



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



25 June 2015

FDA Memorandum Circular
No. 2015-008

TO : ALL MEDICAL DEVICE COMPANIES

SUBJECT : POLICY AND REQUIREMENTS FOR AVAILING OF COMPASSIONATE SPECIAL PERMIT FOR REGISTRABLE MEDICAL DEVICES

The Food and Drug Administration (FDA) recognizes the need for medical devices which are not yet registered or are in the process of registration in the Philippines by patients who need immediate medical attention.

Therefore, the FDA shall henceforth provide for a Compassionate Special Permit (CSP) for Restricted Use of Unregistered Medical Devices when the conditions and requirements specified hereunder exist and are complied with.

A CSP for Restricted Use of Unregistered Medical Devices shall refer to a special permit issued by the CDRRHR Director granting the applicant the privilege to use an unregistered medical device product under the following conditions:

1. The device shall be used for patients suffering from life-threatening conditions.
2. There is no other registered medical device of the same kind available in the Philippine market.
3. The device is brand new.
4. No other CSP was previously issued to the applied product.

The following are the requirements to be submitted when applying for CSP:

1. Letter of intent which will include a brief description of the patient, attending physician, list of specialists who will perform the administration of the medical device, quantity of the medical device required to perform the treatment and the proposed schedule of the medical attention.
2. Attending physician's profile.
3. License to Operate as Medical Device Importer/Distributor if the product is to be supplied by a company.
4. Letter of information regarding the importer if the medical device is to be imported by a private individual.

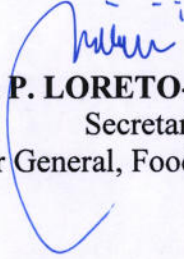


5. Certificate of Product Registration from the country of origin of the medical device to be used. If the medical device is locally manufactured, copy of the License to Operate as Medical Device Manufacturer.
6. Technical description of the medical device from the manufacturer; not downloaded from the company's website.
7. Justification letter from the attending physician regarding the urgency of the use of the medical device.
8. Medical abstract of the patient.
9. A waiver of FDA responsibility from any damage or injury arising from the use of the unregistered medical device to be signed by the applicant company, relative of the patient and the attending physician.
10. A commitment letter from the applicant that a medical report shall be submitted after the operation or use of the medical device in the patient.

Only one time CSP will be given for a specific device, no other CSP shall be issued again.

The company or attending physician shall submit the medical report after the procedure. Failure to submit the medical report shall be a ground for denial of future applications of CSP by the same applicant.

For strict compliance.


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