TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]—Continued

E6(R2) Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Developing a Quality Management System.					

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

E6(R2) Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 5.0.7—Risk Reporting ..... Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits in a Clinical Study Report.	1,457	4.6	6,702	3	20,107

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

E6(R2) Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry	Number of recordkeepers	Number of records per recordkeeper	Total records	Average burden per record	Total hours
Section 5.0—Quality Management (including 5.0.1 to 5.0.7) ..... Developing a Quality Management System.	218	1	218	60	13,080

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

E6(R2) Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 5.0.7—Risk Reporting ..... Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits in a Clinical Study Report.	218	3.69	804	3	2,413

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The collections of information included in the sections marked as ''ADDENDUM'' in the E6(R2) draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information found in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information found in 21 CFR part 312 have been approved under OMB control number 0910–0014; and collections of information found in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information found in 21 CFR part 601 have been approved under OMB control number 0910–0338.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12651 Filed 5–27–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–0403]

Determination That LEVOTHROID (Levothyroxine Sodium) Tablets, 0.025 Milligram, 0.05 Milligram, 0.075 Milligram, 0.088 Milligram, 0.112 Milligram, 0.125 Milligram, 0.137 Milligram, 0.15 Milligram, 0.175 Milligram, 0.1 Milligram, 0.2 Milligram, and 0.3 Milligram, 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 or Agency) has determined that LEVOTHROID

(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]

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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