provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility; (2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Help America Vote Act (HAVA) Narrative Report from States and Units of Local Government is required by federal statute and regulation, the Help America Vote Act (HAVA), Public Law 107–252, Title II, Subtitle D, Part 2, Sections 261 to 265, Payments to States and Units of Local Government to Assure Access for Individuals with Disabilities (42 U.S.C. 15421–25). The report is provided in writing to the Administration for Community Living, Administration on Intellectual & Developmental Disabilities. Each State or Unit of Local Government must prepare and submit an annual report at the end of every fiscal year. The report addresses the activities conducted with the funds provided during the year. The information collected from the annual report will be aggregated into an annual profile of how States have utilized the funds and establish best practices for election officials. It will also provide an overview of the State election goals and accomplishments and permit the Administration on Intellectual & Developmental Disabilities to track voting progress to monitor grant activities. ACL estimates the burden of this collection of information as follows: 55 Chief Election officials respond annually which should be an average burden of 20 hours per State per year or a total of 2,750 hours for all states annually.

Dated: August 14, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2014–19802 Filed 8–19–14; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0424]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Temporary Marketing Permit Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 19, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0133. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i) (OMB Control Number 0910–0133)—Extension

Section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food ''[w]henever . . . such action will promote honesty and fair dealing in the interest of consumers. . . .'' Under section 403(g) of the FD&C Act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) enables the Agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions and standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

In the **Federal Register** of June 5, 2014 (79 FR 32556), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
130.17(c)/Request for Permit	13	2	26	25	650
130.17(i)/Request for Extension	1	2	2	2	4

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total	.....	.....	.....	.....	654

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

The estimated number of temporary marketing permit applications and hours per response is an average based on our experience with applications received for the past 3 years and information from firms that have submitted recent requests for temporary marketing permits. Based on this information, we estimate that there will be, on average, approximately 13 firms submitting requests for 2 temporary marketing permits per year over the next 3 years.

Thus, we estimate that 13 respondents will submit 2 requests for temporary marketing permits annually under § 130.17(c). The estimated number of respondents for § 130.17(i) is minimal because this section is seldom used by the respondents; therefore, the Agency estimates that there will be one or fewer respondents annually with two or fewer requests for extension of the marketing permit under § 130.17(i). The estimated number of hours per response is an average based on the Agency's experience and information from firms that have submitted recent requests for temporary marketing permits. We estimate that 13 respondents each will submit 2 requests for temporary marketing permits under § 130.17(c) and that it will take a respondent 25 hours per request to comply with the requirements of that section, for a total of 650 hours. We estimate that one respondent will submit two requests for extension of its temporary marketing permits under § 130.17(i) and that it will take a respondent 2 hours per request to comply with the requirements of that section, for a total of 4 hours.

Dated: August 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19695 Filed 8–19–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–1510]

Determination That LUPRON DEPOT–PED (Leuprolide Acetate for Depot Suspension), Injectable 3.75 Milligrams/Vial and 7.5 Milligrams/Vial; and LUPRON DEPOT–PED (Leuprolide Acetate for Depot Suspension), Injectable 7.5 Milligrams/Vial and 7.5 Milligrams/Vial, 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 LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 3.75 milligrams (mg)/vial and 7.5 mg/vial; and LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for leuprolide acetate for depot suspension, injectable 3.75 mg/vial and 7.5 mg/vial; and injectable 7.5 mg/vial and 7.5 mg/vial, if all other legal and regulatory requirements are met. However, in considering whether to file an ANDA for leuprolide acetate for depot suspension, future applicants are advised that they may not be able to obtain LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, for bioequivalence testing because the product has not been commercially available for a number of years. An ANDA applicant who is unable to obtain LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, for bioequivalence testing should contact the Office of Generic Drugs for a determination of what is necessary to show bioavailability and the same therapeutic effect.

FOR FURTHER INFORMATION CONTACT: Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 240–402–0979.

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.