requires the submitter's signature, the name and title of the person signing the form, as well as the date signed.

Description of Respondents: The respondents to this collection of information are firms interested in exporting U.S.-manufactured food and cosmetic products to foreign countries that require export certificates.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	FDA form number [2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cosmetics	3613d	600	1	600	1.5	900
Conventional Food (Including Seafood)	3613e	398	1	398	1.5	597
Dietary Supplements, Food for Special Dietary Use, Infant Formula, and Medical Foods	3613e	2,129	4	2,129	1.5	3,194
Food Additives and Food Contact Substances	3613e	167	1	167	1.5	251
Total						4,942

[1] There are no operating and maintenance costs associated with this collection of information.
[2] Form FDA 3613d and Form FDA 3613e may be submitted electronically via the Certificate Application Process.

For the purpose of this information collection request, we are basing our estimate of the average burden per response in column 6 of Table 1 on the estimates previously submitted to and approved by OMB under control number 0910–0498. Our estimate of the average burden per response in column 6 of Table 1 varies according to the product category for which the certificate is requested. We base our estimates of the total annual responses in column 5 of Table 1 on our experience with certificate applications received in the past 2 fiscal years. Some respondents send in requests as often as three or four times a month while others may submit only periodic requests.

We expect that most if not all firms requesting export certificates in the next 3 years will choose to take advantage of the option of electronic submission via the CFSAN Certificate Application Process. Thus, our burden estimates in Table 1 are based on the expectation of 100 percent participation in the electronic submission process. The opportunity to provide the information in electronic format could reduce the Agency's previous estimates for the time to prepare each submission. However, as a conservative approach for the purpose of this analysis, we are assuming that the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission.

Dated: January 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00130 Filed 1–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2258]

Determination That TAGAMET (Cimetidine) Tablets 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 applicants, FDA withdrew approval of NDA 017920 for TAGAMET (cimetidine) Tablets in the **Federal Register** of June 8, 2011 (76 FR 33310), and NDA 018709 for CAPOZIDE (captopril and hydrochlorothiazide) Tablets in the **Federal Register** of March 19, 2012 (77 FR 16039).)

Application No.	Drug	Applicant
NDA 017920	TAGAMET (cimetidine) Tablet; Oral, 200 milligram (mg); 300 mg; 400 mg; 800 mg.	GlaxoSmithKline, 5 Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
NDA 018155	OPTICROM (cromolyn sodium) Solution/Drops; Ophthalmic, 4%.	Allergan Inc., 2525 Dupont Dr., Irvine, CA 92623.
NDA 018709	CAPOZIDE (captopril and hydrochlorothiazide) Tablet; Oral, 25 mg/15 mg; 25 mg/25 mg; 50 mg/15 mg; 50 mg/25 mg.	Apothecon Inc., P.O. Box 4500, Princeton, NJ 08543.
NDA 018976	LEVATOL (penbutolol sulfate) Tablet; Oral, 10 mg; 20 mg	Auxilium Pharmaceuticals LLC, 640 Lee Rd., Chesterbrook, PA 19087.
NDA 019958	CUTIVATE (fluticasone propionate) Cream; Topical, 0.05% ..	Fougera Pharmaceuticals Inc., 1 Health Plaza, Bldg. 434, East Hanover, NJ 07936.
NDA 020713	MIRCETTE (desogestrel and ethinyl estradiol, and ethinyl estradiol) Tablet; Oral-28, 0.15 mg/0.02 mg; 0.01 mg.	Teva Pharmaceutical Products Inc., 41 Moores Rd, P.O. Box 4011, Frazer, PA 19355.
NDA 021410	AVANDAMET (metformin hydrochloride (HCl) and rosiglitazone maleate) Tablet; Oral, 500 mg/Equivalent to 1 mg Base.	SmithKline Beecham Cork Ltd., Ireland, 2301 Renaissance Blvd., MC RN 0420, King of Prussia, PA 19406.
NDA 021571	IQUIX (levofloxacin) Solution/Drops; Ophthalmic, 1.5%	Santen Inc., 555 Gateway Dr., Napa, CA 94558.
NDA 021726	NIRAVAM (alprazolam) Orally Disintegrating Tablets; Oral, 0.25 mg; 0.5 mg; 1 mg; 2 mg.	UCB Inc., 1950 Lake Park Dr., Smyrna, GA 30080.
NDA 021768	FLUDEOXYGLUCLOSE F–18 Injectable; Intravenous 10–100 millicuries/milliliter.	Weill Medical College Cornell University, 516 East 72nd St., New York, NY 10065.
ANDA 076699	PARCOPA (carbidopa and levodopa) Orally Disintegrating Tablets; Oral, 10 mg/100 mg; 25 mg/100 mg; 25 mg/250 mg.	UCB Inc., 1950 Lake Park Dr., Smyrna, GA 30080.
ANDA 080248	ALBALON (naphazoline HCl) Solution/Drops; Ophthalmic, 0.1%.	Allergan Inc., 2525 Dupont Dr., Irvine, CA 92623.

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: January 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00116 Filed 1–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2015 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the Web site location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH or the Center) is intending to publish in Fiscal Year (FY) 2015. In addition, FDA has established a docket, identified in brackets in the heading of this document, where stakeholders may comment on the priority of topics for guidance, provide comments and/or propose draft language for those topics, suggest topics for new or different guidance documents, and comment on the applicability of guidance documents that have issued previously.

DATES: You may submit either electronic or written comments at any time. FDA would appreciate if stakeholders provide feedback by March 10, 2015.

ADDRESSES: Submit electronic comments on the proposed guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Gadiock, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993–0002, 301–796–5736.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the Medical Device User Fee Amendments of 2012 (MDUFA III), title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112–114), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments included:

- Annually posting a list of priority medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the ''A-list'') and