Grantees submit semi-annual reports instead of quarterly report. This will reduce the administrative burden on Grantees, especially the smaller organizations. The majority of content being requested from the grantees essentially remain same except for the frequency of reporting.

*OPR:* The following are proposed content changes to the document: Grantee Information: Report Frequency—This section of OPR will be reformatted to request semi-annual or final project data instead of quarterly information. The other sections of the document with reference to ''quarterly'' information will be changed to reflect the shift from four-times a year reporting requirement to twice per year.

*Objective Work Plan Update:* Content remains the same. No changes are proposed for this section of the OPR.

*Impact indicator:* Current Status of Expected Results and Current Status of Expected Benefits which are reported separately on the OPR will be combined to read ''Current Status of Expected Results and Benefits.'' The content requested in this section is similar to the previous OPR without the added burden of having the reporting organizations provide the analysis that distinguish between 'results and benefits''. Every section of the document will be rewritten to reflect this change.

*OWP:* ANA proposes to reformat the OWP (content is same) by swapping the Objective field with Problem Statement. In other words, this section will require respondents to begin with a concise statement about the problem the project is designed to address and will be followed by more details about the objectives of the project.

The two fields ''Results Expected and Benefits Expected'' will be combined into one field to read ''Results and benefits Expected''. This will reduce redundancy and help reduce the burden on Grantees.

*Respondents:* Tribal Government, Native non-profit organizations, Tribal Colleges & Universities.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| OWP | 500 | 1 | 2 | 1000 |
| OPR | 275 | 2 | 1 | 550 |

*Estimated Total Annual Burden Hours:* 1,550.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendation for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2015–03032 Filed 2–12–15; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0161]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled ''Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates '' that appeared in the **Federal Register** of February 6, 2015 (80 FR 6728). The document announced 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. The document was published with three errors. This document corrects those errors.

**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 the **Federal Register** of Friday, February 6, 2015, in FR Doc. 2015–02348, the following corrections are made:

1. On page 6728, in the third column, under the heading Export of Food and Drug Administration Regulated Products: Export Certificates—(OMB Control Number 0910–0498)—Extension, the following sentence is added at the end of the first paragraph: ''In January 2011, section 801(e)(4)(A) was amended by the Food Safety Modernization Act (Pub. L. 111–353) to provide authorization for export certification fees for food and animal feed.''

2. On page 6728, in the third column, under the heading Export of Food and Drug Administration Regulated Products: Export Certificates—(OMB Control Number 0910–0498)—Extension, in the second paragraph, the first sentence is revised to read as follows: ''This section of the FD&C Act authorizes FDA to issue export certificates for regulated food, animal feed, pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the FD&C Act.''

3. On page 6729, Table 2 is corrected as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

| FDA center | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Center for Biologics Evaluation and Research | 2,114 | 1 | 2,114 | 1 | 2,114 |
| Center for Devices and Radiological Health | 10,528 | 1 | 10,528 | 2 | 21,056 |
| Center for Veterinary Medicine | 1,848 | 1 | 1,848 | 1 | 1,848 |
| Total | | | | | 25,018 |

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

Dated: February 9, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–03005 Filed 2–12–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–P–1055]**

### Determination That SUBUTEX (Buprenorphine Hydrochloride) Sublingual Tablets, Equivalent 2 Milligrams Base and Equivalent 8 Milligrams Base, 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 SUBUTEX (buprenorphine hydrochloride (HCl)) Sublingual Tablets, Equivalent (Eq) 2 milligrams (mg) base and Eq 8 mg base, 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 SUBUTEX, and it will allow FDA to continue to approve ANDAs that refer to SUBUTEX as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 240–402–4191.

**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 sponsors 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. Sponsors of ANDAs 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, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30.

SUBUTEX (buprenorphine HCl) Sublingual Tablets is the subject of NDA 20–732, held by Reckitt Benckiser Pharmaceuticals, Inc. (Reckitt). It was approved on October 8, 2002. After Reckitt discontinued marketing SUBUTEX in 2011, FDA moved SUBUTEX to the ''Discontinued Drug Product List'' section of the Orange Book. Another buprenorphine-containing product, SUBOXONE (buprenorphine HCl and naloxone HCl) Sublingual Tablets, is the subject of NDA 20–733, also held by Reckitt. It was originally approved on October 8, 2002, and later approved in another dosage form (sublingual film) on August 30, 2010, under NDA 22–410. In March 2013, Reckitt discontinued marketing the sublingual tablet dosage form of SUBOXONE.[1] All three products are approved for treatment of opioid dependence.[2]

Actavis Elizabeth LLC submitted a citizen petition dated August 16, 2013 (Docket No. FDA–2013–P–1055), under 21 CFR 10.30, requesting that FDA determine whether SUBUTEX was withdrawn from sale for reasons of safety or effectiveness. The petition contains no data or other information suggesting that SUBUTEX was withdrawn for reasons of safety or effectiveness.

We have carefully reviewed our records concerning the withdrawal of SUBUTEX from sale. Based on the information we have at this time, FDA has determined under § 314.161 that SUBUTEX was not withdrawn for reasons of safety or effectiveness.

The buprenorphine in both SUBUTEX and SUBOXONE is a mu opioid partial agonist that can precipitate withdrawal in patients physically dependent on full opioid agonists. That is, the relative reduction in activity at the mu receptor when buprenorphine replaces a full opioid agonist can cause symptoms of opioid withdrawal. SUBOXONE also contains naloxone. Naloxone is a potent

[1] On September 27, 2012, after Reckitt publicly announced that it was planning to discontinue the product, Lachman Consultant Services Inc. (Lachman) submitted a citizen petition requesting that the Agency determine whether SUBOXONE Sublingual Tablets were withdrawn from sale for reasons of safety or effectiveness (Docket No. FDA–2012–P–1034). After considering Lachman's citizen petition and reviewing our records, including the analysis that the Agency prepared in connection with Reckitt's citizen petition (Docket No. FDA–2012–P–1028), FDA determined that SUBOXONE Sublingual Tablets was not discontinued for reasons of safety or effectiveness (78 FR 34108).

[2] On September 25, 2012, Reckitt submitted a citizen petition requesting that FDA not approve any new drug application or abbreviated new drug application (ANDA) for a buprenorphine product for treatment of opioid dependence unless the applications and products met certain criteria. On February 22, 2013, FDA denied Reckitt's petition (Docket No. FDA–2012–P–1028).