檔　　號:
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衛生福利部食品藥物管理署 函

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受文者：台灣藥品行銷暨管理協會

發文日期：中華民國115年8月25日
發文字號：FDA品字第1151105704號
速別：普通件
密等及解密條件或保密期限：
附件：原料藥廠違反GMP警訊乙份 (A21020000I_1151105704_doc1_Attach1.pdf)

主旨：有關美國FDA發布中國原料藥廠Warning Letter乙案，請轉知所屬會員知照。

說明：

一、美國衛生主管機關Food and Drug Administration（FDA）查核中國原料藥廠「Tianjin Kilo Pharmaceutical Sci-tech Co., Ltd.」（廠址：Room 609, Building 6, no. 6 Ziyuan Road, Huayuan High-tech Industrial Park Tianjin Shi, 300384 China），判定違反CGMP，並於115年8月6日發布Warning Letter（詳附件，115年8月18日公布於美國FDA官網）。

二、鑑於上述原料藥廠未符合GMP規定，具影響藥品製造品質之風險，請轉知所屬會員釐清國產及輸台製劑產品相關原料藥使用情形，並應依風險管理原則執行相關後續處置。

正本：中華民國西藥商業同業公會全國聯合會、中華民國西藥代理商業同業公會、台北市西藥代理商業同業公會、中華民國開發性製藥研究協會、台灣藥品行銷暨管理協會、台灣製藥工業同業公會、中華民國學名藥協會、中華民國製藥發展協會

副本：電子公文交換章 2025/08/25 12:46:16

WARNING LETTER

Tianjin Kilo Pharmaceutical Sci-tech Co., Ltd.

MARCS-CMS 731761 — AUGUST 06, 2026

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Delivery Method:

VIA ELECTRONIC MAIL READ/DELIVERY RECEIPT REQUESTED

Reference #:

320-26-110

Product:

Drugs

Recipient:

Wenjun Liao

General Manager

Tianjin Kilo Pharmaceutical Sci-tech Co., Ltd.

Room 609, Building 6, no. 6 Ziyuan Road

Huayuan High-tech Industrial Park Tianjin Shi, 300384

China

(b)(4) (mailto:(b)(4))

Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

August 6, 2026

WARNING LETTER

Reference number: 320-26-110

To Wenjun Liao:

This warning letter advises you of significant deviations identified during a U.S. Food and Drug Administration (FDA) review of your products, processes, and records. Promptly address the deviations described herein without delay, including ensuring that appropriate resources are allocated to fully address the deviations and prevent their recurrence. This is not intended to be an all-inclusive list of the deviations that exist in connection with your products or operations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations. Failure to adequately address deviations may result in regulatory action without further notice.

FDA Review

Feedback

Deviations were identified and documented during review of your drug manufacturing facility, Tianjin Kilo Pharmaceutical Sci-tech Co., Ltd., FDA Establishment Identifier (FEI) 3012560989. This review was conducted under FDA's statutory authority and public health responsibilities to protect the public from drugs that are unsafe, ineffective, or of poor quality.

Your facility is registered with the FDA as a manufacturer of active pharmaceutical ingredients (APIs). FDA has reviewed the records you submitted in response to our July 7, 2025 request and subsequent correspondence, for records and other information pursuant to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for your facility.

This warning letter summarizes significant deviations from Current Good Manufacturing Practice (CGMP) for APIs.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding of drugs as described in your response to our 704(a)(4) request do not conform to CGMP, your APIs are adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

In addition, violations were identified and documented during a review of your firm's drug listing submissions in FDA's electronic Drug Registration and Listing System (eDRLS). Based on our review, you failed to provide drug listing information for your drugs demecarium bromide and chlorambucil. Failure to provide listing information for a drug in accordance with section 510 of the FD&C Act, 21 U.S.C. 360, is prohibited under section 301(p) of the FD&C Act, 21 U.S.C. 331(p). As a result of this failure, these drugs are misbranded under section 502(o) of the FD&C Act, 21 U.S.C. 352(o) and their introduction into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a). These violations are described in more detail below.

Deviations from the Federal Food, Drug, and Cosmetic Act

The following are deviations identified during our review. As a reminder, this is not an all-inclusive list of deviations at your facility.

1. Failure to demonstrate that your manufacturing process can reproducibly manufacture an API meeting its predetermined quality attributes.

Your response to our request for records or other information pursuant to section 704(a)(4) indicates that you manufactured and distributed **(b)(4)** APIs to the United States (U.S.) without adequate process validation, which is critical to ensure the quality and purity of the API. For example, in response to our request on July 7, 2025, that you provide the process validation summary report for all U.S.-marketed APIs, you indicated that these APIs were still in development and were not commercial products. Therefore, formal documents such as standard operating procedures had not been finalized. However, FDA data shows that your **(b)(4)** APIs were distributed to 503A compounding pharmacies.

Process validation evaluates the soundness of design and state of control of a process throughout its life cycle. Each significant stage of a manufacturing process must be designed appropriately and must ensure the quality of raw-material inputs, in-process materials, and finished drugs. Process-qualification studies determine whether an initial state of control has been established.

Without adequate process validation, your firm lacks the basic assurance that you can reproducibly deliver products that meet specifications. See FDA's guidance document *Process Validation: General Principles and Practices* at https://www.fda.gov/media/71021/download for general principles and approaches that FDA considers appropriate elements of process validation.

In response to this letter, provide the following:

- A detailed summary of your validation program for ensuring a state of control throughout the product life cycle, along with associated procedures. Describe your program for process performance qualification (PPQ) and the ongoing monitoring of both intra-batch and inter-batch variations to ensure a continuing state of control.
- A timeline for performing PPQ for each of your marketed drug products.
- Process performance protocol(s) and written procedures for the qualification of equipment and facilities.

- A risk assessment and any follow-up actions to be taken for the APIs your firm produced and distributed without first performing any process-validation studies.

2. Failure to prepare and use master production and control records.

Your batch record for **(b)(4)** lacked some of the critical processing information necessary to ensure consistent manufacturing and product quality. For example, you did not list **(b)(4)** and major equipment used in the manufacturing process.

You did not provide a batch record for **(b)(4)**, despite being asked to provide this documentation multiple times.

Without suitable batch records, you cannot adequately monitor and analyze both intra-batch and inter-batch variations to ensure that manufacturing processes remain in a state of control.

In response to this letter, provide:

- A comprehensive, independent global review of the adequacy of the design, control, monitoring, and documentation of the production processes used for all your APIs.
- Appropriately detailed master batch records that capture all the significant manufacturing steps for each of your APIs.

3. Failure to validate and verify the suitability of analytical methods.

Based on the records and information you provided, your firm failed to perform test method validation (or verification if compendial testing is used) for each test method used for drugs distributed to the United States.

Test methods must be validated to show that they are suitable for their intended use or verified to show, at a minimum, equivalence with United States Pharmacopeia (USP) compendial methods. Method validation and verification are necessary to support reliable determinations of identity, strength, quality, purity, and potency of drugs. Without evaluating the validity of methods, you lack the basic assurance that the data provided to customers were an accurate reflection of pharmaceutical product quality and safety.

In response to this letter, provide:

- A comprehensive, independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system.
- A list of chemical and microbial test methods and specifications used to analyze each lot of your APIs before making decisions about the disposition of a lot, and the associated written procedures.

4. Failure to design a documented, ongoing stability testing program to monitor the stability characteristics of APIs and to use the results to confirm the appropriate storage conditions and the retest or expiry dates.

Based on the records and information you provided, your firm failed to perform routine stability testing to demonstrate that the quality attributes of your APIs remain acceptable throughout the labeled expiry period. For example, your firm did not provide stability test data for **(b)(4)** manufactured at your facility.

Without an appropriate stability program, you lack adequate scientific evidence to support that your APIs meet established specifications and retain their quality attributes through their labeled expiry period.

In response to this letter, provide:

- A retrospective risk assessment showing how you will ensure that your marketed APIs meet stability specifications throughout their shelf life.
- A comprehensive, independent assessment and CAPA plan to ensure the adequacy of your stability program. Your remediated program should include but should not be limited to:
  o Stability indicating methods

- o Stability studies for each API in its marketed container/closure system before distribution is permitted
- o An ongoing program in which representative lots of each product are added to the program each year to determine if their shelf-life claim remains valid
- o A detailed definition of the specific attributes to be tested at each station (time point)
- o All procedures that describe these and other elements of your remediated stability program

Drug Listing Violations

Section 510(j) of the FD&C Act and 21 CFR Part 207 set forth the requirements for the listing of drugs. Section 510(j) of the FD&C Act and 21 CFR 207.41 require registrants to list each drug they manufacture for commercial distribution. You did not provide drug listing information for demecarium bromide and chlorambucil under your own labeler code, yet you manufactured and shipped these drugs into the United States. Although these drugs are listed in FDA's drug listing database, they are listed under a different company's labeler code, not your own. As the manufacturer distributing these drugs into U.S. commerce, you are required to list them under your own labeler code in accordance with 21 CFR 207.41.

Failure to list drugs in accordance with 510(j) of the FD&C Act, 21 U.S.C. 360(j), is prohibited under section 301(p) of the FD&C Act, 21 U.S.C. 331(p). Furthermore, under section 502(o) a drug is misbranded if it is not included in a list required by section 510(j). Under section 301(a), the introduction or delivery for introduction into interstate commerce of any drug that is misbranded is prohibited.

Complete, accurate, and up-to-date establishment registration and drug listing information is essential to promote and protect patient safety. FDA relies on establishment registration and drug listing information for several key programs, including drug establishment inspections, supply chain security, and post-market surveillance. Establishment registration and drug listing information is also widely used outside FDA for purposes such as electronic prescribing and electronic health records, insurance reimbursement, and patient education.

It is your responsibility to ensure that all drugs manufactured at your establishment comply with all establishment registration and drug listing requirements under section 510 of the FD&C Act, 21 U.S.C. 360, 21 CFR Part 207, and all other applicable FDA regulations. Registration and listing information and instructions on how to properly register an establishment or submit drug listings can be found at Electronic Drug Registration and Listing Instructions.

Conclusion

As previously stated, you are responsible for investigating and determining the root causes of any deviations, and for implementing corrective and preventive measures to ensure future and sustained compliance, so these violations do not recur and any others do not occur.

FDA placed all drugs and drug products offered for import into the United States from your firm on Import Alert 66-40 on July 21, 2026.

FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until any deviations are completely addressed and we confirm your compliance with CGMP. We may inspect to verify that you have completed corrective actions for any deviations.

Failure to address any deviations may also result in the FDA's continuing to refuse admission of articles manufactured at Tianjin Kilo Pharmaceutical Sci-tech Co., Ltd., at Room 609, Building 6, no. 6 Ziyuan Road, Huayuan High-tech Industrial Park, Tianjin 300384, China, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority that appear to be adulterated may be detained or refused admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

Send your written response to CDER OC-OMQ-Communications@fda.hhs.gov within fifteen (15) business days of your receipt of this letter. Identify your written response with **FEI 3012560989** and **ATTN: Marva Taylor** in the letter or in the subject line of the email.

If you have information that you believe demonstrates that your products are not in violation of the FD&C Act and FDA regulations, include that information for our consideration.

Please note that FDA posts Warning Letters on www.FDA.gov.

Sincerely,
/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

/S/

Tina Smith, M.S.
Captain, U.S. Public Health Service
Director
Office of Unapproved Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Cc: **(b)(4)**

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