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]

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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That FUNDUSCEIN-25 (fluorescein sodium injection), 25%, and AK-FLUOR (fluorescein sodium injection), 25%, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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that FUNDUSCEIN-25 (fluorescein sodium injection), 25%, and AK-FLUOR (fluorescein sodium injection), 25%, were not withdrawn from sale for reasons of safety or effectiveness.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]

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