to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements applicable to that device type. If approved, petitions requesting classification from class III to class II or class I provide an alternative route to market in lieu of premarket approval for class III devices. If approved, petitions requesting reclassification from class I or II, to a different class, may increase requirements.

In the **Federal Register** of November 14, 2011 (76 FR 70460), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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
860.123	6	1	6	500	3,000

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

Based on the last 3 years, and actual reclassification petitions received, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who: (1) Are familiar with the requirements for submission of a reclassification petition, (2) have consulted and advised manufacturers on these requirements, and (3) have reviewed the documentation submitted.

Dated: March 20, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–7142 Filed 3–23–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0742]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

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 April 25, 2012.

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 0910–0045. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@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.

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—21 CFR Part 207—(OMB Control Number 0910–0045)—Extension

Requirements for drug establishment registration and drug listing are set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360); section 351 of the Public Health Service Act; and part 207 (21 CFR part 207). Fundamental to FDA's mission to protect the public health is the collection of this information, which is used for important activities such as postmarket surveillance for serious adverse drug reactions, inspection of drug manufacturing and processing facilities, and monitoring of drug products imported into the United States. Comprehensive, accurate, and up-to-date information is critical to conducting these activities with efficiency and effectiveness.

Under section 510 of the FD&C Act, FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510 of the FD&C Act, FDA issued part 207.[1] Under current § 207.20, manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and biological products, including bulk drug substances and bulk drug substances for prescription compounding, and drug premixes as well as finished dosage forms, whether prescription or over-the-counter, are required to register their establishment. In addition, manufacturers, repackers, and relabelers are required to submit a listing of every drug or biological product in commercial distribution. Owners or operators of establishments that distribute under their own label or trade name a drug product manufactured by a registered establishment are not required either to register or list. However, distributors may elect to submit drug listing information in lieu of the registered establishment that manufactures the drug product. Foreign drug

[1] This document addresses the information collection in current part 207. In the **Federal Register** of August 29, 2006 (the 2006 proposed rule) (71 FR 51276), FDA proposed to revise part 207. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list, and describes when and how to register and list and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. The proposed regulations generally also require the electronic submission of all registration and most listing information. The 2006 proposed rule requested comments on the information collection for revised part 207. When the proposal is finalized, the information collection for a revised part 207 will replace the information collection in this document.

establishments must also comply with the establishment registration and product listing requirements if they import or offer for import their products into the United States.

Under current § 207.21, establishments, both domestic and foreign, must register with FDA within 5 days after beginning the manufacture of drugs or biologicals, or within 5 days after the submission of a drug application or biological license application (BLA). In addition, establishments must register annually. Changes in individual ownership, corporate or partnership structure, location, or drug-handling activity must be submitted as amendments to registration under current § 207.26 within 5 days of such changes. Under § 207.20(b), private label distributors may request their own labeler code and elect to submit drug listing information to FDA. In such instances, at the time of submitting or updating drug listing information, private label distributors must certify to the registered establishment that manufactured, prepared, propagated, compounded or processed (which includes, among other things, repackaging and relabeling) the listed drug that the drug listing submission was made. Establishments must, within 5 days of beginning the manufacture of drugs or biologicals, submit to FDA a listing for every drug or biological product in commercial distribution at that time. Private label distributors may elect to submit to FDA a listing of every drug product they place in commercial distribution. Registered establishments must submit to FDA drug product listing for those private label distributors who do not elect to submit listing information.

Under § 207.25, product listing information submitted to FDA by domestic and foreign manufacturers must, depending on the type of product being listed, include any new drug application (NDA) number or biological establishment license number, copies of current labeling and a sampling of advertisements, a quantitative listing of the active ingredient for each drug or biological product not subject to an approved application or license, the NDC number, and any drug imprinting information.

In addition to the product listing information required, FDA may also require, under § 207.31, a copy of all advertisements and a quantitative listing of all ingredients for each listed drug or biological product not subject to an approved application or license; the basis for a determination, by the establishment, that a listed drug or biological product is not subject to marketing or licensing approval requirements; and a list of certain drugs or biological products containing a particular ingredient. FDA may also request, but not require, the submission of a qualitative listing of the inactive ingredients for all listed drugs or biological products, and a quantitative listing of the active ingredients for all listed drugs or biological products subject to an approved application or license.

Under § 207.30, establishments must update their product listing information every June and December or, at the discretion of the establishment, when any change occurs. These updates must include the following information: (1) A listing of all drug or biological products introduced for commercial distribution that have not been included in any previously submitted list; (2) all drug or biological products formerly listed for which commercial distribution has been discontinued; (3) all drug or biological products for which a notice of discontinuance was submitted and for which commercial distribution has been resumed; and (4) any material change in any information previously submitted. No update is required if no changes have occurred since the previously submitted list.

Historically, drug establishment registration and drug listing information have been submitted in paper form using Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors) (collectively referred to as FDA Forms).

Changes in the FD&C Act resulting from enactment of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) (FDAAA) require that drug establishment registration and drug listing information be submitted electronically unless a waiver is granted. Before the enactment of FDAAA, section 510(p) of the FD&C Act expressly provided for electronic submission of drug establishment registration information upon a finding that electronic receipt was feasible, and section 510(j) of the FD&C Act provided that drug listing information be submitted in the form and manner prescribed by FDA. Section 224 of FDAAA, which amends section 510(p) of the FD&C Act, now expressly, requires electronic drug listing in addition to drug establishment registration. In certain cases, if it is unreasonable to expect a person to submit registration and listing information electronically, FDA may grant a waiver from the electronic format requirement.

In the **Federal Register** of June 1, 2009 (74 FR 26248), FDA announced the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing'' (the 2009 guidance). The document provides guidance to industry on the statutory requirement to submit electronically drug establishment registration and drug listing information. The guidance describes the types of information to include for purposes of drug establishment registration and drug listing and how to prepare and submit the information in an electronic format (Structured Product Labeling (SPL) files) that FDA can process, review, and archive.

In addition to the information that previously was collected by the FDA Forms, the guidance addresses electronic submission of other required information as follows:

- For registered foreign drug establishments, the name, address, and telephone number of its U.S. agent (§ 207.40(c));
- The name of each importer that is known to the establishment (the U.S. company or individual in the United States that is an owner, consignee, or recipient of the foreign establishment's drug that is imported into the United States. An importer does not include the consumer or patient who ultimately purchases, receives, or is administered the drug, unless the foreign establishment ships the drug directly to the consumer or the patient) (section 510(i)(1)(A) of the FD&C Act); and
- The name of each person who imports or offers for import (the name of each agent, broker, or other entity, other than a carrier, that the foreign drug establishment uses to facilitate the import of their drug into the United States) (section 510(i)(1)(A) of the FD&C Act).

FDA also recommends the voluntary submission of the following additional information, when applicable:

- To facilitate correspondence between foreign establishments and FDA, the email address for the U.S. agent, and the telephone number(s) and email address for the importer and person who imports or offers for import their drug;
- A site-specific Data Universal Numbering System (DUNS) number for each entity (e.g., the registrant, establishments, U.S. agent, importer);
- The NDC product code for the source drug that is repacked or relabeled;

• Distinctive characteristics of certain listed drugs, i.e., the flavor, the color, and image of the actual solid dosage form; and

• Registrants may indicate that they view as confidential the registrant's business relationship with an establishment, or an inactive ingredient.

In addition to the collection of information, there is additional burden for the following activities:

• Preparing a standard operating procedure (SOP) for the electronic submission of drug establishment registration and drug listing information;

• Creating the SPL file, including accessing and reviewing the technical specifications and instructional documents provided by FDA (accessible at *http://www.fda.gov/oc/datacouncil/spl.html*);

• Reviewing and selecting appropriate terms and codes used to create the SPL file (accessible at *http://www.fda.gov/oc/datacouncil/spl.html*);

• Obtaining the digital certificate used with FDA's electronic submission gateway and uploading the SPL file for submission (accessible at *http://www.fda.gov/esg/default.htm*); and

• Requests for waivers from the electronic submission process as described in the draft guidance.

When FDA published the 2009 guidance on submitting establishment registration and drug listing information in electronic format, the Agency also amended its burden estimates for OMB control number 0910–0045 to include the additional burden for collection of information that had not been submitted using the FDA Forms, and to create and upload the SPL file. The amended burden estimates included the one-time preparation of an SOP for creating and uploading the SPL file. Although most firms will already have prepared an SOP for the electronic submission of drug establishment registration and drug listing information, each year additional firms will need to create an SOP. As provided in table 2 of this document, FDA estimates that approximately 1,000 firms will have to expend a one-time burden to prepare, review, and approve an SOP, and the Agency estimates that it will take 40 hours per recordkeeper to create 1,000 new SOPs for a total of 40,000 hours. The information collection requirements of the Drug Listing and Establishment Registration regulations have been grouped according to the information collection areas of the regulations.

In the **Federal Register** of October 24, 2011 (76 FR 65730), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment.

Comment

The comment raised two issues and asked for several procedural clarifications. The first issue raised suggested that the burden to industry might be greater than the 4.5-hour average provided in the estimate. The next issue questioned the process by which FDA issued a guidance to address the electronic submissions process without changing the regulation that still describes a paper submission process, which would have allowed for public comment on that change. The comment then sought several procedural clarifications on: (1) How to submit changes in ownership of an establishment, (2) how to select a business function, (3) how to ensure that an establishment is represented consistently between a vendor's registration and the client's drug establishment registration, (4) how to link an importer with a particular product, (5) how to list bulk tablets that will be imported for packaging, and (6) how to certify to the registered establishment that the private label distributor has listed the product.

Response

FDA acknowledges that the 2009 guidance is different from the process described in the current part 207. As was stated in the **Federal Register** notice and as acknowledged by the commenter, the current regulation predates the electronic process and describes a paper-based submission process. FDA is in the process of rewriting part 207, and published the draft version for public comment in 2006. Afterward, the FDAAA mandated the electronic submission of drug establishment and drug product information. The 2009 guidance was created to address the mandate of FDAAA. The 2006 proposed rule will be modified appropriately to address the FDAAA mandates as well. With regards to the estimated burden, FDA collaborated with members of industry and international health information data standards organizations to arrive at the current process and estimates for the burden of gathering, assembling, and submitting data. The estimates are considered to be averages that will vary up or down per individual respondent.

The following paragraphs are intended to clarify one of the commenter's issues mentioned previously in this document:

1. Changes to the establishment name, registrant name, or other registration information can be made by submitting an updated registration submission via SPL. Changes in corporate ownership or officers that do not affect names, addresses, or the DUNS number(s) for a registered establishment should be made with Dun and Bradstreet. That data is then referenced as needed by FDA using the DUNS number. Information about submitting SPL can be found at the link at the end of the FDA response. It should be noted that changes in ownership may also require the submission of updates to listing information, labeler code name and DUNS, and application data for NDAs, abbreviated new drug applications (ANDAs), BLAs, new animal drug applications (NADAs), and abbreviated new animal drug applications (ANADAs).

2. For selecting a business operation, a current list of valid business functions and their associated codes can be found at the link at the end of this response. Please note that if more than one business function apply, a registrant should select all that apply and include them in the registration SPL.

3. FDA has implemented an automated validation of all drug product listing submissions to ensure that each establishment referenced in the product listing is registered under the same business operation. For example, a product listing SPL that references a particular facility as a packer of the product will be rejected if that establishment has not chosen Pack as a business operation in its registration. FDA expects vendors and clients to communicate this information directly to each other and, if necessary, coordinate their submissions in order to avoid issues with this validation.

4. The importer information is submitted via the registration of the foreign establishment. Any product listing referencing that foreign establishment should therefore provide the necessary link from importer to product. Information about submitting SPL can be found at the link at the end of the FDA response.

5. A product listing for bulk tablets intended for further processing or packaging should be listed using the SPL product/document type of Bulk Ingredient and a marketing category of Drug for Further Processing. Information about submitting SPL can be found at the link at the end of the FDA response.

6. For finished dosage forms, appearance in the NDC Directory is proof of submission of listing. Note that unfinished products and active pharmaceutical ingredient listings will not appear in the NDC Directory.

Instructions and SPL resources may be found on the SPL Resources Web page at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm*

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New registrations, including new labeler codes requests	39	14.72	574	4.5	2,583
Annual updates of registration information	3,256	2.99	9,735	4.5	43,808
New drug listings	1,567	6.57	10,295	4.5	46,328
New listings for private label distributor	146	10.06	1,469	4.5	6,611
June and December updates of all drug listing information	1,677	11.21	18,799	4.5	84,596
Waiver requests	1	1	1	1	1
Total					183,927

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity resulting from section 510(p) of the FD&C Act as amended by FDAAA	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
One-time preparation of SOP	1,000	1	1,000	40	40,000
SOP maintenance	3,295	1	3,295	1	3,295
Total					43,295

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

Dated: March 20, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–7136 Filed 3–23–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 11, 2012, from 8 a.m. to 5 p.m.

Location: DoubleTree by Hilton Hotel Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301–589–5200.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AVAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 203–100, for a fixed-dose combination tablet of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, submitted by Gilead Sciences, Inc. The application proposes an indication for the treatment of HIV–1 infection in adults who are antiretroviral naïve or have no known substitutions associated with resistance to the individual components.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 27, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 19, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to