

WORLD TRADE ORGANIZATION

G/TBT/N/USA/
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(00-0000)

Committee on Technical Barriers to Trade

NOTIFICATION

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

1.	Member to Agreement notifying: United States If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Food and Drug Administration (FDA) (509) 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:
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other 3.2 []
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading: ICS numbers may be provided in addition, where applicable): Combination products (HS 3004, 9018.11-90) (ICS 71.100, 13.020)
5.	Title, number of pages and language(s) of the notified document: Current Good Manufacturing Practice Requirements for Combination Products; proposed Rule (9 pages, English)
6.	Description of Content: The Food and Drug Administration (FDA or agency) proposes to codify the current good manufacturing practice (cGMP) requirements applicable to combination products. This proposed rule is intended to promote the public health by clarifying which cGMP requirements apply when drugs, devices, and biological products are combined to create a combination product. In addition, the proposed rule sets forth a transparent and streamlined regulatory framework for firms to use when demonstrating compliance with cGMP requirements for single-entity and co-packaged combination products.
7.	Objective and rationale, including the nature of urgent problems where applicable: Consumer protection
8.	Relevant documents: 74 Federal Register (FR) 48423 23 September 2009; Title 21 Code of Federal Regulations (CFR) Part 4.
9.	Proposed date of adoption: Proposed date of entry into force: To be determined
10.	Final date for comments: 22 December 2009
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: Internet URLs: http://edocket.access.gpo.gov/2009/E9-22850.htm http://edocket.access.gpo.gov/2009/pdf/E9-22850.pdf