

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
Surveys, focus groups, and interviews .....	300	2	600	1	600

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

We base our estimate of the average burden per response on review activities familiar to the Agency.

Dated: July 23, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-P-2559]

#### **Determination That FORTAMET (Metformin Hydrochloride) Extended-Release Tablets, 500 Milligrams and 1 Gram, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**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 or Agency) has determined that FORTAMET (metformin hydrochloride) extended-release tablets, 500 milligrams (mg) and 1 gram (g), were not withdrawn from sale for reasons of safety or effectiveness.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 continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:**

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**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.

FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, are the subject of NDA 021574, held by Andrx Labs, LLC, and initially approved on April 27, 2004. FORTAMET is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, are currently listed in the “Discontinued Drug Product List” section of the Orange Book. Ajanta Pharma Limited submitted a citizen petition dated May 27, 2019 (Docket No. FDA-2019-P-2559), under 21 CFR 10.30, requesting that the Agency determine whether FORTAMET

(metformin hydrochloride) extended-release tablets, 500 mg and 1 g, were 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 FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, from sale. We have also independently evaluated relevant literature and data for possible post marketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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: July 23, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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