

WORLD TRADE ORGANIZATION

G/TBT/N/ARG/46

5 June 2002

(02-3122)

Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

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

1.	Member to Agreement notifying: <u>ARGENTINA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: National Drug, Food and Medical Technology Administration (ANMAT) 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: <i>Idem</i> Enquiry point
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): Medicinal preparations for human use
5.	Title, number of pages and language(s) of the notified document: ANMAT Resolution No. 1206/2002, 3 pages in Spanish.
6.	Description of content: This Resolution establishes that the labels/stickers of preparations containing ethyl alcohol which are sold over the counter or on prescription in liquid pharmaceutical form and are intended for oral or parenteral administration, must indicate the ethyl alcohol content as a percentage by weight/volume.
7.	Objective and rationale, including the nature of urgent problems where applicable: This new Resolution repeals ANMAT Resolution No. 3429/00 and extends to situations that were not previously provided for: (1) Alcoholatures, tinctures, liquid extracts containing alcohol to enhance the dissolution of the active principle(s) and which are administered prior to dilution; 2) real possibility of ingesting a mouthwash/spray and related risks. (2) Medicinal preparations containing a quantity of ethyl alcohol that would cause blood alcohol concentrations of greater than 20 mg/dl should not be authorized for paediatric use.
8.	Relevant documents: ANMAT Resolution No. 3429/2000
9.	Proposed date of adoption: - Proposed date of entry into force: 13 April 2002

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10.	Final date for comments:
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: Focal Point of the Argentine Republic National Directorate of Domestic Trade Avda. J. A. Roca 651, 4 th floor, Sector 22 (1322) Buenos Aires Fax: +54 11 4349-4038 Tel.: +54 11 4349-4037 E-mail: vcamal@secind.mecon.gov.ar