Lonza

Lonza Walkersville, Inc
8830 Biggs Ford Road
Walkersville, MD 21793
301-898-7025

Dear Customer,

The purpose of an FDA Master File (also known as a DMF, Drug Master File) is to allow FDA to have access to all GMP documentation related to production, testing, labeling, etc. of the product(s) contained in the Master File. It includes formulation, raw material information and specifications. It also includes any related validation summaries. This Master File is for FDA eyes only and is treated as confidential proprietary information by the FDA.

Customers who use products listed in DMF are either preparing for an FDA submission (new drug or therapeutic procedure) or have already done so. Customers feel more comfortable about using products listed in a DMF, knowing that once they specify it in their submission, provided that the DMF owner has given permission, FDA will have access to it.

To cite the FDA master file for any product (like X-VIVO) please:

- Write a letter requesting permission to cite the FDA Master File.
- Include product name, product catalog number, and a brief description of your intended application (cell therapy, vaccine mfg., etc.), including the title of your submission and any reference number (IND, IDE, BLA, etc.)
- Address to: Allen L. Burgenson, Manager Regulatory Affairs, Lonza Walkersville, Inc. 8830 Biggs Ford Road, Walkersville, MD 21793, USA.

Upon receipt of your written request, we will write you a letter granting the cross-reference to the Master File. We will also write a letter to the FDA informing the permission granted for the cross-reference.

Sincerely,

Allen L. Burgenson
Manager, Regulatory Affairs