TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Amendments/Resubmissions	356h	306	11.6	3,563	20	71,260
Total						335,806.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirements under §§ 601.14, 601.27(a), 601.33, 601.34, 601.35, 610.11(g)(2), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a).
[3] The reporting requirements under §§ 640.70(a), 640.74(b)(3) and (4), 640.84(a) and (c), 640.94(a), 660.2(c), 660.28(a) and (b), 660.35(a), (c-g), and (i-m), 660.45, and 660.55(a) and (b) are included under §§ 610.60 through 610.62.
[4] The reporting requirements under §§ 600.15(b), 610.11(g)(2), 610.53(d), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), and 680.1(d) are included in the estimate under § 601.12(b)
[5] The reporting requirements under §§ 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are included in the estimate under § 601.12(c).
[6] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (f)(2).
[7] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(3).

Under Table 2, the estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
601.91(b)(2)(iii)	1	1	1	1	1

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

Dated: January 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–1741 Filed 2–1–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0052]

Determination That SUSTIVA (Efavirenz) 300-Milligram Tablets Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that SUSTIVA (efavirenz) 300-milligram (mg) tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for efavirenz 300-mg tablets, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors 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 typically a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an 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 generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn 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)).

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.

In a citizen petition dated January 24, 2006 (Docket No. 2006P–0052/CP1), submitted under 21 CFR 10.30, Robert W. Pollock of Lachman Consultant Services, Inc., requested that the agency determine whether SUSTIVA (efavirenz) 300-mg tablets were withdrawn from sale for reasons of safety or effectiveness. SUSTIVA (efavirenz) is approved for the treatment of human immunodeficiency virus (HIV) type 1 infections in combination with other antiretroviral agents. SUSTIVA (efavirenz) 300-mg tablets are the subject of NDA 21–360 held by Bristol-Myers Squibb Pharma Company (BMS). FDA approved the NDA for SUSTIVA (efavirenz) 300-mg tablets on February 1, 2002.

After considering the citizen petition and reviewing agency records, FDA has determined that SUSTIVA (efavirenz)

300-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. To date, BMS has never marketed SUSTIVA (efavirenz) 300-mg tablets. In previous instances (see, e.g., 67 FR 79640, December 30, 2002 (addressing a relisting request for Diazepam Autoinjector)), 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.

The petitioner identified no data or other information suggesting that SUSTIVA (efavirenz) 300-mg tablets were withdrawn from sale as a result of safety or effectiveness concerns. FDA has reviewed its files for records concerning the withdrawal of SUSTIVA (efavirenz) 300-mg tablets. There is no indication that the decision not to market SUSTIVA (efavirenz) 300-mg tablets commercially is a function of safety or effectiveness concerns, and no information has been submitted to the docket concerning the reasons for which SUSTIVA (efavirenz) 300-mg tablets were withdrawn from sale. FDA's independent evaluation of relevant information has uncovered nothing that would indicate that SUSTIVA (efavirenz) 300-mg tablets were withdrawn from sale for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA has determined that SUSTIVA (efavirenz) 300-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list SUSTIVA (efavirenz) 300-mg tablets 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 and effectiveness. ANDAs that refer to SUSTIVA (efavirenz) 300-mg tablets may be approved by the agency, as long as they meet all relevant legal and regulatory requirements for approval of ANDAs.

Dated: January 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–1748 Filed 2–1–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA 225–05–6001

Memorandum of Understanding Between the Food and Drug Administration, Duke University and Duke University Health System, Inc.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA, Duke University (DU) and Duke University Health System, Inc. (DUHS). The purpose of the MOU is to establish the terms of collaboration between FDA, DU and DUHS to support shared interests and will begin with an initiative entitled: The FDA, DU and DUMC Elective Program.

DATES: The agreement became effective September 18, 2006.

FOR FURTHER INFORMATION CONTACT: Nancy L. Pluhowski, Center for Devices and Radiological Health (HFZ–1), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–2890.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: January 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S