09/25/2007

To: Brenda Aguilar
OMB Desk Officer

Subject: Emergency processing request for approval of the collection of information:

" Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification Form 3602 A"

Justification

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) **expires September 30, 2007.** MDUFMA provided FDA with the new responsibilities and resources to keep up with the rapidly growing device industry and changing medical device technology. Congress recently passed an omnibus bill (last week), that includes the Medical Device User Fee Amendments of 2007 ("the 2007 Amendments"), which will reauthorize medical device user fees for fiscal years 2008 through 2012 and make significant changes to the medical device user fee provisions of the act. The 2007 Amendments will provide a new way for a foreign business to qualify as a "small business" eligible to pay a significantly lower fee when a medical device user fee must be paid. The new FDA form 3602 A," FY 2008 MDUFMA Small Business Qualification Certification" will satisfy the requirements for collecting this information under the statue for small business certification. The user fee provisions of the 2007 Amendments provides for an **October 1, 2000 effective date** and FDA expects foreign small businesses will request "small business status" immediately upon enactment. Thus, emergency approval of this request is necessary to meet the statutory deadline