(levothyroxine sodium) tablets, 0.025 milligram (mg), 0.05 mg, 0.075 mg, 0.088 mg, 0.112 mg, 0.125 mg, 0.137 mg, 0.15 mg, 0.175 mg, 0.1 mg, 0.2 mg, and 0.3 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for LEVOTHROID (levothyroxine sodium) tablets, 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.112 mg, 0.125 mg, 0.137 mg, 0.15 mg, 0.175 mg, 0.1 mg, 0.2 mg, and 0.3 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Reena Raman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993–0002, 301–796–7577.

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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

LEVOTHROID (levothyroxine sodium) tablets, 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.112 mg, 0.125 mg, 0.137 mg, 0.15 mg, 0.175 mg, 0.1 mg, 0.2 mg, and 0.3 mg, are the subject of NDA 021116, held by Lloyd Inc., and initially approved on October 24, 2002. LEVOTHROID is used for the following indications:

- Hypothyroidism—As replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. Specific indications include: Primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism. Primary hypothyroidism may result from functional deficiency, primary atrophy, partial or total congenital absence of the thyroid gland, or from the effects of surgery, radiation, or drugs, with or without the presence of goiter.
- Pituitary Thyrotropine-Stimulating Hormone Suppression—In the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's thyroiditis), multinodular goiter, and as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

LEVOTHROID (levothyroxine sodium) tablets, 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.112 mg, 0.125 mg, 0.137 mg, 0.15 mg, 0.175 mg, 0.1 mg, 0.2 mg, and 0.3 mg are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated February 4, 2015 (Docket No. FDA–2015–P–0403), under 21 CFR 10.30, requesting that the Agency determine whether LEVOTHROID (levothyroxine sodium) tablets, 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.112 mg, 0.125 mg, 0.137 mg, 0.15 mg, 0.175 mg, 0.1 mg, 0.2 mg, and 0.3 mg, were withdrawn from sale for reasons of safety or effectiveness.

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 LEVOTHROID (levothyroxine sodium) tablets, 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.112 mg, 0.125 mg, 0.137 mg, 0.15 mg, 0.175 mg, 0.1 mg, 0.2 mg, and 0.3 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LEVOTHROID (levothyroxine sodium) tablets, 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.112 mg, 0.125 mg, 0.137 mg, 0.15 mg, 0.175 mg, 0.1 mg, 0.2 mg, and 0.3 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LEVOTHROID (levothyroxine sodium) tablets, 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.112 mg, 0.125 mg, 0.137 mg, 0.15 mg, 0.175 mg, 0.1 mg, 0.2 mg, and 0.3 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12655 Filed 5–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Clinical Trial Design Considerations for Malaria Drug Development; Notice of Public Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Tuesday, May 10, 2016 (81 FR 28876). The document announced a public workshop entitled ''Clinical Trial Design Considerations for Malaria Drug Development.'' The document was

published with the incorrect title and incorrect Internet address in the *Transcripts* section. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION: In FR Doc. 2016–10913, appearing on page 28876 in the **Federal Register** of Tuesday, May 10, 2016, the following corrections are made:

1. On page 28876, in the first column, the title is corrected to read ''Clinical Trial Design Considerations for Malaria Drug Development.''

2. On page 28876, in the second column, the *Transcripts* section is corrected to read ''Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.1061, Rockville, MD. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Rm. 6–30, Rockville, MD 20857. Transcripts will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm490084.htm* approximately 45 days after the workshop.

If you need special accommodations because of a disability, please contact Jessica Barnes or Lori Benner (see *Contact Person*) at least 7 days in advance.''

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12654 Filed 5–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1269]

Collaboration in Regulatory Systems Strengthening and Standardization Activities To Increase Access to Safe and Effective Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application for award of a cooperative agreement to the World Health Organization (WHO) in support of collaboration in regulatory systems strengthening, development of norms and standards, and innovative research to advance global access to safe and effective biological products that meet international standards. The goal of FDA's Center for Biologics Evaluation and Research (FDA/CBER) is to enhance technical collaboration and cooperation between the FDA, WHO, and its member states to facilitate strengthening regulatory capacity and support product development and standardization activities to increase access to safe and effective biologicals globally.

DATES: The application due date is July 5, 2016.

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: Gopa Raychaudhuri, CBER Liaison to WHO, Office of the Director, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7250, Silver Spring, MD 20993, 240–402–8000, *gopa.raychaudhuri@fda.hhs.gov;* or Leslie Haynes, Foreign Regulatory Capacity Building Coordinator, International Affairs, Office of the Director, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7222, Silver Spring, MD 20993, 240–402–8074, *leslie.haynes@fda.hhs.gov;* or Bryce Jones, Grants Management Specialist, Division of Acquisition and Grants, Office of Acquisitions and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 2026, Rockville, MD 20857, 240–402–2111, *Bryce.Jones@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.grants.gov.* Search by Funding Opportunity Number: RFA–FD–16–044.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–16–044
93.103

A. Background

WHO is the directing and coordinating authority on international health within the United Nations' (UN) system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. WHO assists countries in building capacity to increase and sustain access to medical products to prevent, detect, and treat communicable diseases, including reducing vaccine-preventable diseases. WHO also coordinates efforts to respond to public health emergencies by monitoring the health situation, undertaking risk assessments, identifying priorities, and providing technical guidance and other forms of support to countries and regions.

Providing adequate regulatory oversight throughout the product life cycle (pre- and post-licensure) is essential for assuring the safety, purity, and potency of vaccines and other biologicals. However, this is a major challenge for many National Regulatory Authorities (NRAs) confronted by a steadily increasing number of novel products, complex quality concerns, new regulatory issues arising from rapid technical and technological advances, and emerging infectious diseases (*e.g.,* pandemic influenza, Middle East Respiratory Syndrome, Ebola, Zika). WHO has an important role in strengthening regulatory systems and other supportive activities to increase access to high quality, safe, and effective biological products especially in low-and-middle-income countries. It is the only organization with the mandate, access to technical expertise, and broad reach to meet the research objectives.

FDA/CBER has been a leader and active participant in the global community to improve human health in the world's populations over many years. Its international engagements have been informed by the knowledge that protection of global public health against infectious disease threats translates into protection of public health in the United States. FDA, through CBER, has longstanding collaborations with WHO in the area of biologicals (vaccines, blood and blood products, relevant in vitro diagnostics, and cell and tissue therapies).

FDA/CBER has been a Pan American Health Organization/WHO Collaborating Center for Biological Standardization since 1998 with the current commitment running until 2020 and expectation of future extensions. As a WHO Collaborating Center for Biological Standardization, CBER has provided scientific and technical support to WHO for development of