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]

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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

drug applications (ANDAs) that refer to the 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: Mark Geanacopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 301–796–6925.

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 sponsors 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. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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, drugs are 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 removed 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 table 1 of this document are no longer being marketed.

TABLE 1—DRUG PRODUCTS NO LONGER BEING MARKETED

Application No.	Drug	Applicant
NDA 20–972	SUSTIVA (efavirenz) Capsule, 100 milligrams (mg)	Bristol Myers Squibb.
NDA 20–452	PARAPLATIN (carboplatin) Injection, 50 mg, 150 mg, 450 mg, and 600 mg	Do.

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 listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs for the 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: June 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14633 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–D–0544]

Guidance for Industry on Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed With Approved Applications; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for small business entities entitled ''Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed With Approved Applications; Small Entity Compliance Guide.'' This guidance is intended to help small businesses understand and comply with the requirements of the final rule regarding labeling of drugs with a toll-free number for adverse event reporting, which was published in the **Federal Register** on October 28, 2008 (final rule). The guidance describes certain requirements of the final rule in plain language and provides answers to common questions on how to comply with the rule. FDA prepared this guidance in accordance with the Small Business Regulatory Fairness Act.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Alisea Crowley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5196, Silver Spring, MD 20993–0002, 301–796–3110.