

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

No. 29/Misc./5/2011-DC (41)

Dated: 4 OCT 2011

To,
All the State Drugs Controllers

Sub: - Regulation of Staplers (Staples) as "Drugs" w.r.t. Import, Manufacture, Sale and Distribution under Drugs and Cosmetics Act and Rules thereunder-Reg.

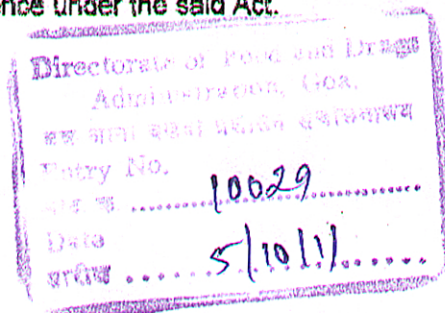
Sir,

Staplers (Staples) which are like sutures and are used for closing of wounds or holds the body tissues together after an injury or surgery are covered under the term "Sutures" as a "Drug" under the Drugs and Cosmetics Act, even though these are regulated as Medical Devices in the most of countries. The import and manufacture of this class of drugs is therefore required to be regulated strictly under the provisions of said Act.

In view of this the proposal to regulate the Stapler (Staples) under the Drugs and Cosmetics Rules 1945, has been examined by the CDSCO in consultation with Ministry of Health and Family Welfare and it has been decided to regulate the Import, Manufacture and Sale of this class of products as "Drugs" under the Drugs and Cosmetics Rules.

Representations has however been received from the industry associations for grant of transitional period for regulation of Staplers (Staples) under the Drugs and Cosmetics Rules. It has now been decided in consultation with Ministry of Health and Family Welfare that a period of 3 (Three) months may be granted as transitional period for regulation these products under the Drugs and Cosmetics Rules in respect of Import, Manufacture, Sale and Distribution.

The Import, Manufacture, Sale and Distribution of Staplers (Staples) without proper Permission, Licences under the Drugs and Cosmetics Rules from 1st Feb 2012 would be considered as an Offence under the said Act.



Yours faithfully,

(Signature)
(Dr. K Bangarurajan)
Dy. Drugs Controller (I)

Copy for information and Necessary action to,

1. All Zonal/Subzonal Offices of CDSCO
2. All Port offices of CDSCO