

WARNING LETTER

Kellin Chemicals Co., Ltd. - Zhangjiagang

MARCS-CMS 716228 — NOVEMBER 06, 2025

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**Delivery Method:**

Via Email Return Receipt Requested

**Product:**

Drugs

**Recipient:**

Zhiyu Du

Marketing and Sales Center Representative

Kellin Chemicals Co., Ltd. - Zhangjiagang

No. 5 Changjiang North Road

Yangzijiang Chemical Industrial Park

Zhenjiang Shi Jiangsu Sheng, 215634

China

**Issuing Office:**

Center for Drug Evaluation and Research (CDER)

United States

Feedback

Warning Letter 320-26-15

November 6, 2025

Dear Zhiyu Du:

Your firm is currently registered as a supplier of active pharmaceutical ingredients (API) (for example, **(b)(4)**) to manufacturers of finished drug products who have distributed to the U.S. market.

The United States Food and Drug Administration (FDA) notified your site, Kellin Chemicals (Zhangjiagang) Co., Ltd., FEI 3017343300, at No. 5 Changjiang North Road, Yangzijiang Chemical Industrial Park, Zhangjiagang, Jiangsu, of a planned inspection of your drug manufacturing facility from July 7 to July 11, 2025. Your United States (U.S.) Agent, Registrar Corp., notified us that your firm refused the preannounced inspection.

Under section 501(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(j), your drugs are adulterated in that they have been manufactured, processed, packed, or held in an establishment where the owner or operator has delayed, denied, limited, and/or refused to permit inspection.

Until FDA is permitted to inspect your facility and confirms compliance with CGMP, we may withhold approval of any new applications or supplements listing your firm as a drug manufacturer. In addition, shipments of articles manufactured at Kellin Chemicals (Zhangjiagang) Co., Ltd., No. 5 Changjiang North Road, Yangzijiang Chemical Industrial Park,

Zhangjiagana, Jiangsu, into the United States. that appear to be adulterated or misbranded are subject to being detained or refused admission pursuant to section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3).

We recommend that you inform any U.S. customers of this letter. Introduction into interstate commerce of adulterated drugs violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a); and receipt in interstate commerce of adulterated drugs, and the delivery or proffered delivery thereof, such as by drug product manufacturers using adulterated API as a component, is a violation of section 301(c) of the FD&C Act, 21 U.S.C. 331(c).

After you receive this letter, respond to this office in writing within 15 working days. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices, and/or submit a request to schedule an FDA inspection.

Send your electronic reply to [CDER-OC-OMQ-Communications@fda.hhs.gov](mailto:CDER-OC-OMQ-Communications@fda.hhs.gov). Identify your response with FEI 3017343300 and ATTN: Maria Pavco.

Sincerely,  
/S/

Francis Godwin  
Director  
Office of Manufacturing Quality  
Office of Compliance  
Center for Drug Evaluation and Research

Cc: Registrar Corp

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Yes

No

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