Labeling Requirements - Misbranding

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Misbranding

Section 502 of the Federal Food, Drug and Cosmetic Act (FFDCA) contains provisions on misbranding including some that relate to false or misleading labeling. A device's labeling misbrands the product if:

- Its labeling is false or misleading in any particular;
- It is in package form and its label fails to contain the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;
- Any required wording is not prominently displayed as compared with other wording on the device, or is not clearly stated;
- Its label does not bear adequate directions for use including warnings against use in certain pathological conditions or by children where its use may be dangerous in health or against unsafe dosage, or methods, or duration of administration or application;
- It is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling; or
- It does not comply with the color additives provisions listed under Section 706 of the FFDCA;
- The device's established name (if it has one), its name in an official compendium, or any common or usual name is not prominently printed in type at least half as large as that used for any proprietary name;
- The establishment is not registered with FDA as required by Section 510 of the FFDCA and has not listed the device as

required by Section 510(j) of the FFDCA or obtained applicable premarket notification clearance as required by Section 510(k) of the FFDCA;

- The device is subject to a performance standard and it does not bear the labeling prescribed in that standard;
- There is a failure or refusal to comply with any requirement related to notification and other remedies prescribed under Section 518 of the FFDCA, if there is a failure to furnish any materials or information required by, or requested by the Secretary pursuant to, Section 519 of the FFDCA, or if there is a failure to furnish materials or information relating to reports and records required by Section 522 of the FFDCA; or
- There is any representation that creates an impression of official approval because of the possession by the firm of an FDA registration number.

Note: *Previously, it was a prohibited act to have the premarket approval application (PMA) number on the device labeling. The FDA Modernization Act of 1997 (FDAMA) repealed the restriction in Section 301(l) of the FFDCA, which prohibited reference to FDA approval in the labeling or advertising of medical devices that have an approved PMA or IDE.*

False or Misleading Labeling

Section 502(a) declares that a drug or device is misbranded if its labeling proves false or misleading in any particular. Section 201(n) states that if an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.