正本

檔　　號：
保存年限：

236

新北市政府衛生局 函

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受文者：新北市藥師公會

發文日期：中華民國104年3月11日
發文字號：新北衛食字第1040397598號
速別：普通件
密等及解密條件或保密期限：
附件：原函及相關資料影本各1份

主旨：檢送有關「Fucidin Ointment」（批號EE7501）及「Fucidin Cream」（批號EE8296）」產品涉違反衛生法令相關資料，為維護國民之健康與安全，惠請轉知所屬會員，如有案內違規產品應立即下架勿販售，請　查照。

說明：依據衛生福利部食品藥物管理署104年3月6日FDA企字第1041200864號函辦理。

正本：新北市藥師公會
副本：

局長 林奇宏

本案依分層負責規定授權業務主管決行

檔　　號：
保存年限：

衛生福利部食品藥物管理署　函

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受文者：新北市政府衛生局

發文日期：中華民國104年3月6日
發文字號：FDA企字第1041200864號
速別：普通件
密等及解密條件或保密期限：
附件：資料乙份(10412008640-1.pdf)

主旨：檢送案內所陳「Fucidin Ointment」（批號EE7501）及「Fucidin Cream」（批號EE8296）」產品，於中國大陸發現偽品流通，涉屬藥事法所稱之偽禁藥相關資料乙份，為維護國民之健康與安全，請將該產品於市面可能販售及網路刊售之情事列入稽查工作重點，查明依法處辦，請 查照。

說明：依據本署104年3月2日接獲愛爾蘭Health Products Regulatory Authority (HPRA)經PIC/S Rapid Alert System通報藥品不良品暨回收警訊相關資料辦理。

正本：各縣市衛生局
副本：電2015-03-06文交11:37章

1041200864

IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

	Reference Number **IE/I/49/01**

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

1. To: see list attached	
2. Product Recall Class of Defect: I	3. **Confirmed Falsified**
4. Product: 1. Fucidin Ointment 2. Fucidin Cream	5. Marketing Authorisation Number: The marketing authorisation numbers stated on the falsified packs are the genuine MA numbers for the following markets: 1. Fucidin Ointment: Lebanon, Bolivia, Chile, Costa Rica, Hong Kong, Malaysia, Pakistan, Singapore, United Arab Emirates, Uruguay, Vietnam 2. Fucidin Cream : Bolivia, Hong Kong, Lebanon, Malaysia, Panama, Singapore, United Arab Emirates, Uruguay, Vietnam Genuine product for use in humans
6. Brand/Trade Name: 1. Fucidin 2. Fucidin	7. INN or Generic Name: The genuine product contains: 1. Sodium fusidate 2. Fusidic acid
8. Dosage Form: The dosage forms of the genuine products are 1. Ointment 2. Cream	9. Strength: The genuine products contain: 1. Sodium fusidate 20mg/g in neutral ointment base 2. Fusidic acid 20mg/g in neutral cream base The genuine active substances were not identified in samples of the falsified ointment and cream upon testing.

10. Batch number: The following genuine Leo batch numbers were applied to the falsified units: 1. Fucidin Ointment: EE7501 2. Fucidin Cream: EE8296	11. Expiry Date: The expiry dates for the genuine batches are: 1. Fucidin Ointment: 01/2014 2. Fucidin Cream: 02/2014 The expiry dates for the falsified batches are: 1. Fucidin Ointment: 11/2017 2. Fucidin Cream: 11/2017
12. Pack size and Presentation: 1. Fucidin Ointment: 15g ointment in a tube. Contained in an outer carton. 2. Fucidin Cream: 15g cream in a tube. Contained in an outer carton.	13. Date Manufactured: The dates of manufacture of the genuine batches are 1. Fucidin Ointment: 01/2011 2. Fucidin Cream: 02/2011 The dates of manufacture of the falsified units are stated as: 3. Fucidin Ointment: 11/2014 4. Fucidin Cream: 11/2014
14. Marketing Authorisation Holder: The falsified packs state: LEO Pharmaceutical Products Ballerup – Denmark - Dinamarca The MAH for the genuine products is LEO Laboratories Limited, Cashel Road., Dublin 12, Ireland.	
15. Manufacturer†: Falsified product: Unknown Genuine product: Manufactured in LEO Laboratories Limited, Cashel Road., Dublin 12, Ireland	16. Recalling Firm: The Chinese governing body YuYao FDA is recalling the falsified product in China Contact Person: YuYao Market Supervision Administration Tel: +86 0574 6273 0627
17. Recall Number Assigned: QDR-H-15-030 and QDR-H-15-031	

18. Details of Defect/Reason for Recall:

The falsified packs were detected at a local manufacturing operation in China which is not the authorised manufacturer for these products.

The following anomalies were identified with the falsified products:

1. No active substance was identified in samples of the falsified units upon testing.
2. The batch numbers are genuine LEO batch numbers. However the genuine batches were manufactured in 2011. Manufacturing dates of 11/2014 were assigned to the falsified units.
3. The expiry dates for the genuine batches are 01/2014 for the ointment and 02/2014 for the cream. Expiry dates of 11/2017 were applied to the falsified units for both the ointment and the cream.
4. The ointment sample was physically characteristic of a cream rather than an ointment.
5. The odours of the falsified products are different to the genuine products, which are almost odourless.
6. The package leaflets in the falsified packs are exact copies of the genuine package leaflets but the paper quality is not the same.
7. The cartons on the falsified units are in both the English and Spanish languages.
8. The falsified package leaflets are in both the English and Arabic languages.

19. Information on distribution including exports:

The falsified packs were detected at a local manufacturing operation in China.

The genuine LEO batches were distributed to:

Fucidin Ointment (EE7501) – Syria, Lebanon, Palestine, United Arab Emirates (UAE)

Fucidin Cream (EE8296) – Iraq, Israel, Oman, Palestine, Syria, UAE

20. Action taken by Issuing Authority:

Falsified packs have not been identified on the Irish market.

21. Proposed Action:

Local action as considered necessary.

22. From (Issuing Authority): Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.	23. Contact Person: Telephone:+353 1 676 4971

24. Signed: Amy Kelly Digitally signed by Amy Kelly DN: cn=Amy Kelly, o=HPRA, ou, email=amy.kelly@hpra.ie, c=IE Date: 2015.03.02 14:02:29 Z	25. Date: 02/Mar/2015	26. Time: 15:30