FDA
Food and Drug Administration
PHILIPPINES

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

April 08, 2013

FDA Memorandum Circular
No. 2013- 012

Subject: Revised Policies on the Application for Automatic Renewal of Certificate of Product Registration (CPR) for Medical Devices excluding In-Vitro Diagnostic Products

With the complete transfer of the regulatory functions for medical device products from the Food and Drug Administration, Alabang to Center for Device Regulation, Radiation Health, and Research (CDRRHR) by virtue of the Republic Act No. 9711 known as the FDA Act of 2009, the following revised policies on the application for automatic renewal of Certificate of Product Registration shall be implemented:

1. All Certificates of Product Registration (CPR) shall be covered by this memorandum except for in-vitro diagnostic products.
2. Applications for the automatic renewal of CPR shall be filed at the Center for Device Regulation, Radiation Health, and Research (CDRRHR) at least ninety (90) days before the expiration of the CPR.
3. The requirements for the application for automatic renewal of the CPR shall be as follows:

    a. Duly accomplished notarized application form (Doc. No. 011-004-R-02B)
    b. Duly accomplished assessment form (Doc No. 011-004-R-03C)
    c. Copy of valid LTO
    d. Original copy of CPR
    e. Copy of authenticated foreign agency agreement
    f. Copy of ISO/GMP Certification
    g. Unattached commercial product label and specimen labeling of all labeling materials per pack size (immediate label, secondary, carton, package insert, etc., whichever is applicable). If unattached labels are not available, a picture of the label (all angles/sides) of all layers of packaging showing clearly all the labeling requirements can be submitted.
    h. Clear picture of commercial product sample (Bring the actual sample for verification).

4. The filing of applications shall follow FDA Memorandum Circular No. 2013-001 as amended by FDA Memorandum Circular No. 2013-001-A (e-copy).
5. The schedule of filing of applications shall follow FDA Memorandum No. 2012-008.
6. All approved applications for renewal of CPRs shall be reissued and shall have a validity of five (5) years.

7. All applications for automatic renewal shall be processed within thirty (30) days upon filing. An application that complies with all the requirements shall merit an approval and the CPR shall be reissued and shall have a validity of five (5) years. An application that did not comply with all the requirements shall be given a notice of deficiency.
8. An application filed within one hundred twenty (120) days after the expiration date of the CPR shall still qualify for the renewal of the CPR following the above mentioned requirements. However, corresponding fees and surcharges shall be imposed as per Administrative Order No. 50 s. 2001 and FDA Memorandum Circular No. 2011-004.
9. An application filed after the one hundred twenty (120) days grace period shall be considered an application for initial registration and the applicant shall not be allowed to market the product unless the new CPR is approved.

This memorandum circular supersedes BHDT Bureau Memorandum No. 2011-001 dated June 10, 2011.

This memorandum shall take effect on April 15, 2013.

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Director General