FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment.'' This guidance assists sponsors in all phases of drug development including nonclinical development, early phases of clinical development, phase 3 protocol designs, and endpoints for the treatment of HIV. This guidance specifically addresses HIV drug development in populations in need of additional HIV drugs for maintaining HIV suppression including trial designs for heavily treatment-experienced patients (multiple-drug-resistant patients with few remaining options); use of early virologic assessments as primary endpoints in trials evaluating antiretroviral drugs in heavily treatment-experienced patients; recommended trial durations based on medical need; and risk-benefit in the targeted patient population.

This guidance finalizes the draft guidance of the same name published in the **Federal Register** June 5, 2013 (78 FR 33848), and replaces the guidance for industry entitled ''Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval'' issued October 2002.

The public comments received on the draft guidance have been considered and the guidance has been revised to: (1) Clarify definitions of treatment-naïve and treatment-experienced patient categories with respect to both drug susceptibility and clinical history; (2) add recommendations for trial designs that investigate switching treatment regimens in patients who are suppressed on current therapy; and (3) briefly discuss recommendations for labeling claims for safety endpoints.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on developing antiretroviral drugs for the treatment of HIV infection. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001, and the collections of information referred to in the guidance for industry entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27935 Filed 11–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0902]

Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Prescription Drug Product Labeling; Medication Guide Requirements

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 (the PRA).

DATES: Fax written comments on the collection of information by December 3, 2015.

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 0910–0393. 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.

Prescription Drug Product Labeling; Medication Guide Requirements OMB Control Number 0910–0393—Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included is information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA:

- 21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.
- 21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.
- 21 CFR 208.24(c)—Each distributor or packer that receives Medication Guides, or the means to produce Medication Guides, from a manufacturer under paragraph (b) of this section shall provide those Medication Guides to each authorized dispenser to whom it ships a container of drug product.

• 21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under 21 CFR 208.26.

• 21 CFR 208.26(a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

In the **Federal Register** of May 29, 2015 (80 FR 30688), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment.

One comment requested clarification of FDA's burden estimates for 21 CFR 208.24(c)—how the burden estimates were calculated and clarification of the definitions of ''respondent,'' ''average burden per respondent,'' and ''disclosures per respondent''. The comment asked whether ''respondent'' means the total number of individual warehouses owned and operated by all wholesale distribution companies or the number of wholesale distribution companies (which have multiple warehouses). The comment asked whether ''disclosures per respondent'' includes every instance that a Medication Guide is provided with any drug in 1 year or if it means the number of different types of drugs that a distributor would sell in a year for which a manufacturer was required to develop and supply a Medication Guide. The comment said that the number of ''disclosures per respondent'' would vary greatly depending on whether the word ''respondent'' means individual warehouses or wholesale distribution companies.

Concerning the burden hour estimates, the comment asked whether 1.25 hours (average burden per disclosure) includes the varying ways that wholesale distributors receive and distribute Medication Guides with shipments. The comment said that Medication Guides are provided to wholesale distributors from the manufacturer by multiple methods: For example, they are sometimes included with the package insert alone, provided in the package with the drug, or as loose leaf sheet(s) of paper and bulk-shipped to the wholesale distributor as a separate shipment or placed within the container in which the prescription product is shipped to the wholesale distributor. The comment said that if the Medication Guide is included on tear-off sheets or as loose-leaf paper, wholesale distributors would be responsible for coordinating the movement of those papers, taking significantly more time.

FDA Response: FDA has used, in part, information previously provided by stakeholders to determine the burden estimates. The 191 respondents under 21 CFR 208.24(c) in table 2 refers to the number of distribution centers. The 1.25 hour estimate for the ''average burden per respondent'' includes considerations such as the burden to receive, process, copy, store, select, and ship Medication Guides. The burden is an average estimate to address the various scenarios for distributing Medication Guides including electronically and in paper format. The ''disclosures per respondent'' refers to the number of instances Medication Guides are provided to distributors in a format that is physically separate from the drug product and must be handled and processed separately. Because the comment did not indicate if the calculations were overestimated or underestimated, we continue to use 191 for the number of respondents, 9,000 for the number of disclosures per respondent, and 1.25 hours as the average burden per disclosure.

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
Content and Format of a Medication Guide—208.20	57	1	57	320	18,240
Supplements and Other Changes to an Approved Application—314.70(b)(3)(ii), 601.12(f)	108	1	108	72	7,776
Exemptions and Deferrals—208.26(a)	1	1	1	4	4
Total					26,020

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Distributing and Dispensing a Medication Guide—208.24(e)	88,736	5,000	443,680,000	0.05 (3 minutes)	22,184,000
Total					24,332,750

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

Dated: October 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27945 Filed 11–2–15; 8:45 am]

BILLING CODE 4164–01–P