Wuxi Kaili Pharmaceutical Company LTD. 6/22/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993-0002

Warning Letter

WL: GDUFA-15-022

June 22, 2015

Mr. Zhinan Hu
Wuxi Kaili Pharmaceuticals Co., Ltd.
1 Penggan Village, Zhoutie
Yixing City Jiangsu 214261
China

FEI - 3003780949

Dear Mr. Hu:

The owner of the above referenced facility has failed to pay the appropriate facility fee as required by the Generic Drug User Fee Amendments of 2012 (GDUFA). *See* 21 U.S.C. §§ 379j-41to 379j-42.

GDUFA defines a facility in relevant part as "a business or other entity . . . at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form." 21 U.S.C. §§ 379j-41(5)(A)(i).

If such a facility is identified or intended to be identified in a pending or approved generic drug submission, the person that owns that facility must submit information concerning the facility to FDA (self-identify) each year in accordance with 21 U.S.C. § 379j-42(f). Self-identification for fiscal year 2013 was required on or before December 3, 2012. Self-identification for fiscal year 2014 was required from May 1, 2013, to June 1, 2013. Self-identification for fiscal year 2015 was required from May 1, 2014, to June 1, 2014.

If such a facility is identified or intended to be identified in a pending or approved generic drug submission on the facility fee due date, the person that owns that facility must pay an annual facility fee. 21 U.S.C. § 379j-42(a)(4). The fees for fiscal year 2013 were due on March 4, 2013, the fees for fiscal year 2014 were due on October 18, 2013, and the fees for fiscal year 2015 were due on October 1, 2014. Only facilities that manufacture positron emission tomography drugs are exempted from this and other GDUFA fee requirements. *See* 21 U.S.C. § 379j-42(l).

Any drugs or active pharmaceutical ingredients (API) manufactured, prepared, propagated, compounded, or processed at a facility for which required facility fees have not been paid or required self-identifying information has not been submitted, or drugs containing an active pharmaceutical ingredient manufactured, prepared, propagated, compounded, or processed at such a facility are misbranded. 21 U.S.C. §§ 352(aa), 379j-42(g)(4)(A)(iii). It is a violation of federal law to ship misbranded products in interstate commerce, which includes causing such products to be imported into the United States. 21 U.S.C. § 331(a). Such violations can result in injunctions or seizures of the misbranded products. *See* 21 U.S.C. §§ 332 and 334. Products that appear to be misbranded may also be denied entry into the United States. 21 U.S.C. § 381(a)(3).

Facilities that fail to pay the annual facility fee are placed on a publicly available GDUFA facility arrears list. Any generic drug submission from the person responsible for paying the fee, or from an affiliate of that person, will not be received by FDA within the meaning of 21 U.S.C. § 355(j)(5)(A). In addition, any new generic drug submission that references such a facility will not be received, within the meaning of 21 U.S.C. § 355(j)(5)(A), if the outstanding facility fee is not paid within 20 calendar days of FDA providing notification to the sponsor of the failure of the owner of the facility to pay the facility fee. 21 U.S.C. § 379j-42(g)(4)(A)(ii).

The above-referenced facility is a drug manufacturing facility as defined under GDUFA. It was identified in a pending and/or approved ANDA on the dates for self-identification for fiscal years 2013, 2014, and 2015, and on the due dates for facility fees for fiscal years 2013 and 2014. The facility has self-identified for fiscal years 2013, 2014, and 2015 but, has not paid the 2013, 2014, and 2015facility fees as required by GDUFA. Therefore, all finished dosage forms of drugs or APIs, as well as drug containing an API, manufactured at the facility are misbranded.

Your facility has been placed on a publicly available GDUFA facility arrears list for failure to pay required fees in fiscal years 2013, 2014, and 2015. Seelink to arrears list at: http://www.fda.gov/forindustry%20/userfees/genericdruguserfees/default.htm. Failure to correct these violations promptly may result in regulatory action, including but not limited to seizure or injunction without further notice. Your facility may also be placed on import alert such that any drug the facility manufactures will be refused admission into the United States.

You should take prompt action to correct the violations noted above by immediately paying fiscal years 2013, 2014, and 2015 fees. Information, including who is required to self-identify, how the information is submitted to FDA, who is required to pay facility fees, the penalty for failure to self-identify or to pay a facility fee, and the technical specifications for self-identification and fee payment, is available on FDA's GDUFA Web page at www.fda.gov/gdufa.

This letter is not intended to identify all of the ways in which your activities might be in violation of law. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Please notify this office in writing within 15 working days of receipt of this letter of any steps you have taken to correct the noted violations. If the corrective action(s) cannot be completed within 15 working days, state the reason for the delay and the time within which the correction(s) will be completed. Your response and any other inquiries concerning this letter should be sent to: GDUFACompliance@fda.hhs.gov.

If email is not available, please send to:

David Mazyck
10903 New Hampshire Ave.
WO51, RM2260
Silver Spring, MD 20993-0002

Sincerely,
/S/
Michael Levy, J.D.
Deputy Director
Office of Compliance
Center for Drug Evaluation and Research

More in 2015

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