Instructions: How to Facilitate an Import into Mexico for Stem Cell Products

The Mexican regulatory authority, COFEPRIS, requires that all blood samples and stem cell products have a permit for import into Mexico. To issue the permits without delay, it is important all information provided to COFEPRIS be accurate and correct. This permit is required prior to the start of patient conditioning or filgrastim administration. This tool includes instructions for donor centers, apheresis, and collection centers to help obtain permits for collected products from US and non-US based sites to Mexico.

Currently, blood samples for confirmatory typing and pre-collect requests are sent to a central NMDP contracted laboratory in the US where they are inspected and sent to the transplant center designated laboratory. All IDM samples are shipped directly to an NMDP contracted IDM laboratory for testing.

Import Permit for product:	Time to Issue Permit:	Validity of Permit:
Stem Cell Products	45 days from submission[1,2]	6 months for 8 bags of stem cell product. A product divided into two bags for transport is counted as two products/bags.

[1]Note: The Mexican Ministry of Health closes for several extended holiday breaks throughout the year. These holiday breaks may result in additional delays as the backlog of requests is addressed.

[2] Note: COFEPRIS has up to 45 days from time of submission to process a permit request. Current time from submission to issue of permit is much shorter at 2-3 weeks.

For US based apheresis or collection centers (AC/CCs), follow instructions in Section I. For non-US based sites, see instructions in Section II.

Section I. Requests for Import Permits from US-based site to Mexico

1. Obtaining an import permit for stem cell products from US-based AC/CC to Mexico transplant center (TC).
    a. The AC/CC in the US is required to provide the following documents to the case manager at NMDP MX:
        - Acceptance Letter to the Establishment written by AC/CC to the transplant center in Mexico. A color copy is required to be sent on the hospital's letterhead and for it to be signed (not stamped) by the medical director.
        - Template attached.
    - FDA Human Cell and Tissue Establishment Registration (HCTERS) for AC/CC. Find the AC/CC's HCT/P registration:
        - This task will be fulfilled by NMDP.
        - Go to the FDA's Human Cell and Tissue Establishment Registry Public Query (https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/Index.cfm)
        - Locate the AC/CC by using search parameters.

        - *Search results are sensitive. The AC/CC may not be registered under the most obvious name. Try one keyword from the AC/CC's name with the state if having trouble locating the AC/CC*.
    - Print and save the registration as a PDF and include with the letter
b. Submit the documents to the appropriate Case Manager at NMDP MX.
c. NMDP MX works with the TC in Mexico to apply for the permit and confirms with all parties when the permit has been issued.

Section II. Requests for Import Permits from non-US based site to Mexico

1. Obtaining an import permit for stem cell products from non-US based AC/CC to Mexico transplant center (TC).
    a. The non-US based AC/CC is required to provide the following documents to the case manager at NMDP MX:
        - Acceptance Letter to the Establishment written by AC/CC to the transplant center in Mexico. A color copy is required to be sent on the hospital's letterhead and for it to be signed (not stamped) by the medical director.
        - Template attached.
        - Certification showing registration of the AC/CC with appropriate local health authority. This could be a sanitary license or a certificate from the Ministry of Health.
            - Ensure certificate/license is current for the correct year
            - International registries cannot apply on behalf of their AC/CC. The certification must be the AC/CC that is collecting the donor who applies.
            - *Note: "Certification showing registration of the AC/CC with appropriate local health authority" refers to the local health authority where the AC/CC resides.*
    b. Submit the documents to the appropriate Case Manager at NMDP MX.