

08 July 2013

FDA CIRCULAR
No. **2013-017**

SUBJECT: Registration of Human Stem Cell-Based Products

I. Background / Rationale

Pursuant to Administrative Order 2013-0012 known as "Rules and Regulations Governing the Accreditation of Health Facilities Engaging in Human Stem Cell and Stem-Cell Based or Cellular Therapies in the Philippines" strengthening of the regulatory framework to ensure access to safe and quality health facilities engaging in human stem cell and cell-based or cellular therapies in the Philippines has been promulgated.

The Food and Drug Administration, assigned to regulate stem cells and stem cell-based or cellular products, hereby stipulates the requirements and procedure for the registration of human stem cell-based products for the guidance and compliance of all concerned.

This circular does not cover cellular or cell-based therapeutic products intended to replace blood volume or alter the coagulative properties of blood.

II. Implementing Details

A. Documentary Requirements for the Registration of Stem Cell-Based Products

1. Notarized Application Form in duplicate (See Annex A)
2. Electronic Copy (E-Copy) Affidavit
3. Copy of Marketing Authorization from the National Regulatory Authority (NRA) of the exporting country or the country of origin
4. Copy of License to Operate of Importer / Distributor
5. List of countries where the product is already approved and the date(s) of approval
6. Copy of valid agreement between the manufacturer and the importer / distributor
7. Copy of GMP Certificate of the stem cell-based product manufacturer
8. Scientific evidence to support each claimed indication (at least one peer-reviewed and

published)

9. Information on the product and its manufacture/production

9.1 Person (s) responsible for production, control and release of the product: name(s), position, Department and specimen signature

9.2 Formulation of the product

9.3 Information on the source of the stem cells and the raw materials used, including their specifications and the tests to demonstrate compliance with specifications

9.4 Specifications of the finished product and the tests to demonstrate conformance with Specifications

9.5 Information on the method of manufacture, including the in-process control tests and limits, bulk and final product specifications, and test methods

9.6 Specifications of packaging materials (immediate and others), including the tests used to demonstrate compliance to specifications

10. Claimed shelf-life and stability studies undertaken to justify the shelf-life (Stability Testing of Biotechnological / Biological Products Q5C, ICH Harmonized Tripartite Guideline)

11. Description of the cold-chain procedures employed (required storage conditions, transport conditions and storage in distribution outlets)

12. Copy of labeling materials (3 copies). For allogeneic stem cell products, include product information on the following: indications and directions for use, storage conditions and description of the immediate packaging as well as secondary packaging, if any

13. Certificate of Analysis of at least one batch of product

14. Name of the person who will be responsible for any eventuality resulting from use of the product

15. DVD-R of the requirements 1-15

The FDA reserves the right to require submission of additional documents that it deems necessary for the evaluation of the product.

For imported allogeneic human stem cell-based products, submit requirements 1- 15. Use of appropriate mode of transport and storage is required. Hand-carried stem cell-based products are not allowed.

For autologous stem cell therapy, submit requirements 2 1, 2, 5, 8, 9.1 to 9.6, 13, 14, and 15.

B. Procedure in Applying for Registration of Stem Cell-Based Products

The basic procedure for the registration of drug products shall be followed for the registration of stem cell-based products. Transactions pertaining to registration shall be made every Tuesday and Wednesday only.

The fee for registration of a drug product under monitored release, plus legal research fund, shall be charged for registration of stem cell-based products.

1. The applicant shall proceed to the FDA cashier with the accomplished Assessment slip and amount required for registration
2. The required documents and the proof of payment shall be submitted to the receiving section of the Center for Drug Regulation and Research (CDRR)
3. The applicant receives the duplicate of the Notarized Application Form where the Routing Slip Number (RSN) is stamped by the CDRR staff.
4. Follow-up may be entertained after 60 working days.

C. Other Considerations

Stem cell-based products of animal origin as well as the other products classified as restricted under V.B.1.b of Administrative Order 2013-0012 are not allowed to be registered or used until the issuance of a separate circular for these products.

Stem cell-based products under V.B.1.a of Administrative Order 2013-0012 are not allowed to be registered since they are prohibited from creation, importation, promotion, marketing and use, namely:

1. human embryos for research purposes
2. human embryonic stem cells and their derivatives
3. aborted human fetal stem cells and their derivatives
4. plant parts labeled as stem cell

III. Repealing Clause

Pertinent sections and provisions of existing Circulars and Memorandums in conflict with this Circular are hereby revised and modified accordingly.

IV. Effectivity

This Circular shall take effect immediately.


KENNETH Y. HARTIGAN-GO, MD
Acting Director IV

ANNEX A

FOR INCOMING REGISTRATION OF HUMAN STEM CELL-BASED PRODUCT

KENNETH Y. HARTIGAN-GO, MD
Acting Director General
FOOD AND DRUG ADMINISTRATION
Alabang, Muntinlupa City

Attention: Center for Drug Regulation and Research

Sir/Madam:

In accordance with RA 9711 and other related issuances, we wish to apply for the registration of our product:

Name	
Brand Name	
Dosage Strength	
Dosage Form	
Indications	
Route of Administration	
Primary Packaging	
Suggested Retail Price	

Enclosed are the documents stated in the Checklist of Requirement for Registration.

We categorically declare that all data and information submitted in connection with this application as well as other submission in the future are true and correct and reflect the total information available.

We certify that we have examined the following statements and we attest to their accuracy:

1. The Current Good Manufacturing Practice Guidelines for stem cell-based products is applied in full in the manufacture of this product.
2. The person releasing the product for sale is an authorized and / or qualified person.
3. The market authorization holder has a standard operating procedure for handling adverse reaction reports on its products.
4. The market authorization holder has a standard operating procedure for handling batch recalls of its products.

RSN:	
RECEIVED	
By:	
Date	

5. All documentation referred to in this application is available for review during a GMP inspection

6. Should the IPO or court of law of competent jurisdiction decide, with finality, that the applicant has no intellectual property right involving, or attached to, the product, then any CPR/Marketing Authorization issued to the product in question shall be deemed automatically cancelled and / or revoked.

7. We shall change the brand name so submitted should the proper authority decides with finality that we have no right to appropriate and utilize the said brand name.

8. We shall acknowledge and agree to indemnify and / or hold FDA free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with FDA.

9. We assume responsibility for any eventuality resulting from the use of our stem cell-based product.

1. MEDICAL PRACTITIONER

Signature _____
Name (print or type) _____
Position (print or type) _____
Date _____

2. OWNER/GENERAL MANAGER/AUTHORIZED REPRESENTATIVE

Signature _____
Name (print or type) _____
Position (print or type) _____
Date _____

ACKNOWLEDGEMENT

SUBSCRIBED AND SWORN TO BEFORE ME this _____
personally appeared the following:

Name	Residence Certificate No.	Date issued	Place issued
1.			
2.			

Known to me and to me known to be the same persons who executed the foregoing instrument and they acknowledged that the same is their free and voluntary act and deed.

WITNESS MY HAND AND SEAL on the date and place first above written

Doc. No. _____
Page No. _____
Book No. _____