

July 31, 2012

The Honorable Barbara A. Mikulski
United States Senator
901 South Bond Street, Suite 310
Baltimore, MD 21231

Dear Senator Mikulski:

Thank you for your recent inquiry on behalf of Dr. Gary Pasternack, concerning a Federal Drug Administration's (FDA) User Fee Waiver request under the Small Business Exemption for New Drug Application. The FDA asked the U.S. Small Business Administration (SBA) to perform a size determination in order to establish whether Asklepion is eligible to receive the waiver.

A size determination is being performed on Asklepion in order to ascertain the business size in conjunction with guidelines established by the Federal Government. To receive the User Fee Waiver, Dr. Pasternack's firm must be a small business. This specific case is complicated because his firm is owned by charitable organizations in Australia. Also, Dr. Pasternack is seeking an exemption of affiliation from the foreign owners.

We acknowledge that this firm had a formal size determination performed by the SBA in 2007 when it was determined to be a small business. However, case law issued since that time has changed the interpretation and application of many regulations. Currently, this office is working with the SBA Office of General Counsel (OGC) to determine whether current case law will affect the 2012 size determination.

We understand Dr. Pasternack's concern with the time that it is taking. As noted, the size specialist is working with the SBA OGC to complete this complicated determination. The Agency seeks to ensure that only eligible small businesses benefit from the regulatory preferences that Congress has established. Therefore, we need to determine whether Asklepion is currently entitled to the benefit being sought. We assure you that we are giving Dr. Pasternack's size determination priority attention. In the meantime, if Dr. Pasternack has any questions regarding this matter, he may contact the SBA Office of Government Contracting, Area II Office, Size Program Manager, Vincent Mazzotta, at (610) 382-3190

We appreciate your support of the SBA and the Maryland small business community. If you and your staff have any additional questions, please contact the SBA Office of Congressional Legislative Affairs at (202) 205-6700.

Sincerely,

Kenneth W. Dodds
Director
Office of Government Contracting

