published a **Federal Register** notice on August 1, 2011 (76 FR 45826), announcing fees for fiscal year (FY) 2012. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a ''small business.'' This means there are two levels of fees, a standard fee and a reduced or waived small business fee. You can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than $100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours, and the total must be no more than $100 million. If your gross receipts or sales are no more than $30 million, including all of your affiliates, partners, and parent firms, you will also qualify for a waiver of the fee for your first (ever) premarket application (product development protocol, biologics licensing application, or premarket report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the ''small business'' criteria (Form FDA 3602, ''FY 2012 MDUFMA Small Business Qualification Certification—For A Business Headquartered in the United States''). The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a ''small business'' within the meaning of MDUFMA.

The 2007 Amendments provide an alternative way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid (Form FDA 3602A, ''FY 2012 MDUFMA Foreign Small Business Qualification Certification—For a Business Headquartered Outside the United States''). Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected. In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a ''National Taxing Authority Certification,'' must: Be in English; be from the national taxing authority of the country in which the business is headquartered; provide the business' gross receipts or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars; provide the dates during which the reported receipts or sales were collected; and bear the official seal of the national taxing authority.

Both Forms FDA 3602 and FDA 3602A are available in the guidance document, ''Guidance for Industry, Food and Drug Administration Staff, and Foreign Governments: FY 2012 Medical Device User Fee Small Business Qualification and Certification,'' available on the Internet at: *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM267051.pdf.* This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2012.

The Form FDA 3602 burden is based on the number of applications received in the last 3 years. FDA believes most entities that submit Form FDA 3602A will not have any affiliates, and very few will have more than three or four affiliates. Based on our experience with Form FDA 3602A, FDA believes each business will require 1 hour to complete the form.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Form 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: April 10, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–9241 Filed 4–17–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–E–0310 (previously FDA Docket No. 2005E–0245)]

Determination of Regulatory Review Period for Purposes of Patent Extension; KEPIVANCE; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 2, 2007 (72 FR 15699). The document concerned FDA's determination of the regulatory review period for KEPIVANCE. The document cited an incorrect statute under which the KEPIVANCE biologics license application was submitted. This document corrects the citation.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: In FR Doc. 2007–15699 on page 15700 in the **Federal Register** of Monday, April 2, 2007, the following correction is made:

1. On page 15700, in the first column, in the first line, ''505(b) of the act'' is corrected to read ''351 of the Public Health Service Act (42 U.S.C. 262).''

Dated: February 28, 2012.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012–9325 Filed 4–17–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0888]

Determination That FUNDUSCEIN-25 (fluorescein sodium injection), 25%, and AK-FLUOR (fluorescein sodium injection), 25%, 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 FUNDUSCEIN-25 (fluorescein sodium injection), 25%, and AK-FLUOR (fluorescein sodium injection), 25%, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for fluorescein sodium injection, 25%, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jane Inglese, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6210, Silver Spring, MD 20993–0002, 301–796–3601.

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 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).

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 ((21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

FUNDUSCEIN-25 (fluorescein sodium injection), 25%, is the subject of NDA 17-869, held by Novartis Pharmaceuticals Corp., and initially approved on November 10, 1976. FUNDUSCEIN-25 is indicated for use in diagnostic fluorescein angiography or angioscopy of the retina and iris vasculature. AK-FLUOR (fluorescein sodium injection), 25%, is the subject of NDA 22-186, held by Akorn Inc., and initially approved on August 8, 2008. AK-FLUOR also is indicated for use in diagnostic fluorescein angiography or angioscopy of the retina and iris vasculature.

FUNDUSCEIN-25 (fluorescein sodium injection), 25%, and AK-FLUOR (fluorescein sodium injection), 25%, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Foley & Lardner LLP submitted a citizen petition dated December 7, 2011 (Docket No. FDA–2011–P–0888), under 21 CFR 10.30, requesting that the Agency determine whether FUNDUSCEIN-25 (fluorescein sodium injection), 25%, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address AK-FLUOR (fluorescein sodium injection), 25%, that product has also been discontinued. On our own initiative, we have therefore also determined whether AK-FLUOR was withdrawn for safety or effectiveness reasons.

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 FUNDUSCEIN-25 (fluorescein sodium injection), 25%, and AK-FLUOR (fluorescein sodium injection), 25%, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that FUNDUSCEIN-25 (fluorescein sodium injection), 25%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FUNDUSCEIN-25 (fluorescein sodium injection), 25%, and AK-FLUOR (fluorescein sodium injection), 25%, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that FUNDUSCEIN-25 (fluorescein sodium injection), 25%, and AK-FLUOR (fluorescein sodium injection), 25%, were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FUNDUSCEIN-25 (fluorescein sodium injection), 25%, and AK-FLUOR (fluorescein sodium injection), 25%, 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 FUNDUSCEIN-25 (fluorescein sodium injection), 25%, or AK-FLUOR (fluorescein sodium injection), 25%, 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: April 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–9292 Filed 4–17–12; 8:45 am]

BILLING CODE 4160–01–P