Board of Governors of the Federal Reserve System, June 11, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–13999 Filed 6–13–14; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns the NIOSH Childhood Agriculture, RFA OH–14–005, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 1:00 p.m.–4:00 p.m., July 8, 2014 (Closed)

Place: Teleconference

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''NIOSH Childhood Agriculture, RFA OH–14–005.''

Contact Person for More Information: Nina Turner, Ph.D., Scientific Review Officer, 1095 Willowdale Road, Morgantown, WV 26506, Telephone: (304) 285–5976.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–13998 Filed 6–13–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0420]

Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications on Food and Drug Administration-Regulated Products Used in Animals

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 communication studies involving FDA-regulated products intended for use in animals. This information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the Agency's mission to protect the public health.

DATES: Submit written or electronic comments on the collection of information by August 15, 2014.

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.

Testing Communications on FDA/Center for Veterinary Medicine (CVM)—Regulated Products Used in Animals—21 U.S.C. 393(d)(2)(D) (OMB Control Number 0910–0689)—Extension

FDA is authorized by section 393(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of CVM-regulated products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. FDA expects that improving communications about the safety of regulated animal drugs, feed, food additives, and devices will involve many research methods, including individual indepth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about the use of FDA-regulated products for use in animals. Knowledge of consumer and veterinary professional decision-making processes will provide the better understanding of target audiences that FDA needs to design effective communication

strategies, messages, labels, and labeling. These communications will aim to improve public understanding of the risks and benefits of using regulated animal drugs, feed, food additives, and devices by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

FDA estimates the burden of this collection of information based on recent prior experience with the various types of data collection methods described in this document:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. 393(d)(2)(D)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual Indepth Interviews	360	1	360	0.75 (45 minutes) ..	270
General Public Focus Group Interviews	288	1	288	1.5	432
Intercept Interviews: Central Location	600	1	600	0.25 (15 minutes) ..	150
Intercept Interviews: Telephone	[2] 10,000	1	10,000	0.08 (5 minutes)	800
Self-Administered Surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper Reviews	400	1	400	0.50 (30 minutes)	200
Omnibus Surveys	2,400	1	2,400	0.17 (10 minutes)	408
Total (General Public)	16,448		16,448		2,860
Veterinarian/Scientific Expert Focus Group Interviews	288	1	288	0.75	216
Total (Veterinarians/Scientific Experts)	288	1	288		216
Total (Overall)	16,736	1	16,736		3,076

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] These are brief interviews with callers to test message concepts and strategies following their call-in request to an FDA Center 1–800 number.

Annually, FDA projects about 30 studies with 16,736 respondents, using a variety of research methods and lasting an average of 0.17 hours each (varying from 0.08–1.5 hours).

Dated: June 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13929 Filed 6–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–1654]

Determination That LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 Milligrams/1 Milliliter, 10 Milliliter Total Fill Volume, Was 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 LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 milligrams (mg)/1 milliliter (mL), 10 mL total fill volume, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–0978.

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 under an ANDA procedure. ANDA applicants 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

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 known generally 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, is the subject of ANDA 40147, held by Hospira, Inc. (Hospira), and was initially approved on June 25, 1997. LEUCOVORIN CALCIUM-