DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–0895]

Determination That OPANA ER (Oxymorphone Hydrochloride) Drug Products Covered by New Drug Application 21–610 Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that OPANA ER (oxymorphone hydrochloride (HCl)) Extended-Release Tablet products approved under new drug application (NDA) 21–610 were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs for oxymorphone HCl extended-release tablets if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 U.S.C. 355(j)(7)(C); 21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made before approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Endo submitted a citizen petition dated August 10, 2012 (Docket No. FDA–2012–P–0895), under 21 CFR 10.30, requesting that the Agency: (1) Determine that OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets approved under NDA 21–610 were discontinued for reasons of safety, (2) refuse to approve any pending ANDA for a generic version of OPANA ER approved under NDA 21–610, and (3) suspend and withdraw the approval of any ANDA referencing OPANA ER approved under NDA 21–610 as the reference listed drug (Petition at 1).

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that the original OPANA ER was not withdrawn for reasons of safety or effectiveness. We describe the basis for this determination in our letter response to Endo's citizen petition (available on *http://www.regulations.gov* under Docket No. FDA–2012–P–0895).

Accordingly, the Agency will continue to list OPANA ER (oxymorphone HCl) Extended-Release Tablets approved under NDA 21–610 in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' includes drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of ANDAs that refer to these drug products. Additional ANDAs that refer to OPANA ER (oxymorphone HCl) Extended-Release Tablets may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs.

Dated: June 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15099 Filed 6–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0010]

Regulatory Systems Strengthening

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Office of International Programs. The goal of the Cooperative Agreement is to strengthen global regulatory capacity through activities that may include: Development of global norms and standards for product regulation; generation and analysis of evidence of regulatory systems performance; and provision of technical support to national regulatory systems strengthening efforts.

DATES: Important dates are as follows:

1. The application due date is August 9, 2013.
2. The anticipated start date is September 10, 2013.
3. The opening date is July 10, 2013.
4. The expiration date is August 10, 2013.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov*. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Charles Preston, Office of Science Policy Analysis/Office of International Programs, HFG–1, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993, 301–796–0654, *charles.preston@fda.hhs.gov;* or Daniel Lukash, Office of Acquisitions and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 2028, Rockville, MD 20857, 301–827–6771, *Daniel.Lukash@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/InternationalPrograms/CapacityBuilding/default.htm*.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–024
93.103

A. Background

The World Health Organization (WHO) has responsibility for helping to ensure access to essential medical products of assured safety, quality, and efficacy within its 193 Member States. It does so in three primary areas: (1) Setting global norms and standards; (2) articulating evidence-based policy options, including those relating to regulatory systems performance; and (3) providing technical support to national regulatory authorities and governments. These activities help to strengthen national regulatory systems. In this era of globalization, products can be imported from anywhere in the world within increasingly complex supply chains. As national and global health programs work to scale up access to medicines and health products, strong national regulatory systems are more important than ever before.

What are the necessary constituents of an effective medical products regulatory system? This is an important question, and one which the U.S. Institute of Medicine recently addressed, identifying some core elements of a successful regulatory system. These include sound government; good manufacturing, clinical, and laboratory practices; staff development and professionalization; monitoring and evaluation of product quality using laboratories; inspection and surveillance of products throughout the supply chain; risk assessment, analysis, and management; and emergency response. WHO helps to strengthen medical products regulatory systems through activities that include disseminating global quality norms and standards; facilitating the exchange of regulatory information; assessing regulatory authorities; providing training; distributing scientific materials and information on aspects of regulation from regional and global perspectives; expanding the global monitoring and surveillance system for falsified and substandard products; supporting national pharmacovigilance programs; and building capacity as a component of WHO's prequalification programs.

Another important area of work on regulatory systems strengthening is through a new Member State Mechanism (MSMech) on Substandard, Spurious, Falsified, Falsely-labeled, and Counterfeit (SSFFC) medical products, which was established as part of a resolution at the 65th World Health Assembly in May 2012. The MSMech is designed to address SSFFC issues and advance medical product safety and quality through the strengthening of national regulatory capacities. The first meeting of the MSMech occurred in Buenos Aires, Argentina, in November 2012, and the representatives agreed to form a global steering committee with representation from the WHO regions to support implementation of the workplan; the creation and management of selected work groups to address specific work areas; and the development of data-driven approaches to SSFFC issues. Participants also stressed the need for initiatives to educate consumers on the threats of SSFFC, for methodologies and instruments to obtain more accurate information about the nature and magnitude of the SSFFC problem, and for guidelines on how to better respond to the detection of SSFFC medical products.

FDA has been actively engaged with WHO on a number of these fronts. FDA experts participate in WHO drug and vaccine safety advisory committees, which develop important international norms and standards for the regulation of medical products. In addition, FDA has implemented a number of Cooperative Agreements with WHO on medical product safety and quality in recent years. In 2010, the Office of International Programs (OIP)/FDA set up a Cooperative Agreement with WHO to develop a global monitoring platform for SSFFC medical products. A steering group of experts from relevant FDA Centers provides guidance, direction, and advice regarding this cooperative effort. The overarching priority is the exchange of information about and expertise on matters relating to SSFFC so that data can be collected and contribute to the formulation of policies and programs that combat the problem. The system allows participating countries to report SSFFC information using a simple, electronic rapid alert form. Once the information has been submitted, WHO can take the appropriate first-response measures to circulate such information to governments, WHO regional offices, and other stakeholders as necessary. Analyses, threat assessments, thematic reporting, and bulletins based on the reported data may also be completed and shared.

B. Research Objectives

The Cooperative Agreement announced in this FOA represents the further expansion of well-established collaborations between WHO and OIP/FDA in support of data-driven and science-based public health strategies and approaches. These collaborations align well with FDA domestic and global goals, as outlined in its 2011 Pathway Report to Global Product Safety and Quality, including addressing medical product safety and quality problems. Relevant strategies include: (1) Developing global norms and standards; (2) generating and analyzing evidence on regulatory systems performance; and (3) providing technical support to national regulatory systems strengthening efforts. This Cooperative Agreement is expected to support the following types of collaboration:

- Developing global norms and standards
  - Enabling the sharing of scientific findings and data through expert meetings and technical consultations;
  - Assisting Member States in the implementation and subsequent evaluation of internationally recognized standards and guidelines, e.g. WHO guidelines and standards and those emerging from standards development venues such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);
  - Utilizing WHO's convening power to engage with relevant stakeholders on science-based norms and standards;
- Generating and analyzing evidence of regulatory systems performance
  - Contributing to the knowledge base of the current state of medical product regulation globally, including challenges, risks, and emerging trends;
  - Enabling and/or further strengthening the development of data/information systems as sources of inputs for evidence-based regulatory decisions and actions and enhanced knowledge management systems, coalitions, and networks;
- Providing technical support to national regulatory systems strengthening efforts
  - Enabling the strengthening of regulatory systems at the national and international levels in such critical domains as good manufacturing, clinical, and laboratory practices; developing curricula that supports regulatory professionalization; monitoring and evaluating product quality; laboratory capacity; inspection and surveillance of products throughout the supply chain; pharmacovigilance systems building and analyses; risk assessment, analysis, and

management; and making the business case for investments in regulatory systems.

C. Eligibility Information

This is a Single Source Cooperative Agreement.

II. Award Information/Funds Available

A. Award Amount

An award of up to $1,500,000 for this cooperative agreement will be available the first year (fiscal year (FY) 2013) based on available appropriations. Funding for subsequent years for this 5-year award will be contingent on the availability of appropriations and successful performance in the award not to exceed $1,500,000 per year.

B. Length of Support

The initial period of performance is 1 year. Contingent upon successful performance, additional awards may be available in FYs 2014, 2015, 2016, and 2017.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at *http://www.fda.gov/InternationalPrograms/CapacityBuilding/default.htm.* (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Obtain Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit electronic applications to: *http://www.grants.gov.*

Dated: June 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15101 Filed 6–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0012]

Building Research Capacity in Global Tobacco Product Regulation Program (U18)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Tobacco Product's (CTP's) Building Research Capacity in Global Tobacco Product Regulation Program. FDA intends to accept and consider a single source application for award to the World Health Organization (WHO) to identify, support, develop, conduct, and coordinate research efforts relating to tobacco control laws and rules in foreign countries that will directly inform and support FDA's exercise of its authority to regulate the manufacture, distribution, marketing, and sale of tobacco products in the United States. The Building Research Capacity in Global Tobacco Product Regulation Program seeks to advance and expand research in support of tobacco product regulation, in order to reduce the morbidity and mortality associated with tobacco use both within the United States and internationally. The program will advance FDA's and CTP's mission by utilizing WHO Member States' expertise and extensive international contacts in global tobacco control, as well as WHO's own programmatic expertise, to inform and support adequate manufacture, distribution, and market regulations of tobacco products for the protection of public health in the United States.

DATES: Important dates are as follows:

1. The application due date is July 31, 2013.
2. The anticipated start date is September 2013.
3. The opening date is July 1, 2013.
4. The expiration date is August 1, 2013.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov.* For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Caitlin Addorisio, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–796–0371; or Lisa Ko, Office of Acquisition and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–5095.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.grants.gov.* Search by Funding Opportunity Number: RFA–FD–13–032.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–032.
93.103.

A. Background

1. Authority

The Building Research Capacity in Global Tobacco Product Regulation Program is authorized by 42 U.S.C. 241 of the Public Health Service Act and the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31).

2. Program Background

Tobacco use is the foremost preventable cause of premature death in America. It causes over 443,000 deaths in the United States each year, and another 8.6 million smokers have at least one serious illness due to smoking. A compelling body of evidence illustrates that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

On June 22, 2009, President Obama signed the Tobacco Control Act, giving FDA regulatory authority to regulate the manufacturing, labeling, sale, distribution, advertising, and promotion of tobacco products.

Some key FDA activities authorized or required by the Tobacco Control Act include:

- Mandating larger, more varied, and more prominent warning labels on cigarette and smokeless tobacco products (Title II of the Tobacco Control Act).
- Restricting tobacco product sales, advertising, and promotion (section 906(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 387f(d)); section 102 of the Tobacco Control Act)).
- Establishing product standards to regulate the contents, design, components, emissions, and other characteristics of tobacco products