visits facilitates the verification of the accuracy and completeness of the information the IDTF furnished on its CMS–855B enrollment application. The worksheet is completed by CMS or its contractors. Some of the answers to the questions/data elements on the worksheet are verbally furnished by the IDTF during the site visit; *Form Number:* CMS–10221 (OCN 0938–1029); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 2,000; *Total Annual Responses:* 2,000; *Total Annual Hours:* 4,000. (For policy questions regarding this collection contact Michael Collett at 410–786–6121. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Medicare Enrollment Application for Physician and Non-Physician Practitioners. *Use:* Health care practitioners who wish to enroll in the Medicare program must complete the CMS 855I enrollment application. It is submitted at the time the applicant first requests a Medicare billing number. The application is used by the Medicare Administrative Contractor (MAC), to collect data to assure the applicant has the necessary professional and/or business credentials to provide the health care services for which they intend to bill Medicare including information that allows the MAC to correctly price, process and pay the applicant's claims. It also gathers information that allows the MAC to ensure that the practitioner is not sanctioned from the Medicare program, or debarred, suspended or excluded from any other Federal agency or program. *Form Number:* CMS–855I (OCN: 0938–0685). *Frequency:* Once and Occasionally. *Affected Public:* Private Sector (Business or other for-profit and not-for-profit institutions). *Number of Respondents:* 345,000. *Total Annual Responses:* 345,000. *Total Annual Hours:* 824,000. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* New collection. *Title of Information Collection:* Medicare Enrollment Application—Reassignment of Medicare Benefits. *Use:* Health care practitioners who wish to reassign their benefits in the Medicare program must complete the CMS 855R enrollment application. It is submitted at the time the physician or non-physician practitioner first requests reassignment of his/her Medicare benefits to a group practice, as well as any subsequent reassignments or terminations of established reassignments as requested by the physician or non-physician practitioner. The application is used by the Medicare Administrative Contractor (MAC) to collect data to assure the applicant has the necessary information that allows the MAC to correctly establish or terminate the reassignment. *Form Number:* CMS–855R (OCN: 0938–New). *Frequency:* Occasionally. *Affected Public:* Private Sector (Business or other for-profit and not-for-profit institutions). *Number of Respondents:* 100,000. *Total Annual Responses:* 100,000. *Total Annual Hours:* 50,000. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374. 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 address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email 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.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 16, 2012.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: June 12, 2012.

Martique Jones,

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

[FR Doc. 2012–14673 Filed 6–14–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0593]

Agency Information Collection Activities; Proposed Collection; Comment Request; Eye Tracking Experimental Studies To Explore Consumer Use of Food Labeling Information and Consumer Response to Online Surveys

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled ''Eye Tracking Experimental Studies to Explore Consumer Use of Food Labeling Information and Consumer Response to Online Surveys.''

DATES: Submit either electronic or written comments on the collection of information by August 14, 2012.

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: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@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 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 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) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Eye Tracking Experimental Studies To Explore Consumer Use of Food Labeling Information and Consumer Response to Online Surveys—(OMB Control Number 0910—NEW)

I. Background

Eye tracking is a consumer research technique often used to determine where a person is looking while interacting with a visual display, such as a product package and elements of information on the package. The technique collects eye movement data, i.e., fixations and saccades (jumps of the eye), which may be superimposed on the display image to reveal: (1) Which parts of the display captured the viewer's attention; (2) the order and path in which visual elements were seen; and (3) the length of time they were viewed. These data provide detailed information on what individuals pay attention to on product packages, how long they spend looking at different package elements, and how visual attention may be related to their reaction to the images (Refs. 1–4, 7). Data from eye-tracking studies can also help improve questionnaire design. Different respondents may pay differing degrees of attention to the elements of a survey question or response options. Eye tracking data can help to identify the need and strategies for improving the design (Refs. 5 and 6). Finally, eye tracking data can provide information on the decision strategies that individuals use under different levels of time pressure, which can help reveal the influence of time on busy individuals' food choices (Refs. 4 and 7).

As a public health agency, the FDA helps consumers make informed dietary decisions by regulating nutrition information on food labels, among other activities. An understanding of how visual elements (e.g., labeling statements such as claims, disclosure statements, logos, and Nutrition Facts label) influence consumers' perceptions and choices of products can assist the Agency in developing labeling information to help consumers make informed dietary decisions. In addition, FDA uses self-administered questionnaires in online experimental studies to assess consumer reactions to nutrition information on food packages. An understanding of how respondents react to survey materials that are presented visually will enhance the Agency's ability in collecting better consumer data to help it fulfill its missions.

The proposed data collection will use eye tracking research to examine consumers' eye movements to achieve three goals: (1) To better understand consumer reaction to specific food labeling information; (2) to better understand survey respondent reaction to specific survey questions related to nutrition and health; and (3) to better understand how time pressure influences the priority and quality of decision making and survey response. In order to observe consumers' eye movement in different types of settings, we propose to conduct two separate studies, one in each of two different settings. Study 1 is a laboratory study that will ask participants to view on a computer screen mockups of food labels and perform tasks as well as answer other survey questions. Study 2 is an in-store study that will record eye movement data from grocery shoppers while they shop for preselected product categories. The studies will use two different survey instruments. Study participants will come from two separate convenience samples.

A. Study 1 (Laboratory Study)

Study 1 is a controlled randomized experiment. It has two objectives. The first objective is to collect data on how consumers view and process label information. The data will be used to test the hypothesis that one or more label and information characteristics will cause variations in viewing and processing. Examples of these characteristics include: (1) The presence or absence of a specific component (e.g., a nutrition symbol); (2) the presence or absence of other labeling components on the panel (e.g., a ''Rich in Antioxidant Vitamins'' statement); (3) the degree of clutter on the panel (e.g., the number and prominence of pictorial images); (4) the relevance or irrelevance of the component (e.g., a ''cholesterol-free'' statement on a savory snack product versus the same statement on a vegetable oil product); and (5) the featured nutrient or health benefit (e.g., ''helps protect immune system'' versus ''supports a healthy cardiovascular system'').

Label images will be created to allow the study to focus on consumer reaction to specific components of information on a food label. All images will be mockups resembling food labels that may be found in the marketplace but without any real or fictitious brand name.

The second objective of Study 1 is to examine how time pressure affects information processing. The data will be used to test the hypothesis that time pressure will cause variations in participant reactions (notice, attention, use, perception, and intention) to information. To test this hypothesis, the study will expose participants to 5 randomly assigned time conditions, such as 5 seconds per question versus 10 seconds per question.

The study will also include certain questions selected from previous online research sponsored by the Agency in order to examine which part(s) of a question or which response options participants notice and pay attention to when they are asked to answer a question. Time conditions may also be applied to this part of the study to test the hypothesis that time pressure will cause variations in viewing patterns, response strategies, and quality of response.

In the study, we plan to collect data from 200 participants using a 15-minute computer-assisted self-administered questionnaire and a 5-minute debriefing questionnaire. Forty interviews are planned for each of 5 locations across the contiguous 48 States. Participants will be recruited from residents at each location, and the study will aim to have a reasonable degree of diversity in participant gender, age, and education. On a computer screen, participants will first view a series of label images and answer questions about their perceptions and behavioral intention in response to the label that they see. Then participants will view a set of previously administered survey questions and provide answers to the questions they see. Each participant will be randomly assigned to an experimental condition that differs

primarily in label components and time limit. To help understand the data, the study will also collect information on each participant's background, such as health status, label reading behavior, and dietary preferences.

B. Study 2 (In-Store Study)

In Study 2, we plan to collect observations of what information grocery shoppers notice and pay attention to while they do their shopping in the store. The study will gather eye-movement data to provide an indepth understanding of subconscious and conscious factors that influence food purchases. Specifically, the study will explore the role that the Principal Display Panel and other label information and components play in purchase decisions. The data will be used to test hypotheses such as whether product familiarity or personal needs will cause variations in information seeking and whether design elements (e.g., prominence, text vs. graphics) will cause variations in information seeking. To keep the study within a manageable scope, only shoppers who plan to shop for one or more of preselected product categories will be eligible to participate. Other than product categories, however, participants will not be restricted to which products they examine, what label information they view, or how much time they spend in completing any part of the study. To help understand the data, the study will also collect information on each participant's background, such as health status and shopping practices. Study 2 plans to collect data from 60 participants who will each spend an average of 45 minutes in the study, including a practice session, the shopping trip, and a debriefing. The study will be conducted in two different locations. Participants will be recruited at storefronts.

Both the laboratory study (Study 1) and the in-store study (Study 2) are part of the Agency's continuing effort to enable consumers to make informed dietary choices. The Agency will use the studies to assess consumer attention to and use of various pieces of information on food packages and the information's influence on product perceptions and choices. The assessment will provide the Agency background information to help identify and develop more effective labeling information and education in the future. In addition, the Agency will use Study 1 to assess consumer behaviors when they are asked to respond to a sample of questions used in the Agency's consumer research. The assessment will help enhance FDA's ability to conduct research that provides useful information. Wherever possible, the Agency will also attempt to compare findings from the two studies to assess how much results observed in the laboratory reflect actual behaviors in the market. For example, do laboratory and in-store participants pay attention to different labeling elements when they make a shopping choice? The results of the studies will neither be used to develop population estimates nor be directly used to inform policy.

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
Laboratory Pretest Invitation	30	1	30	.033 (2 minutes)	1
Laboratory Pretest	15	1	15	1	15
Laboratory Study Invitation	500	1	500	0.033 (2 minutes)	17
Laboratory Study	200	1	200	0.333 (20 minutes)	67
In-store Study Invitation	300	1	300	0.083 (5 minutes)	25
In-store Study	60	1	60	0.75 (45 minutes)	45
Total					170

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

II. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

1. Jones, G. and M. Richardson. An Objective Examination of Consumer Perception of Nutrition Information Based on Healthiness Ratings and Eye Movements. *Public Health Nutrition* 10: 238–244, 2007.
2. Bialkova, S. and H.C.M. van Trijp. What Determines Consumer Attention to Nutrition Labels? *Food Quality and Preference* 21: 1042–1051, 2010.
3. van Herpen, E. and H.C.M. van Trijp. Front-of-Pack Nutrition Labels, Their Effect on Attention and Choices When Consumers Have Varying Goals and Time Constraints. *Appetite* 57: 148–160, 2011.
4. Fox, R.J., D.M. Krugman, J.E. Fletcher, and P.M. Fischer. Adolescents' Attention to Beer and Cigarette Print Ads and Associated Product Warnings. *Journal of Advertising* 27: 57–68, 1998.
5. Galesic, M., R. Tourangeau, M.P. Couper, and F.G. Conrad. Eye-Tracking Data: New Insights on Response Order Effects and Other Cognitive Shortcuts in Survey Responding. *Public Opinion Quarterly* 72: 892–913, 2008.
6. Graesser, A.C., Z. Cai, M.M. Louwerse, and F. Daniel. Question Understanding Aid (QUAID): A Web Facility That Tests Question Comprehensibility. *Public Opinion Quarterly* 70: 3–22, 2006
7. Reutskaja, E., R. Nagel, C.F. Camerer, and A. Rangel. Search Dynamics in Consumer Choice under Time Pressure: An Eye-Tracking Study. *American Economic Review* 101: 900–926, 2011.

Dated: June 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14631 Filed 6–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0528]

Determination That PARAPLATIN (Carboplatin) Injection and SUSTIVA (Efavirenz) Capsules 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 two 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