REPUBLIC OF THE PHILIPPINES
**DEPARTMENT OF HEALTH**
**FOOD AND DRUG ADMINISTRATION**
Civic Drive, Filinvest Corporate City
Alabang, City of Muntinlupa

**FDA MEMORANDUM**
**No.** 2012-008

**To** : **All the Medical Device Industry**

**Subject** : **New policies for filing of application for medical device product registration and medical device establishment license**

In the interest of service, the following procedures for filing of application for medical device product registration and medical device establishment license shall be implemented at the Center for Device Regulation, Radiation Health, and Research **starting** March 15, 2012 : 4pm

1.0 The following schedule shall be followed by the companies in the submission of their applications for a **Certificate of Product Registration (CPR) and a License to Operate (LTO) a medical device establishment, including the Certificate of Product Exemption** depending on the first letter of the first name of the company:

a. A – F – every Tuesday only
b. G – M – every Thursday only
c. N – R – every Wednesday only
d. S – Z – every Friday only

In the event that the name of the company starts with a number, the schedule to be followed will be that of A-F.

2.0 Submission of applications for CPR (initial registration, renewal, exemption, and/or amendment for both medical device and in-vitro diagnostic products/reagents) and LTO shall be accepted from Tuesday to Friday from **8:00am to 3:00pm** only with no noon break following the schedule in 1.0. No applicants shall be given a transaction number after **3:00pm**.

3.0 Submission of compliance documents, including re-application (for CPR) shall be accepted Tuesday to Friday from **8:00am to 3:00pm** only.

4.0 Only the company pharmacist or the regulatory affairs officer registered with the CDRRHR or the company owner/president is allowed to file the application for the license to operate and/or certificate of product registration. No application shall be accepted when filed by the

consultant without the presence of the company pharmacist or any authorized organic accountable officer of the company.

5.0 The CDRRHR shall only accept letter or memo duly signed by the company pharmacist or company owner/president. This is to ensure that the CDRRHR is transacting business only with accountable company officer/s. Those who are signing for and on-behalf of the company pharmacist or company owner/president shall be an organic employee of the company and authorized to sign on-behalf of the signatories. This person shall attach a copy of his/her company ID.

6.0 All existing LTOs of in-vitro diagnostic (IVD) device companies shall remain in effect until the end of the validity of the license. Upon renewal, the LTO for in-vitro diagnostics shall be converted to an LTO for medical device establishment. The requirements for the renewal of the license shall follow the requirements for renewal of the LTO of a medical device establishment. New LTO number shall be assigned.

7.0 All existing CPRs of in-vitro diagnostic device products shall remain in effect until the end of the validity of the CPR. Upon renewal, the CPR for in-vitro diagnostics shall be converted into the CPR form of a medical device product, however, the registration number shall be retained. For new applications, the requirements shall still follow the checklist for registration of in-vitro diagnostic product and the protocol of testing issued by the respective DOH reference laboratories. However, the product registration number for all approved initial applications of IVD shall be changed to IVDR-XXXX.

1. Telephone follow-up on the status of the application shall only be entertained every Monday. All updates regarding the list of approved CPR, LTO, and Certificate of Exemption for release shall be posted at the bulletin board at the ground floor lobby of Bldg. 24, San Lazaro Compound, Sta. Cruz, Manila.

2. For the release of the CPR, LTO, and Certificate of Exemption, the applicant shall fill up the Certificate Release Form (Annex A) at the Guard post. The guard shall forward all the forms to the Licensing and Regulation Division of CDRRHR. All applicants shall wait for the release of the certificate at the reception area. Certificates and licenses shall only be released to the company pharmacist or to the duly authorized representative of the company upon presentation of a copy of the company ID and authorization letter.

For immediate compliance.

**SUZETTE H. LAZO, MD, FPSECP**
Acting Director IV

02/23/12

**ANNEX A**

*CDRRHR/LRD/2012Form1*

## CERTIFICATE RELEASE FORM

**Date:**

| | | |
|---|---|---|
| **Name of Company:** | | |
| **Name of Pharmacist or Authorized Representative:** | | |
| **Nature of Authorization to be claimed:** | | |
| ☐ CPR<br>☐ Medical Device<br>☐ VD | ☐ Initial<br>Control No.<br><br>☐ Amendment<br>Control No./Registration No. | ☐ Automatic Renewal<br>Control No./Registration No.<br><br>☐ Regular Renewal<br>Control No./Registration No |
| ☐ LTO | ☐ Opening<br>☐ Renewal/Reissuance<br>☐ Amendment (Add/Delete Source) | |
| ☐ Certificate of Exemption | ☐ Control No/s. | |

**Received by:**

**Released by:**

_____
**Signature over Printed Name**

_____

*CDRRHR/LRD/2012Form1*

## CERTIFICATE RELEASE FORM

**Date:**

| | | |
|---|---|---|
| **Name of Company:** | | |
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| ☐ LTO | ☐ Opening<br>☐ Renewal/Reissuance<br>☐ Amendment (Add/Delete Source) | |
| ☐ Certificate of Exemption | ☐ Control No/s. | |

**Received by:**

**Released by:**

_____
**Signature over Printed Name**

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