2017 on January 13, 2012. If enacted into law, FDA's proposed PDUFA V recommendations will include an FDA commitment to implement a new review program for NME NDAs and original BLAs to enhance review transparency and communication between FDA and applicants on these complex applications.

II. PDUFA V NME NDA and Original BLA Review Program

FDA's existing review performance goals for priority and standard applications, 6 and 10 months respectively, were established more than 15 years ago. Since that time, additional requirements in the drug review process and scientific advances in drug development have made those goals increasingly challenging to meet, particularly for more complex applications like NME NDAs and original BLAs that generally are discussed in an FDA advisory committee meeting. FDA further recognizes that increasing communication between the Agency and applicants during FDA's review has the potential to increase efficiency in the review process.

To promote greater transparency and improve communication between the FDA review team and the applicant, FDA has proposed a new review model for NME NDAs and original BLAs in PDUFA V. The Program provides opportunities for increased communication by building in mid-cycle communications and late-cycle meetings between FDA and applicants. To accommodate this increased interaction during regulatory review and to address the need for additional time to review these complex applications, FDA's review clock will begin after the 60-day administrative filing review period for applications reviewed under the Program. The Program will apply to all NME NDAs and original BLAs received from October 1, 2012, through September 30, 2017. The goal of the Program is to improve the efficiency and effectiveness of the first-cycle review process by increasing communication with sponsors before application submission to improve the quality and completeness of submissions, and by increasing communications during application review. This will provide sponsors with opportunities to clarify previous submissions and provide additional data and analyses that are readily available, potentially avoiding the need for an additional review cycle when FDA's concerns about an application can be promptly resolved, but without compromising FDA's traditional high standards for approval. An efficient and effective review process that allows for timely responses to FDA questions can help ensure timely patient access to safe, effective, and high quality new drugs and biologics. To understand the Program's effect on the review of these applications, interim and final assessments by an independent contractor are key components of the Program. The performance commitments state that the statement of work for this effort will be published for public comment before beginning the assessment (section II.B). Because the assessment needs to commence at the beginning of PDUFA V on October 1, 2012, if the program is reauthorized, FDA must publish the statement of work for public comment in advance of that reauthorization to be able to begin the assessment on October 1, 2012. Accordingly, FDA is seeking public comment now on the proposed statement of work for the assessment of the Program, available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm304793.pdf.*

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.

Dated: June 29, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–16529 Filed 7–5–12; 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.

Exposing T Cells to Fas Ligand (FasL)-Fas Receptor (FasR) Antagonists Withholds Differentiation and Increases Expansion Making T Cells More Suitable for Use in Cancer Immunotherapy

Description of Technology: NIH scientists have developed methods to make a better immunotherapy by exposing T cells to Fas ligand (FasL) or Fas receptor (FasR) antagonists and agonists. Researchers have found that FasL–FasR antagonists suppress T cell differentiation leaving them in a naïve state. These T cells are a more ideal cell type for adoptive cell transfer therapies since they have not exhausted their effector functions and demonstrate greater proliferation, enhanced persistence and survival, and better activity against their target antigen when infused in vivo to treat cancer. Also, the prevention of T cell differentiation/effector function in vivo