



14 December 2015

(15-6598)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 9 December 2015, is being circulated at the request of the delegation of Viet Nam.

TITLE: The draft Circular amending and supplementing a number of articles of Circular No. 03/2012/TT-BYT of the Ministry of Health Guidelines for Clinical trials on Drugs (3 pages, in Vietnamese).

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SUMMARY:

1. Delete Clause 3 of Article 7 of Circular No. 03/2012/TT-BYT
2. Article 20. Stages of clinical trial of pharmaceutical products of herbal origin of Circular No. 03/2012/TT-BYT is amended and supplemented in order to provide more details on purpose, sample size and evaluation in each stage and to define the criteria for exemption of clinical trial at certain stages.

Proposed date of adoption: to be determined

Proposed date of entry into force: 45 days after adoption
Final date for comments: 60 days after notification date

URLs: http://moh.gov.vn/LegalDoc/Pages/OpinionPollInfo_V2.aspx?CateID=223
