

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>REPUBLIC OF KOREA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Ministry of Commerce, Industry and Energy Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Korea Food and Drug Administration
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): Bulk drug substance
5.	Title, number of pages and language(s) of the notified document: Amendment of "The Consolidated Public Notice" (1 page, in Korean)
6.	Description of content: To maintain consistency and balance in the policies on managing bulk drug substances according to the Bulk Good Manufacturing Practice (BGMP) system which will go into effect as of 1 July 2002 in order to strengthen the standards of manufacturing and quality for the domestically produced bulk drug substances. - When bulk drug substance is imported, a certificate of BGMP should be submitted; - The certificate is issued by the government or the public organization concerned of the manufacturing country and proves that the bulk drug substance is being manufactured in conformity with the relevant laws and regulations of the manufacturing country.
7.	Objective and rationale, including the nature of urgent problems where applicable: Human health
8.	Relevant documents: MOCIE notification 2002-157(2002.1.3)
9.	Proposed date of adoption: 3 January 2002 Proposed date of entry into force: 1 July 2002
10.	Final date for comments:

11. Texts available from: National enquiry point [] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:

International Cooperation Division
Ministry of Health and Welfare
1 Jungang-Dong
Kwacheon-City
Kyoungi-Do
427-760
Republic of Korea

Tel: +82-2-2110-6152/3

Fax: +82-2-504-6418