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-

PRESERVATIVE FREE is indicated for treatment of megaloblastic anemia and to counteract the therapeutic and toxic effects of folic acid antagonists.

In a letter dated January 14, 2005, Hospira notified FDA that LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Gordon Johnston, on behalf of Gordon Johnston Regulatory Consultants, LLC, submitted a citizen petition dated December 13, 2013 (Docket No. FDA–2013–P–1654), under 21 CFR 10.30, requesting that the Agency determine whether LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to LEUCOVORIN CALCIUM-PRESERVATIVE FREE Injection, 10 mg/1 mL, 10 mL total fill volume, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13906 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–2009–D–0011]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 6 on Uniformity of Dosage Units General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 6: Uniformity of Dosage Units General Chapter.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Uniformity of Dosage Units General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. The guidance is in the form of an annex to the core guidance on the Q4B process entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions'' (core ICH Q4B guidance).

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. 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:

Regarding the guidance: Robert H. King, CDER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4166, Silver Spring, MD 20993–0002, 301–796–1242; or Stephen Ripley, CBER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Michelle Limoli, CDER, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3342, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input