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DEPOT–PED (Leuprolide Acetate for Depot Suspension), Injectable 7.5 Milligrams/Vial and 7.5 Milligrams/Vial, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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.

LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 3.75 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, are the subject of NDA 020263, held by Abbvie Endocrine, Inc., and initially approved on April 16, 1993. LUPRON DEPOT–PED is indicated for treatment of children with central precocious puberty.

In a report dated January 30, 1999, Abbvie notified FDA that LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 3.75 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 being discontinued, and FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Joan Janulis, on behalf of Lachmann Consultant Services, Inc., submitted a citizen petition dated November 4, 2013 (Docket No. FDA–2013–P–1510), under 21 CFR 10.30, requesting that the Agency determine whether LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, 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 LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, 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 LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 14, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–19713 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–2014–N–1179]

Request for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels and Request for Notification From Consumer Organizations Interested in Participating in the Selection Process for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for current vacancies and for those that will or may occur through December 2014.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to the FDA (see **ADDRESSES**) by September 19, 2014, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by September 19, 2014.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should submit their information electronically to *kimberly.hamilton@fda.hhs.gov* or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, FAX 301–847–8640.

Consumer representative nominations should be submitted electronically by logging into the FDA advisory Committee Membership Nomination Portal at *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or by fax to 301–847–8640. Additional information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER GENERAL INFORMATION CONTACT: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5117, Silver Spring, MD 20993–0002, 301–796–6319, email: *kimberly.hamilton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: For questions relating to specific advisory committees or panels, contact the following persons listed in table 1: