

114年度國外藥廠管理與檢查實務研討會

輸入藥品涉違反GMP國際警訊 之代理商應配合辦理事項

品質監督管理組
黃薇羽 稽查員
114年5月23日



衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration

<http://www.fda.gov.tw/>

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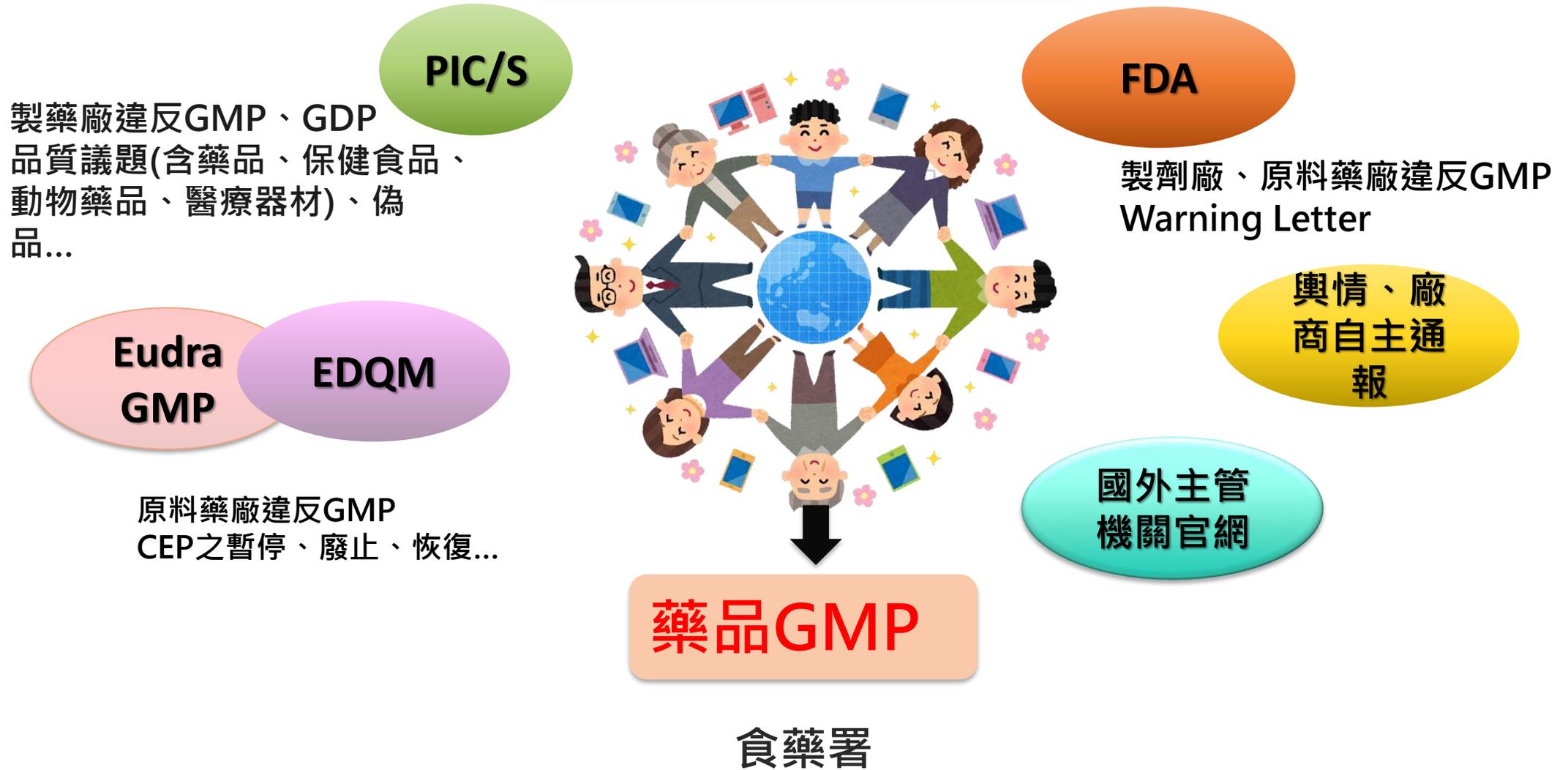
警訊來源



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警訊來源



風險判定



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風險分級

- 撤銷GMP證明
- 判定停工
- 嚴重違反GMP，缺失內容涉及製藥品質系統失效、系統性造假或產品交叉污染等情形
- 限制輸入

重要!



製造廠違反GMP之缺失內容未涉上述高風險情事者

原則上參考國外衛生主管機關對警訊案之處置建議，並視實際違反GMP情節判定風險等級



高風險警訊處理措施



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製劑廠涉及高風險GMP警訊

代理商檢附警訊審查資料

- 查廠報告
- 調查報告及矯正與預防措施(CAPA)
- 後續改善情形
- 其他相關資料
- 輸台產品是否啟動回收評估報告

代理商檢附解除警訊文件

- ✓ PIC/S 會員國:原判國、出產國或其他PIC/S 會員國查核通過證明
- ✓ 非PIC/S會員國:PIC/S會員國查核通過證明

FDA closeout letter 也可以作為解除文件

食藥署接獲警訊

- 限制產品通關或出貨
- 發函業者限期檢附警訊審查資料



結案

- 原申請案准駁或暫不予核定

*視警訊涉及情節辦理，必要時將註銷核准函

解除

重要!

- 解除輸入或出貨限制
- 原案續審/重新申請
- 始具定期檢查資格

原料藥廠涉及高風險GMP警訊

代理商檢附警訊審查資料

- 查廠報告
- 調查報告及矯正與預防措施(CAPA)
- 後續改善情形
- 其他相關資料
- 輸台產品是否啟動回收評估報告

代理商檢附解除警訊文件

重要!

- ✓ PIC/S 會員國:原判國、出產國或其他PIC/S 會員國查核通過證明
- ✓ 非PIC/S會員國:PIC/S會員國查核通過證明

FDA closeout letter 也可以作為解除文件



食藥署接獲警訊

- 限制產品通關或出貨
- 發函業者限期檢附警訊審查資料



結案

- 原申請案逕予結案或暫不予核定
- 警訊涉及之原效期內核准函之部分或全部核定項目予以廢止

*視警訊涉及情節辦理，必要時將註銷核准函

解除

- 解除輸入或出貨限制
- 原案續審/重新申請



低風險警訊處理措施



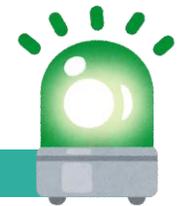
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國外藥廠涉及**低風險**GMP警訊

▶ 代理商檢附警訊審查資料

- 查廠報告
- 調查報告及矯正與預防措施(CAPA)
- 後續改善情形
- 其他相關資料
- 輸台產品是否啟動回收評估報告



▶ 食藥署接獲警訊

- 發函業者限期檢附警訊審查資料

▶ 視補件情形及案件狀況，必要時將調整為**高風險**

必要時

原以工廠資料(PMF)申請GMP檢查者則改以**實地查核**方式進行，或依情節納入後續**實地查廠優先挑選名單**

輸入製劑登錄使用原料藥涉 違反GMP警訊



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製劑廠使用原料藥涉違反GMP警訊

製劑廠應自行依GMP 執行風險評估及管理

- 使用涉及警訊缺失影響原料藥製造之輸入藥品(已有輸台)或國產製劑，應評估生產產品品質，倘，無法確保產品品質應啟動產品回收作業。
- 製劑廠應針對已購入原料藥之品質執行適當管理措施，並取得佐證資料釐清其品質疑慮，必要時，應評估是否暫停使用涉案藥廠原料藥或變更原料藥供應商等。
- 新購原料藥部分，應優先考量其GMP符合性現況。
- 如有供應短缺請至本署西藥醫療器材供應資訊平台通報。



如何查詢國外藥廠是否已取得解除警訊文件



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Compliance Dashboards

 **U.S. FOOD & DRUG ADMINISTRATION**
DATA DASHBOARD

[Data Dashboard Home](#) > [Compliance Dashboards](#) > [FSMA Data Search](#) > [Resources](#) >

[Home](#) > [Compliance Dashboards](#)

Compliance Dashboards

Explore and analyze public FDA data within the below compliance-related datasets.



[Inspections](#)

U.S. domestic and foreign inspections by fiscal year, classification, product type, etc.



[Compliance Actions](#)

Warning letters, injunctions and seizures by fiscal year, product type, etc.



[Recalls](#)

Recalls by fiscal year, classification, product type, status, etc.



[Imports Summary](#)

Imports summary data by fiscal year, import lines, product categories, countries, etc.



[Import Refusals](#)

Import refusals by fiscal year, product categories, country, divisions, etc.



[Imports Entry](#)

Imports entry data by fiscal year, country of origin, port of entry district, etc.



FDA

Compliance Dashboards

The screenshot displays the FDA U.S. Food & Drug Administration Data Dashboard. The header includes the FDA logo and navigation links for Data Dashboard Home, Compliance Dashboards, FSMA Data Search, and Resources. The main content area is titled "Inspections" and includes a "NEW!" notice about the ORA Unified Logon application and published 483s data. It also lists caveats regarding data presentation and important notes about inspection inclusions and final classifications. At the bottom, there is a data table with columns for "Inspections Region" and "Classification", and a search bar with the text "AA|".

U.S. FOOD & DRUG ADMINISTRATION
DATA DASHBOARD

Data Dashboard Home > Compliance Dashboards > FSMA Data Search > Resources >

Home > Compliance Dashboards > Inspections

Inspections

NEW!

- Dashboard has been integrated with the [ORA Unified Logon](#) application. To obtain the credentials necessary to use the API, please submit authorization key requests using the online [ORA Unified Logon](#) application.
- Published 483s data is now available on the [Inspections Dashboard](#) and Firm Profiles.

Caveats:

- Certain information in these datasets may not be presented or may have changed since the posting. The datasets are updated weekly and only include final actions. If you need to present more recent or more complete data for official purposes or have questions about obtaining other data, please contact the [Division of Freedom of Information](#) about what materials may be available in electronic reading rooms or inquire about other datasets that would satisfy your needs.

[+ Show more](#)

Important Notes:

- Not all inspections are included in the database. Inspections conducted by States, pre-approval inspections, mammography facility inspections, inspections waiting for a final enforcement action, and inspections of nonclinical labs are not included. Inspections of nonclinical labs are available at [Nonclinical Laboratories Inspected under Good Laboratory Practices](#).
- The results show final classifications of [No Action Indicated \(NAI\)](#), [Voluntary Action Indicated \(VAI\)](#), [Official Action Indicated \(OAI\)](#) for each [project area](#) within an inspection.

Filters: Graphs Data Tables Download Dataset

Search: AA|

Legal Name: 24 / 112027

City Name: Aachen, Koog aan de Zaan, Aarau, Aarhus N, Aalborg Ost, Adist, Alphen aan Den Rijn, Krimpen aan Den IJssel, Aartselaar, Ouderkerk aan den IJssel, Aarhus C, Guntershausen B, Adorf, Adsmæ Kula

Legal Name: AAK USA K1-K2 LLC, Aarons Apple House, Aaito Scientific Limited, Adron Thomas Company Inc, AAK Foodservice, AAA Pharmaceutical, Inc., Duhon Farm Bin, Adron, AAA Eggs Depot Inc, AA Noodle Mfg Corp, AAK USA Richmond Corp, Adiba Dent, Inc., AALA Tofu Co, Adron Lancaster, Adron Thomas Company, Inc., AFES Waco Distribution Center, Akash Chemical & Dye-Stuffs Inc, AA Food, Inc., AABG LLC, AADCO Medical Inc., AAP Implantate Ag, AA Customs Brokers, Inc, Aroma Baking Company, AA Chile Inc., AAA Molybdenum Products Inc, Adja Produce Inc, AAF Imports Inc, Aarti Drugs Limited, AA Food Services Inc., Arthun Enterprises LLC, AAK International Hull, Adji & Manten International, LLC, AA USA Trading Inc, AAFAB, INC., Adh! Coffee, Inc, Adla Meat Market Incorporated, Ardema Dairy #5, AALST CHOCOLATE, AA Dairy, LLC, Adha Impex Pvt. Ltd., AAM Seafoods Corp., Sandbulte, Adron E, Aarti Pharamolabs Limited, AA-HOM Acupuncture Clinic, Adxis Medical Products (Suzhou) Co., Ltd., Asp Biomaterials, GmbH, Admir Z. Jamal, MD, Krishna Adhar, Inc., Adron D. Coons, Adnex Inc., AA Laboratory Eggs, Inc. (+62 more results)

6 | Inspections Region | 6 | Classification



Compliance Dashboards

FEI Number

3 [REDACTED]

Firm Name

M [REDACTED]

Firm Address

Pl [REDACTED]



[FDA Actions Timeline](#)

[Inspections](#)

[Compliance Actions](#)

[Recalls](#)

[Import Refusals](#)

[Import Alerts](#)

[Warning Letters](#)



- Search results are not returned based on an exact match of the firm name. Users should review the search results to determine whether the firm appears in the Import Alert and that the firm's products are allowed into the country.
- Only current/active Import Alerts are displayed. For more information see [Import Alerts](#).

No Import Alerts data found for the selected firm.

Warning Letters



- The search results below should be reviewed to determine whether the firm is directly or indirectly referenced in the Warning Letter.
- Only Warning Letters issued in the last 5 years are displayed. For more information see [Warning Letters](#).

Firm: M [REDACTED]
URL: [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/\[REDACTED\]](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/[REDACTED])
Subject: CGMP/Active Pharmaceutical Ingredient (API)/Adulterated
Issue Date: 01/31/2023
Snippet: M [REDACTED]

Firm: M [REDACTED]
URL: [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/\[REDACTED\]](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/[REDACTED])
Subject: CGMP/Active Pharmaceutical Ingredient (API)/Adulterated
Issue Date: 03/09/2018
Snippet: [REDACTED]

FDA

CLOSEOUT LETTER

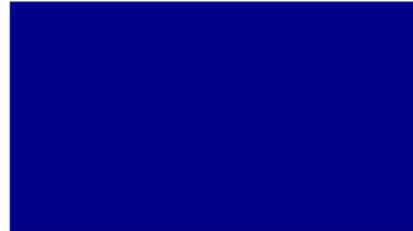
Ma [REDACTED]

MARCS-CMS 5 [REDACTED] — JANUARY 31, 2023

Reference #: [REDACTED]

Product: Drugs

Recipient:



India

Issuing Office:

Center for Drug Evaluation and Research |
CDER
United States

Dear Mr. [REDACTED]

The Food and Drug Administration (FDA) has completed an evaluation of your firm's corrective actions in response to our Warning Letter [REDACTED] dated March 09, 2018.

Based on our evaluation, it appears that you have addressed the deviations contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and



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Eudra GMP database

EudraGMDP

MIA | GMP | API REG | WDA | GDP | Sites Help

Mon 21 Apr 2025 14:11:43 BST

GMP Compliance Menu

- Search
- [GMP Certificates](#)
- [Non-Compliance Report](#)

Search GMP Compliance

Certificate Number:

From Date:  (YYYY-MM-DD)

To Date:  (YYYY-MM-DD)

Site Details

DUNS Number: - -

Name:

City:

Country:  *

Postcode:

常見補件缺失及提醒事項



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常見補件缺失

查廠報告

- 遮蔽過多
- 缺頁
- 未翻譯
- 直接再檢附一次網站上之 Warning letter。

(b)(4)

輸台產品是否啟動回收之評估

- 非由原製造廠出具
- 僅檢附PQR或放行時之COA
- 未有相關評估說明
- 未針對嚴重缺失評估輸台產品是否有類似情形or是否受影響

解除警訊文件

- 無法確認是否為改善完成後，重新取得查核通過之證明
- 僅檢附產品無品質疑慮說明函，申請解除警訊

提醒事項



確實掌握製造廠狀況，及時報備



確保檢附資料之完整性



高風險警訊案應確實申請解除