

CLARIFICATION OF SECTION 3.4 OF A.O. 96 S. 90 ON THE EXEMPTION FROM THE CRITERIA PRESCRIBED FOR FIXED-DOSE-COMBINATION

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Fixed-dose-combinations (FDC) which are listed in International Compendia such as United States Pharmacopeia, British Pharmacopeia, World Health Organization Compendia, other similar listings, and deemed essential by the Department of Health, may be exempted from the criteria required before such FDC may be registered. As recommended by the National Drug Committee (NDC) in a letter dated August 5, 1991 (Ref. OD-3602 and LICD 3866), BFAD will consider

1. topical non-absorbable (without systemic effect) drugs
2. multivitamins with iron

as among the products that may be exempted from the said criteria.

Any drug establishment therefore, who shall seek exemption shall submit together with his application for registration, a position paper and evidence to show that the FDC applied for is listed in an international compendia and is an essential drug product.

This is for the information of all parties concerned.

Adopted: 28 Jan. 1992

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