Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection (Request for a new OMB Control Number); *Title of Information Collection:* Medicaid State Plan Preprint for Use by States When Implementing Section 6505 of the [Patient Protection and] Affordable Care Act; *Use:* [The] CMS has developed a Medicaid State Plan Preprint for use by States and specific to support the January 1, 2011, mandate of the prohibition on payments outside of the United States. The Preprint follows the format and requested information from prior preprints provided to the States by CMS and provides a placeholder and assurance of compliance with section 1902(a) of the Social Security Act; *Form Number:* CMS–10367 (OMB#: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 5. (For policy questions regarding this collection contact Carla Ausby at 410–786–2153. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *February 22, 2011:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: December 17, 2010.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–32197 Filed 12–22–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0266]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer Print Advertisements for Prescription Drugs; 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 December 3, 2010 (75 FR 75477). The document announced a proposed collection of information that has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA). The document was published with an error. FDA, upon further review, realized that 3 comments had been submitted in response to the 60-day notice and the responses to those comments are included in this notice. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. 2010–30385, appearing on page 75480, in the **Federal Register** of Friday, December 3, 2010, the following correction is made:

On page 75480, in the third column, the last sentence in the sixth complete paragraph states that no comments were received on the paperwork burden for the 60-day notice that published in the **Federal Register** of June 16, 2010 (75 FR 34142). FDA is correcting that statement to read: Three comments were received that expressed support for the research and recommended minor improvements to the study. The responses to those comments are included in the following paragraphs.

(Comment 1) Several of this comment's suggestions have already been incorporated into our study design. Specifically, we agree that the study design should include the variables of age, education, ethnicity, race, health literacy, and whether the respondent is currently being treated with a prescription drug, and have included them in the questionnaire. Also, we have contracted with an organization that produces realistic ads and stimuli to ensure that we will show respondents realistic materials.

Another question from this comment was the presentation of our manipulations. To clarify, the specific format of the presentation will be text only. We are investigating the use of charts and other visuals in another study (FDA–2009–N–0263 (January 5, 2010), "Presentation of Quantitative Effectiveness and Risk Information to Consumers in Direct-to-Consumer (DTC) Broadcast and Print Advertisements for Prescription Drugs," OMB control number 0910–0663.) Because all of the respondents in the current study will see the information in the same format, this will not compromise our ability to answer the current research questions.

The comment also recommends expanding the physician study to include all health care professionals who have the ability to prescribe (*i.e.,* nurse practitioners and physician assistants). This is a good idea, but it changes our research question from how physicians use labels to how prescribers use labels. These groups vary in education and may vary in experience and training in how to interpret and use clinical trial data. Because we do not have a sample size that is large enough to analyze differences between these groups, we will limit the sample to physicians in this study.

Finally, the comment recommends that FDA publish findings from the preliminary study related to the current project, "Mental Models Study of Health Care Providers' Understanding of Prescription Drug Effectiveness" (FDA–2008–N–0589; April 3, 2009). We agree

and have taken steps to publish this report on FDA's Division of Drug Marketing, Advertising, and Communications Web site: *http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090276.htm*.

(Comment 2) This comment had several suggestions regarding the physician study. First, it recommended that we show physicians the Prescribing Information (PI) in a manner consistent with how physicians usually view sections of it, particularly since how each physician views the PI may be highly individualized. We agree. Because there is likely much variability in the way physicians view prescription drug information, we have designed this part of the study to examine specifically those habits. To do so, we will show physicians a highlights section that is hyperlinked to the more complete sections of the PI. We will record the order in which physicians access each section and how much time they spend there. This will provide us with information to gauge how physicians view the information in the PI, something that we currently have no data on.

Second, this comment recommends that we show physicians final magazine ads rather than conceptual ads. We agree and, as discussed in the response to the previous comment, we have contracted with an organization that produces professional-quality ads.

Third, this comment recommends increasing the sample size from 500 to 800 individuals. We agree that a larger sample would be desirable, however, given resource constraints we are not able to increase the sample size. Moreover, we have conducted a power analysis and have determined that our current sample size is adequate to answer our research questions.

Fourth, the comment recommends the removal of statements in the questionnaire that the drug is fictitious and instead label it a "potentially new drug." FDA had many internal discussions regarding this issue and decided that because of the particular sample, it is necessary to be upfront with them about the nature of the drug. Physicians will be more savvy about the particulars of the chemical entities and the realism of the clinical benefits and we do not wish to make them skeptical of our purposes. We agree that this approach is preferable for consumers and so we will inform them that this is a potentially new drug in that part of the study.

Fifth, we agree that the characteristics of participants who are at risk and those who are or are not treating with a prescription drug may differ and we will include these variables in our analyses.

Sixth, the comment recommends altering question 17 of the questionnaire to reflect the physicians' use of the DTC ad versus their guess as to the understandability of the ad for patients. We agree that we are asking physicians to estimate the level of understanding their patients have. These perceptions are of specific interest to us as they relate to physicians' perceptions of DTC advertising and of the presentation of information in the ads. Physicians who have been in practice for any length of time may have a sense of how their patients will understand materials. This is a question that we will also investigate in relation to the number of years physicians have been in practice.

Seventh, the comment recommends that question 30 be split into two questions to separately assess the effect of DTC advertising on patients and the effect of DTC advertising on their practice. We agree and will make that change.

This comment also had two suggestions for the consumer part of the study. First, the comment recommended against delivering this study on a handheld device, as the viewing of the ad may render the concept unclear. We agree and have struggled with this issue, but due to the constraints of the internet panel, we cannot specify the type of device on which participants must take the survey. We have included a question to assess this variable, and we will analyze it to determine if there are sizable differences based on viewing medium.

Second, the comment recommends that the questionnaire avoid medical terminology and reference to the "prescribing information." We have attempted to make the questionnaire clear for consumers and do not see the word "prescribing information" in the questionnaire. The questionnaire provided for comment includes programming notes that the respondent will not see.

(Comment 3) First, this comment recommends evaluating the benefits and risks together and in a similar format so as not to bias the results. We agree that the benefits and risks should be evaluated together and have several measures to investigate both. We are keeping the risk information constant across all of our conditions specifically so as not to bias the results. Our research questions involve the conveyance of information about benefits. Because of the complexity of DTC ads, we cannot manipulate both benefits and risks at the same time. We are conducting other studies examining the presentation of risk information (For example, FDA–2010–N–0417 (August 26, 2010), "Experimental Study of Format Variations in the Brief Summary of Direct-to-Consumer Print Advertisements") and collectively, this body of research will answer questions of benefit and risk presentation. To clarify, risk information will be presented similarly to how it is currently presented in DTC print ads.

Second, the comment recommends the introduction of a control arm that is similar to what is currently being used in the marketplace. Our design includes control conditions that do not present placebo information. These ads will look identical to the ads for products that are currently on the market.

Third, the comment questions the use of comparative benefit and comparative safety questions. We are using these measures for reliability as another way to assess consumers' perceived risk and benefits. As recommended in the comment, we are using them for informational purposes only and not as a specific, separate measure of comparative advertising.

Fourth, the comment recognizes the complexity of the data that are available to be conveyed in DTC ads. We agree that there are a number of questions to be answered that cannot be addressed in the current study: *E.g.,* variations in clinical study designs, instruments used, populations studied, and varying degrees of severity of illness. We cannot address all questions in one study and have chosen to focus on the issues of placebo and framing in a treatment and prevention approach. We hope that the results of this study will spur additional follow on studies conducted by FDA and others. Although the issue of different therapeutic areas is also relevant, and a study looking at the two ends of the disease-seriousness spectrum would be a great follow on, the basic concepts of information processing should not differ depending on drug class. Although we agree that replication is valuable and necessary, we do not believe that limiting the study to two therapeutic areas impugns the internal validity of the study.

Fifth, the comment recommends wording changes to the question about taking the drug if the doctor prescribed it. Although we understand the rationale for changing this question, it is a measure of behavioral intention and as such, we wanted to have a more blunt measure of intention. It will not be used to assess doctor-patient interaction issues.

Sixth, the comment questions the inclusion of physicians in the study, citing concerns that consumer responses

cannot be compared to physician responses and that this comparison is not relevant to the regulation of DTC advertisements. Indeed, the primary reason for conducting the study with physicians is to explore their processing of the prescribing information (PI), wholly separate from the consumer study. Nevertheless, since we have the two samples, we are conducting some exploratory analyses to compare the responses of consumers to information about a drug to the physicians' understanding of the drug. While this does have relevance to the regulation of DTC advertising (*e.g.,* a DTC ad that features a presentation of information that brings consumers closer to the assessment of the physician will be preferred over that same ad with a presentation of information that moves them farther away), we are approaching this comparison as a first, exploratory attempt at this type of analysis.

Dated: December 20, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–32278 Filed 12–22–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0074]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, e-mail: *Jonnalynn.Capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 7, 2010 (75 FR 25267), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0650. The approval expires on December 31, 2012. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: December 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–32277 Filed 12–22–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0631]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's "Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices." The guidance describes procedures and responsibilities for updating information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use, and also describes procedures for making corresponding changes to susceptibility test interpretive criteria for antimicrobial susceptibility testing (AST) devices.

DATES: Submit either electronic or written comments on the collection of information by February 22, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4)