[FDA CIRCULAR NO. 2014-010, April 24, 2014]

SALE AND DISTRIBUTION OF EMPTY GELATIN CAPSULES

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The Food and Drug Administration has received inquiries regarding the sale and distribution of empty gelatin capsules.

Empty gelatin capsules or hard gelatin capsule shells are composed of gelatin, sugar, water, and sometimes colorants and opaquants. These are commonly used (1) as components of finished drug products in capsule form, or (2) as placebo in clinical trials to determine the efficacy of an investigational drug product.

According to Administrative Order No. 56 s.1989, "Revised Regulations for the Licensing of Drug Establishments and Outlets", pharmaceutical industry may be classified as: (1) drug establishments, which include manufacturers, traders, and distributors (i.e., importers, exporters, and wholesalers), or (2) drug outlets, which include drugstores, pharmacy or botica including hospital pharmacy and retail outlet for non-prescription drugs. Drug establishments may procure both ! raw materials and finished products either for its own use or for distribution, while drug outlets may procure, sell and distribute only finished products.

Empty gelatin capsules are not drugs nor classified as finished products; they are considered components only, and therefore classified as raw materials. As such, only drug establishments may procure empty gelatin capsules for manufacture of solid dosage forms in capsule; **drug outlets are not allowed** to procure, sell and distribute empty gelatin capsules.

Any violation of this FDA Circular shall be a ground for filing of appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, and suspension, cancellation, or revocation of License-to-Operate of drug outlets.

For your information and compliance.

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