title ''Application for Participation in the Food and Drug Administration Commissioner's Fellowship Program.'' 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.

Application for Participation in the FDA Commissioner's Fellowship Program; (OMB Control Number 0910—New)

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. Collecting applications for the Commissioner's Fellowship Program will allow FDA's Office of the Commissioner to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with FDA.

In the **Federal Register** of August 4, 2014 (79 FR 45196), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and, therefore, will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/5 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394	600	1	600	1.33	798
Total	.....	.....	.....	.....	798

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

FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 5 years.

Dated: October 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25893 Filed 10–30–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0801]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exports: Notification and Recordkeeping Requirements; 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 October 14, 2014. The document announced that a proposed collection of information had been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. In this document, we correct some errors that appeared in the notice.

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 FR Doc. 2014–24293, appearing on page 61643 in the **Federal Register** of October 14, 2014 (79 FR 61643), we make the following correction: On page 61644, replace table 1 with the following table:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.101(d) (Non-Tobacco) (CBER)	5	193	965	15	14,475
1,101(d) (Non-Tobacco) (CDER)	5	180	900	15	13,500
1.101(d) (Non-Tobacco) (CDRH)	63	130	8,190	15	122,850
Total [2]	.....	.....	.....	.....	150,825

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

[2] Due to a clerical error, the reporting burden for ''Exports: Notification and Recordkeeping Requirements'', which published on July 3, 2014 (79 FR 38036), was incorrect. Table 1 of this document contains the correct reporting burden for this collection.

Dated: October 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25910 Filed 10–30–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1577]

Determination That TOPICORT (Desoximetasone) Cream and Other Drug Products 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 the drug products listed in this document 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 these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6223, Silver Spring, MD 20993–0002, 301–796–5418, *Amy.Hopkins@fda.hhs.gov.*

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 approved 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 generally known 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. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 020611 for DOVONEX (calcipotriene) Solution and NDA 020239 for KYTRIL (granisetron hydrochloride) in the **Federal Register** of July 19, 2013 (78 FR 43210)).

Application No.	Drug	Applicant
NDA 017856	TOPICORT (desoximetasone) Cream; Topical 0.25%	Taro Pharmaceuticals North America Inc., 5 Skyline Dr., Hawthorne, NY 10532.
NDA 020239	KYTRIL (granisetron HCl) Injectable; Injection, Equivalent to (EQ) 0.1 milligram (mg) Base/milliliter (mL); EQ 1 mg Base/mL; EQ 3 mg Base/mL; EQ 4 mg Base/4 mL.	Hoffmann La Roche Inc., 340 Kingsland St., Nutley, NJ 07110.
NDA 020611	DOVONEX (calcipotriene) Solution; Topical, 0.005%	Leo Pharma Inc., 1 Sylvan Way, Parsippany, NJ 07054.
NDA 021275	LUMIGAN (bimatoprost) Solution/Drops; Ophthalmic, 0.03%.	Allergan Inc., 2525 Dupont Dr., Irvine, CA 92623.
NDA 021864	LYBREL (ethinyl estradiol; levonorgestrel) Tablet; Oral, 0.02 mg/0.09 mg.	Wyeth Pharmaceuticals Inc., P.O. Box 8299, Philadelphia, PA 19101.
ANDA 075222	Ketorolac Tromethamine Injectable; Injection, 15 mg/mL; 30 mg/mL.	Bedford Laboratories Inc., 300 Northfield Rd., Bedford, OH 44146.
ANDA 075228	Ketorolac Tromethamine Injectable; Injection, 30 mg/mL	Do.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. 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: October 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25911 Filed 10–30–14; 8:45 am]

BILLING CODE 4164–01–P