



30 November 2017

(17-6577)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION¹臺灣 通知-原料藥

The following notification is being circulated in accordance with Article 10.6

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| 1. | Notifying Member: <u>THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU</u> 臺灣 If applicable, name of local government involved (Article 3.2 and 7.2): |
| 2. | Agency responsible: Food and Drug Administration Ministry of Health and Welfare No.161-2, Kunyang St, Nangang District, Taipei City 115-61, Taiwan Tel: (886-2) 27878000#7486 Fax: (886-2) 27877498 E-mail: chuyiyang@fda.gov.tw Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: |
| 3. | Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other: |
| 4. | Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Active pharmaceutical ingredients (APIs) 原料藥 |
| 5. | Title, number of pages and language(s) of the notified document: Draft of the Import Regulation of "F04" (1 page(s), in English; 1 page(s), in Chinese) |
| 6. | Description of content: The Ministry of Health and Welfare proposes to add the import regulation of "F04": if imported commodities belong to active pharmaceutical ingredients, importation of commodities shall follow the "Regulations Governing the Border Inspection of Imported Pharmaceuticals." The importer shall apply for inspection to the Food and Drug Administration (FDA), Ministry of Health and Welfare. 衛福部預告增訂輸入規定代碼「F04」:如屬原料藥,應自行依照「輸入藥物邊境抽查檢驗辦法」規定,向衛生福利部食品藥物管理署申請辦理輸入查驗。 |
| 7. | Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety; Quality requirements |
| 8. | Relevant documents: Article 71-1 of the Pharmaceutical Affairs Act |
| 9. | Proposed date of adoption: To be determined Proposed date of entry into force: To be determined |

¹ Please note this notification was submitted to the WTO on 2 November 2017.

10. Final date for comments: 60 days from notification

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

WTO/TBT Enquiry Point
Bureau of Standards, Metrology and Inspection
Ministry of Economic Affairs
No.4, Sec.1, Jinan Rd.
Zhongzheng Dist., Taipei City 100, Taiwan
Tel: (886-2) 23431813
Fax: (886-2) 23431804
E-mail: tbtenq@bsmi.gov.tw

https://members.wto.org/crnattachments/2017/TBT/TPKM/17_4975_00_e.pdf