ASX Company Announcement

22 January 2007

SUN BIOMEDICAL LIMITED
UPDATE ON ORALINE FDA 510(k) SUBMISSION

Sun Biomedical Limited (ASX: SBN or the Company) advises that it has received formal advice from the US Food and Drug Administration (FDA) that the Company's 510(k) submission for saliva drug testing device OraLine has not met FDA requirements for 510(k) clearance.

The FDA's notification cites that the performance data provided in the submission did not demonstrate the device to be as effective as legally marketed devices. The Company notes that at present there is no legally marketed point of care saliva device.

The FDA 510(k) clearance model is based on establishing equivalency to existing cleared devices (predicates) which in the case of drugs of abuse tests is urine point of care devices and laboratory based saliva tests. Given that there are no equivalent cleared point of care saliva devices the Company may have chosen an alternative submission route however based on discussions with the FDA the Company formed a view that a conventional 510(k) would be acceptable and would receive a favorable review by the FDA. As the Company's submission has not been accepted by the FDA the Company is now obliged to follow a more time consuming planning and submission processes.

Part of this process will be to agree a plan with the FDA to produce the information that will satisfy the FDA's requirements including the methodology to be used in producing the necessary data. Tests to be undertaken include Cut-Off Characterisation and Precision, Usability and Method Comparison Studies. In meeting the FDA's requirements the Company's notes that the most significant issue to resolve is the ability to replicate the presence of drugs of abuse in a laboratory environment wherein spiked pooled or synthetic saliva does not consistently yield the same level of drugs observed in the clinical environment.

Sun Biomedical Limited
ABN 18 001 285 230

Suite 401, 480 Collins Street, Melbourne, Victoria, Australia, 3000
T: +61 3 8610 6370 | **F:** +61 3 8610 6374 | **E:** info@sunbiomed.com

ASX:SBN
www.sunbiomed.com

While the Company has commenced the planning process, a meeting with the FDA has yet to occur, and the Company is unable to provide reliable timelines for the likely completion of studies, re-submission and the realisation of 510(k) clearance. The complexity of the studies required to meet FDA requirements will not be fully understood until the Company has met with the FDA. The Company now expects that realisation of 510(k) clearance may be delayed by as much as 12 months.

The marketing constraints on OraLine imposed by the FDA in April 2007 remain unchanged and the Company may continue to market OraLine for forensic applications such as in Law Enforcement, within the Drug Court system, to Medical Examiners, in Prisons and Juvenile Detention Centres and in Parole and Probation programs. Accordingly, the Company does not anticipate that delays in realising 510(k) clearance for OraLine will have any material influence on sales in financial year 2008.

Concerning the status of the Company's submission for 510(k) clearance for point of care testing for the Company's urine products, the Company has been requested to provide additional supporting data and has met with FDA reviewers and agreed on a plan of action that is currently being executed. While the Company has not received clearance for the Company's urine products, the FDA has verbally advised that they will exercise their discretion in allowing the Company to market the Company's urine products for workplace testing whilst the Company's 510(k) submission is still under review.

Mr. Peter King
Chairman