TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]—Continued

Activity/section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notifying immediate previous source of the article of food under section 417(d)(7)(C)(i) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(7)(C)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Total	.....	.....	.....	.....	2,880

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

Third Party Disclosure

We estimate that approximately 1,200 reportable food events with mandatory reporters will occur annually. Based on past FDA experiences, we estimate that we could receive 200 to 1,200 ''reportable'' food reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. We utilized the upper-bound estimate of 1,200 for these calculations.

We estimate that notifying the immediate previous source(s) will take 0.6 hours per reportable food and notifying the immediate subsequent recipient(s) will take 0.6 hours per reportable food. We also estimate that it will take 0.6 hours for the immediate previous source and/or the immediate subsequent recipient to also notify their immediate previous source(s) and/or immediate subsequent recipient(s). The Agency bases its estimate on its experience with mandatory and voluntary reports submitted to FDA.

Although it is not mandatory under FDAAA section 1005 that responsible persons notify the sources and recipients of instances of reportable food, for purposes of the burden estimate we are assuming FDA would exercise its authority and require such notifications in all such instances for mandatory reporters. This notification burden will not affect voluntary reporters of reportable food events. Therefore, we estimate that the total burden of notifying the immediate previous source(s) and immediate subsequent recipient(s) under section 417(d)(6)(B)(i), (d)(6)(B)(ii), (d)(7)(C)(i), and (d)(7)(C)(ii) of the FD&C Act for 1,200 reportable foods will be 2,880 hours annually (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours). This annual burden is shown in table 1.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/section	Number of recordkeepers	Number of records per recordkeeping	Total annual records [2]	Average burden per record	Total hours
Maintenance of reportable food records under section 417(g) of the FD&C Act—Mandatory reports.	1,200	1	1,200	0.25 (15 minutes) ..	300
Maintenance of reportable food records under section 417(g) of the FD&C Act—Voluntary reports.	600	1	600	0.25 (15 minutes) ..	150
Total	.....	.....	.....	.....	450

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] For purposes of estimating number of records and hours per record, a ''record'' means all records kept for an individual reportable food by the responsible party or a voluntary reporter.

Recordkeeping

As noted previously, section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods reports and notifications under section 417 of the FD&C Act for a period of 2 years. Based on past FDA experiences, we estimate that each mandatory report and its associated notifications will require 30 minutes of recordkeeping for the 2-year period, or 15 minutes per record per year. The annual recordkeeping burden for mandatory reportable food reports and their associated notifications is thus estimated to be 300 hours (1,200 × 0.25 hours).

We do not expect that records will always be kept in relation to voluntary reportable food reports. Therefore, we estimate that records will be kept for 600 of the 1,200 voluntary reports we expect to receive annually. The recordkeeping burden associated with voluntary reports is thus estimated to be 150 hours annually (600 × 0.25 hours). The estimated total annual recordkeeping burden will be 450 hours annually (1,200 × 0.25 hours) + (600 × 0.25 hours). This annual burden is shown in table 2.

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–20021 Filed 8–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Advisory Committee Renewals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of certain FDA advisory committees by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the

charters of the committees listed in the following table for an additional 2 years beyond charter expiration date. The new charters will be in effect until the dates of expiration listed in the following table.

DATES: Authority for these committees will expire on the dates indicated in the following table unless the Commissioner formally determines that renewal is in the public interest.

Name of committee	Date of expiration
Advisory Committee for Pharmaceutical Science and Clinical Pharmacology	January 22, 2016.
Gastrointestinal Drugs Advisory Committee	March 3, 2016.
Bone, Reproductive and Urologic Drugs Advisory Committee (formerly Reproductive Health Drugs Advisory Committee).	March 23, 2016.
Arthritis Advisory Committee	April 5, 2016.
Pharmacy Compounding Advisory Committee	April 25, 2016.
Anesthetic and Analgesic Drugs Advisory Committee	May 1, 2016.
Blood Products Advisory Committee	May 13, 2016.
Pulmonary-Allergy Drugs Advisory Committee	May 30, 2016.
Drug Safety and Risk Management Advisory Committee	May 31, 2016.
Science Advisory Board to the National Center for Toxicological Research	June 2, 2016.
Peripheral and Central Nervous System Drugs Advisory Committee	June 4, 2016.
Psychopharmacologic Drugs Advisory Committee	June 4, 2016.
Transmissible and Spongiform Encephalopathies Advisory Committee	June 9, 2016.
Science Board to the Food and Drug Administration	June 26, 2016.
Allergenic Products Advisory Committee.	July 9, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Director, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–443–0572 or 1–800–741–8138. For further information related to FDA advisory committees please visit us at: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–20017 Filed 8–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–P–0549]

Determination That SULAR (Nisoldipine) Extended-Release Tablets, 10 Milligrams, 20 Milligrams, 25.5 Milligrams, 30 Milligrams, and 40 Milligrams, 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 SULAR (nisoldipine) extended-release tablets, 10 milligrams (mg), 20 mg, 25.5 mg, 30 mg, and 40 mg, 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 these drug products, and it will allow FDA to approve ANDAs for nisoldipine extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Emily Gebbia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 240–402–0980.

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.

SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, is the subject of NDA 20–356, held by Shionogi Inc., and initially approved on February 2, 1995. SULAR is indicated for the treatment of hypertension.

SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Emcure Pharmaceuticals USA, Inc., submitted a citizen petition dated April 28, 2014 (Docket No. FDA–2014–P–0549), under 21 CFR 10.30, requesting that the Agency determine whether SULAR (nisoldipine) extended-release tablets, 25.5 mg, was withdrawn from sale for