

Committee on Technical Barriers to Trade

NOTIFICATION

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

1.	Member to Agreement notifying: <u>UNITED STATES</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Food and Drug Administration (51) Agency or authority designated to handle comments regarding the notification can 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): Drug products
5.	Title, number of pages and language(s) of the notified document: Current Good Manufacturing Practice; Proposed Amendment of Certain Requirements for Finished Pharmaceuticals (12 pages)
6.	Description of content: The Administration is proposing to amend certain requirements of the Current Good Manufacturing Practice (CGMP) Regulations for finished pharmaceuticals. These amendments would clarify certain manufacturing, quality control, and documentation requirements and would ensure that the requirements regulations more accurately encompass CGMP. In addition, the Agency is updating the requirements for process and methods validation to incorporate guidance previously issued to industry and to reflect current practice.
7.	Objective and rationale: To enhance the integrity of the drug manufacturing process and the safety of drug products.
8.	Relevant documents: 61 FR 20104, 3 May 1996; 21 CFR Parts 210 and 211. Will appear in the Federal Register when adopted.
9.	Proposed date of adoption: The Administration proposes that any final rule that may issue based upon this proposal become effective 90 days after its date of publication in the Federal Register. Proposed date of entry into force:
10.	Final date for comments: 1 August 1996
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: