ANNOUNCEMENT 12/10/MDS-AN002

SUBJECT: Publication of Guidance documents in relation to the Medical Devices Interim Regulation and its Implementing Rules.

ADDRESSEES: Manufacturers of medical devices (both local and overseas), authorised representatives for both local and overseas manufacturers and organizations involved in importation and/or distribution of medical devices within the KSA.

The SFDA's intends to publish a series of guidance documents on its website on January 20th, 2011. These guidelines will assist organizations operating in the field of medical devices to understand their obligations under the Medical Devices Interim Regulation and its Implementing Rules.

These guidance are:

- **Guidance for Medical Device Importers and Distributors**
- **Guidance for Medical Device Authorized Representatives**
- **Guidance on Marketing Authorization procedures**
- **Guidance for local manufacturers**
- **Guidance for overseas manufacturers**