

EXTENSION OF THE VALIDITY PERIOD OF RENEWAL REGISTRATION OF MEDICAL AND DENTAL DEVICES

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The current validity period for renewal registration of medical and dental devices is only for one (1) year. BFAD considers, however, that the efficacy and safety of these devices vis-a-vis their intended use have been evaluated and passed upon during their initial registration.

After consultations, we find it proper to adopt the recommendation of the industry to extend the validity periods of the renewal registration from one (1) year to five (5) years. Hence, effective upon the signing of this circular, the validity period of the renewal registration of medical and dental devices shall be five (5) years until the specific standards and requirements for the registration of medical devices shall have been promulgated by an appropriate administrative issuance.

The validity period for initial registration shall remain one (1) year, in the meantime.

This circular does not preclude the BFAD from imposing certain conditions whenever necessary in the Certificate of Product Registration relating to the product's safety, efficacy or details in registration; And this shall cover application for renewal registration after the date of approval and those that are pending registration as of the same date.

Adopted: 3 Aug. 1998

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