FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3602	4,200	1	4,200	1	4,200
3602A	900	1	900	1	900
Total					5,100

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

Dated: January 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02093 Filed 1–30–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–0916]

Determination That DIFFERIN (Adapalene) Solution, 0.1%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that DIFFERIN (adapalene) solution, 0.1% (NDA 20–338), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for adapalene solution, 0.1%, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–4455.

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 approved 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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DIFFERIN (adapalene) solution, 0.1%, is the subject of NDA 20–338, held by Galderma Laboratories, L.P., and initially approved on May 31, 1996, and is indicated for the topical treatment of acne vulgaris. This product is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Ei, Inc., on behalf of Call, Inc. (d/b/a Rochester Pharmaceuticals), submitted a citizen petition dated August 23, 2012 (Docket No. FDA–2012–P–0916), under 21 CFR 10.30, requesting that the Agency determine whether DIFFERIN (adapalene) solution, 0.1%, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that DIFFERIN (adapalene) solution, 0.1%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DIFFERIN (adapalene) solution, 0.1%, from sale. We also have independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list DIFFERIN (adapalene) solution, 0.1%, 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 DIFFERIN (adapalene) solution, 0.1%, 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: January 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02087 Filed 1–30–13; 8:45 am]

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