

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Documentation .....	1	1	1	3	3

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We expect the total number of pesticide tolerances that are revoked, suspended, or modified by EPA pursuant to dietary risk considerations in the next 3 years to remain at a low level, as there have been no changes to the safety standard for pesticide residues in food since 1996. Thus, we expect the number of submissions we will receive pursuant to the guidance

document will also remain at a low level. However, to avoid counting this burden as zero, we have estimated the burden at one respondent making one submission a year for a total of one annual submission.

We based our estimate of the hours per response on the assumption that the information requested in the guidance is readily available to the submitter. We

expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for submission to FDA. The submitter will almost always merely need to copy existing documentation. We believe that this effort should take no longer than 3 hours per submission.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeping	Total annual records	Average burden per record	Total hours
Develop documentation process .....	1	1	1	16	16

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In determining the estimated annual recordkeeping burden, we estimated that at least 90 percent of firms maintain documentation, such as packing codes, batch records, and inventory records, as part of their basic food production or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not be currently maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. In previous information collection requests, this recordkeeping burden was estimated to be 16 hours per record. We have retained our prior estimate of 16 hours per record for the recordkeeping burden. As shown in Table 1, we estimate that one respondent will make one submission per year. Although we estimate that only 1 out of 10 firms will not be currently maintaining the necessary documentation, to avoid counting the recordkeeping burden for the 1 submission per year as  $\frac{1}{10}$  of a recordkeeper, we estimate that 1 recordkeeper will take 16 hours to develop and maintain documentation recommended by the guidance.

Dated: August 19, 2014.

**Peter Lurie,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2014-P-0637, FDA-2014-P-0315]

#### Determination That FUSILEV (Levoleucovorin Calcium), Injection, 175 Milligrams/17.5 Milliliters and 250 Milligrams/25 Milliliters, 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 FUSILEV (levoleucovorin calcium), Injection, 175 milligrams (mg)/17.5 milliliters (mL) and 250 mg/25 mL, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for levoleucovorin calcium, injection, 175 mg/17.5 mL and 250 mg/25 mL, 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 (§ 314.162 (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). FDA may not approve an ANDA that does not refer to a listed drug.

FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, are the subjects of NDA 020140, held by Spectrum Pharmaceuticals, and were initially approved on April 29, 2011 (supplemental approval). FUSILEV is indicated for rescue after high-dose methotrexate therapy in osteosarcoma, to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists, and for use in combination chemotherapy with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer.

FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, are currently listed in the "Discontinued Drug Product List" section of the Orange Book. Spectrum Pharmaceuticals has never marketed FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL. In previous instances (see, e.g., 72 FR 9763 and 61 FR 25497), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc. (Lachman), submitted two citizen petitions, dated March 18, 2014, and May 14, 2014 (Docket Nos. FDA-2014-P-0315 and FDA-2014-P-0637, respectively), under 21 CFR 10.30, requesting that the Agency determine whether FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, were withdrawn from sale for reasons of safety or effectiveness.

After considering the Lachman citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, were not withdrawn from sale for reasons of safety or effectiveness. Lachman has identified no data or other information suggesting that FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, were withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal from sale of FUSILEV (levoleucovorin calcium),

Injection, 175 mg/17.5 mL and 250 mg/25 mL. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, 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 FUSILEV (levoleucovorin calcium), Injection, 175 mg/17.5 mL and 250 mg/25 mL, 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 19, 2014.

**Peter Lurie,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0745]

#### Reopening of Docket and Request for Comments on the Food and Drug Administration Safety and Innovation Act Action Plan

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice: reopening of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the action plan issued as required by section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA) and the reopening of a public docket for comments pertaining to the action plan.

**DATES:** Submit electronic or written comments by October 21, 2014.

**ADDRESSES:** Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Jonca Bull, Office of Minority Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4239, Silver Spring, MD, 20993-0002, 301-796-8000, [jonca.bull@fda.hhs.gov](mailto:jonca.bull@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On July 9, 2012, the President signed FDASIA (Pub. L. 112-144) into law. Section 907 of FDASIA requires that FDA report on and address certain information regarding clinical trial participation by demographic subgroups and subset analysis of the resulting data. Specifically, section 907(a) of FDASIA requires the Secretary of Health and Human Services (the Secretary), acting through the FDA Commissioner, to publish on FDA's Internet Web site a report "addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the FDA," and provide such publication to Congress. The report, entitled "Reporting of Inclusion of Demographic Subgroups in Clinical Trials and Data Analysis in Applications for Drugs, Biologics, and Devices," was posted on FDA's Internet Web site in August 2013 and is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FDASIA/ucm356316.htm>.

Section 907(b) of FDASIA further requires the Secretary, again acting through the Commissioner, to publish an action plan on FDA's Internet Web site and provide such publication to Congress. The action plan is to contain recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness and in labeling; on the inclusion of such data, or the lack of availability of such data in labeling; and on ways to improve public availability of such data to patients, health care providers, and researchers. These recommendations are to include, as appropriate, a determination that distinguishes between product types and applicability. The action plan is due not later than 1 year after the publication of the report described previously. The action plan entitled