believes were discontinued prior to November 2010, were listed in the notice.

TABLE 1—PROPOXYPHENE DRUG PRODUCT APPLICATIONS FOR WHICH FDA PROPOSED TO WITHDRAW APPROVAL

Application No.	Drug	Applicant or holder
ANDA 083544	Kesso-Gesic (propoxyphene hydrochloride (HCl)) Capsules, 65 milligrams (mg).	MK Laboratories Inc., 424 Grasmere Ave., Fairfield, CT 06430.
ANDA 084551	Propoxyphene HCl Capsules, 65 mg	Whiteworth Towne Paulsen Inc.
ANDA 084553	Compound 65 (aspirin, caffeine, and propoxyphene HCl) Capsules, 389 mg/32.4 mg/65 mg.	Alra Labs, 3850 Clearview Ct., Gurnee, IL 60031.

In its March 10, 2014, notice of opportunity for a hearing, CDER provided these ANDA holders an opportunity to request a hearing to show why approval of the ANDAs should not be withdrawn. No timely request for a hearing on this matter was received following publication of the notice in the **Federal Register**.

Therefore, under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs, approval of the applications listed in table 1 and all amendments and supplements thereto is withdrawn (see **DATES**). Introduction or delivery for introduction of these products into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 331(d))).

Dated: September 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21729 Filed 9–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the **Federal Register** of April 25, 2014 (79 FR 22995). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, 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: *PDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 25, 2014, FDA announced that a meeting of the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee would be held on October 16, 2014. On page 22996, in the first column, the *Agenda* portion of the document is changed to read as follows:

Agenda: The committees will discuss safety data from observational studies and a meta-analysis of randomized controlled clinical trials that have been conducted since the original signal of serious neuropsychiatric adverse events with CHANTIX (varenicline tartrate tablets, NDA 21928, Pfizer, Inc.) emerged. The committees will also discuss whether any action needs to be taken with regard to how this risk is described in product labeling.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: September 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21780 Filed 9–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Food and Drug Administration (FDA) and the National Cancer Institute (NCI) Health Communication Survey (FDA–NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 8, 2014, Vol. 79, No. 89, page 26439 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Bradford W. Hesse, Ph.D., Health Communication and Informatics Research Branch, 9609 Medical Center

Drive, MSC 9761, Room 3E610, Rockville, MD 20850 or call non-toll free number 240–276–6721 or Email your request, including your address, to *hesseb@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Food and Drug Administration (FDA) and the National Cancer Institute (NCI) Health Communication Survey (FDA–NCI), 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This partnership between NCI and FDA will include assessing the public's knowledge of medical devices, communications related to product recalls, nutritional supplement labeling, and topics to inform FDA's regulatory authority over tobacco, such as risk perceptions about new tobacco products and labels. This NCI–FDA survey will couple knowledge-related questions with inquiries into the communication channels through which understanding is being obtained, and assessment of FDA-regulated material. This survey will extend the information collected and priorities from the Health Information National Trends Survey (HINTS) which has been to provide a comprehensive assessment of the American public's current access to, and use of, information about cancer across the cancer care continuum from cancer prevention, early detection, diagnosis, treatment, and survivorship.

OMB approval is requested for 1 year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,159.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Individuals	4,318	1	30/60	2,159

Dated: September 8, 2014.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–21783 Filed 9–11–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Cancer Epidemiology Descriptive Cohort Database (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 18, 2014, Vol. 79, page 34766 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Daniela Seminara, Senior Scientist and Cohort and Consortia Coordination Team Lead, Epidemiology and Genomics Research Program (EGRP), Division of Cancer Control and Population Sciences (DCCPS), 9609 Medical Center Drive, Rockville, Md. 20892 or call non-toll-free number 240–276–6748 or email your request, including your address to: *seminard@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Cancer Epidemiology Descriptive Cohort Database, 0925—New, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The NCI Epidemiology and Genomics Research Program (EGRP) supports large-scale collaborations across numerous cancer epidemiology cohorts. The collaborative approach to date has been lacking in easily accessible, centralized, and searchable information. To address the need for better collaborative research and increased transparency, EGRP will develop a Cancer Epidemiology Descriptive Cohort Database (CEDCD) accessible through a public Web site. The information collected from the current survey will be used to populate the CEDCD. This public Web site will allow investigators to know what data and specimens exist among other cohorts. Respondents will be cohort Principal Investigators. The data collection forms will be sent to participating cohort PIs annually to update any information that has changed so that the CEDCD Web site will remain current. No cohort participant-level data is being collected from any of the cohorts.

The information to be collected will be aggregate descriptive information and protocols. Though the CEDCD has a biospecimen component (similar to the Specimen Resource Locator), the CEDCD is not a biospecimen locator database. It is a database focusing exclusively on descriptive data pertaining to large, prospective epidemiology cohorts.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 550.