and 802 of the FD&C Act. FDA has developed five types of certificates that satisfy the requirements of section 801(e)(4)(B) of the FD&C Act: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, and (4) Non-Clinical Research Use Only Certificates. Table 1 of this document lists the different certificates and details their use:

TABLE 1—CERTIFICATES AND USES

Type of certificate	Use
''Supplementary Information Certificate to Foreign Government Requests''.	For the export of products legally marketed in the United States.
''Exporter's Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)''.	''Exporter's Certification Statement Certificate to Foreign Government.''
''Supplementary Information Certificate of Exportability Requests'' ..... Exporter's Certification Statement Certificate of Exportability''	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act.
''Supplementary Information Certificate of a Pharmaceutical Product'' ... ''Exporter's Certification Statement Certificate of a Pharmaceutical Product''.	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license.
''Supplementary Information Non-Clinical Research Use Only Certificate''. ''Exporter's Certification Statement (Non-Clinical Research Use Only).''	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&C Act.

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1 of this document. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the FD&C Act, not only at the time that they submit their request to the appropriate center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for follow up. Making or submitting to FDA false statements on any documents may constitute violations of 18 U.S.C. 1001, with penalties including up to $250,000 in fines and up to 5 years imprisonment.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research	2,114	1	2,114	1	2,114
Center for Devices and Radiological Health	6,463	1	6,463	2	12,926
Center for Veterinary Medicine	855	1	855	1	855
Total	.....	.....	.....	.....	15,895

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

Dated: November 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26999 Filed 11–13–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1819]

Agency Information Collection Activities; Proposed Collection; Comment Request; Spousal Influence on Consumer Understanding of and Response to Direct-To-Consumer Prescription Drug Advertisements

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 research entitled, ''Spousal Influence on Consumer Understanding of and Response to Direct-To-Consumer (DTC) Prescription Drug Advertisements.'' This study will examine differences between consumers viewing prescription drug ads with a spouse or partner versus alone through empirical research.

DATES: Submit either electronic or written comments on the collection of information by January 13, 2015.

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: 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: 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.

Spousal Influence on Consumer Understanding of and Response to DTC Prescription Drug Advertisements—(OMB Control Number 0910–NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

Consumers are often thought of as individual targets for prescription drug advertisements (ads), as if they are always exposed to DTC ads individually and subsequently make judgments about advertised products on their own. However, judgments about prescription drugs portrayed in DTC ads are likely made in social contexts much of the time. For example, a potential consumer and his or her spouse (e.g., marital or domestic partner) may view an ad together and discuss drug benefits, side effects, and risks. These social interactions may result in unique reactions relative to consumers who view DTC prescription drug ads alone. For example, spouses may influence their partner by expressing concern about risks and side effects that might occur, or pressuring their partner to consider the drug despite its risks and side effects. These outcomes have important public health implications. The Office of Prescription Drug Promotion plans to examine differences between consumers viewing prescription drug ads with a spouse versus alone through empirical research.

The main study will be preceded by pretesting, designed to delineate the procedures and measures used in the main study. Pretest and main study participants will be couples who are married or in a marital-like living arrangement in which one member (consumer) has asthma and the other does not (spouse). All participants will be 18 years of age or older. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Data collection will take place in person.

Participants will be randomly assigned to one of four experimental conditions in a 2×2 design, as depicted in Table 1. We will compare one version of an ad that depicts a low-benefit and low-risk drug with a second version that depicts a high-benefit and high-risk drug. Participants will be randomly assigned to view the ad alone or together with their spouse. Participants in both viewing conditions will individually complete a prequestionnaire. In the ''together'' condition, participants will view the ad with their spouse and then engage in a brief discussion together about the ad. In the ''alone'' condition, participants will view the ad without their spouse, take a short break, and then respond to a postquestionnaire consisting of questions about information in the ad. The short break in the ''alone'' condition will facilitate reflection about the ad to mirror discussion engaged in by those in the ''together'' condition. The consumer in the ''together'' condition will complete the same postquestionnaire administered to those in the ''alone'' condition, and the spouse will complete a slightly different questionnaire that assesses key measures that relate to consumer reactions. These procedures are depicted in Table 2. Participation is estimated to take approximately 60 minutes.

Preliminary measures are designed to assess memory and understanding of risk and benefit information as well as other ad content, intention to seek more information about the product, and variables pertaining to the consumer-spouse relationship such as relationship closeness and communication style. The draft questionnaire is available upon request.

TABLE 1—EXPERIMENTAL STUDY DESIGN

Viewing condition	Risk/Benefit condition	
	Low risk/low benefit	High risk/high benefit
Alone	Condition A	Condition B.
Together	Condition C	Condition D.

TABLE 2—OVERVIEW OF DATA COLLECTION PROCESS FOR ALONE AND TOGETHER CONDITIONS

Steps	Viewing condition	
	Alone	Together
1	Consumer completes prequestionnaire	Consumer and spouse complete prequestionnaire separately (spouse completes selected measures).
2	Consumer views advertising stimuli alone	Consumer and spouse view advertising stimuli together.
3	Break	Couples engage in a 5-minute semistructured conversation related to the advertising stimuli.
4	Consumer completes postquestionnaire	Consumer and spouse complete postquestionnaire separately (spouse completes selected measures).

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described below, we will have sufficient power to detect small-to-medium sized effects in the main study.

FDA estimates the burden of this collection of information as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretesting					
Number to complete the screener	700	1	700	0.08 (5 minutes)	56
Number of completes	120	1	120	1	120
Main study					
Number to complete the screener	4,060	1	4,060	0.08 (5 minutes)	325
Number of completes	792	1	792	1	792
Total					1,293

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

Dated: November 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26918 Filed 11–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1617]

Blood Products 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 the meeting of the Blood Products Advisory Committee. This meeting was announced in the **Federal Register** of October 22, 2014. 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: Bryan Emery or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6132, Silver Spring, MD 20993, 240–402–8054 or 240–402–8129, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 22, 2014 (79 FR 63131), FDA announced that a meeting of the Blood Products Advisory Committee would be held on December 2 and 3, 2014. On page 63131, in the third column, the *Agenda* portion of the document is changed to read as follows:

Agenda: On December 2, 2014, the Committee will meet in open session to hear scientific data related to reconsideration of the current blood donor deferral policy for men who have had sex with another man (MSM) even one time since 1977. The Committee will be presented with an update on the November 13, 2014, meeting of the U.S. Department of Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability where the MSM blood donor deferral policy will be discussed. In the afternoon, the Committee will hear an informational presentation on Ebola virus, the potential implications for blood safety in the United States and FDA's considerations on the collection of convalescent plasma for investigational use.

On December 3, 2014, the Blood Products Advisory Committee will be seated as a device classification panel. In open session, the panel will discuss the appropriate device classification of