

# WORLD TRADE ORGANIZATION

G/TBT/N/USA/63

21 June 2004

(04-2683)

Committee on Technical Barriers to Trade

Original: English

## NOTIFICATION

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

1.	<b>Member to Agreement notifying:</b> <u>UNITED STATES</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Department of Health and Human Services, Food and Drug Administration (FDA) (67) <b>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:</b>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Pharmaceutical Clinical Studies (HS Chapter 3004) (ICS 11.120).
5.	<b>Title, number of pages and language(s) of the notified document:</b> Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application (9 Pages, in English)
6.	<b>Description of content:</b> The Food and Drug Administration (FDA) is proposing to revise its regulations on its acceptance of foreign clinical studies not conducted under an investigational new drug application (IND) as support for an IND or marketing application for a drug or biological product. We are proposing to replace the requirement that such studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki (Declaration) with a requirement that the studies be conducted in accordance with good clinical practice (GCP), including review and approval by an independent ethics committee (IEC). The proposed rule is intended to update the standards for the acceptance of non IND foreign studies and to help ensure the quality and integrity of data obtained from such studies.
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of Human Life and Health.
8.	<b>Relevant documents:</b> 69 Federal Register (FR) 32467 10 June 2004; Title 21 Code of Federal Regulations (CFR) Part 312. Will appear in the Federal Register when adopted.
9.	<b>Proposed date of adoption:</b> <b>Proposed date of entry into force:</b> } To be determined
10.	<b>Final date for comments:</b> 8 September 2004

- 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://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-13063.htm>

<http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/pdf/4-13063.pdf>