

**“Adverse Event Pilot Program for Medical Devices” (MedSun)
(OMB NO: 0910-0471)**

Change Request 83-C

October 19, 2011

FDA is submitting this nonmaterial/non-substantive change request (83-C) in order to allow MedSun hospitals to electronically transfer data directly from hospitals’ electronic incident reporting systems into the MedSun database. The change will provide hospitals with the choice to either put the data in the current MedSun format or to simply transfer the data to the FDA, at which time will be formatted by the FDA using HL7 infrastructure and functionality.