

NEW ADVISORY ON LABELING SELECTIVE CYCLOXYGENASE -2 (COX -2) INHIBITORS AND NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

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In pursuance to further enhance safe use of selective Cyclooxygenase-2 (COX-2) inhibitors and non-steroidal anti-inflammatory drugs (NSAIDS), the BFAD would like to issue the following directives:

1. Companies are instructed to use remedial labeling to their package inserts of the existing stocks.
2. The remedial labels shall include the boxed warning stating absolute contraindications for COX-2 and NSAIDS. Please refer to Annexes A[*] and B[*] of BC No. 11, s. 2005.
3. Companies are granted up to 31 March 2006 to exhaust these stocks with remedial labeling.

For immediate compliance of those concerned.

Adopted: 12 Oct. 2005

(SGD.) PROF. LETICIA BARBARA B. GUTIERREZ, MS
Director IV

[*] Please See NAR 16 Volume 2, page 741.

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