

# Getting Started in the Bottled Water Business: Licensing and Labeling

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The FDA regulates bottled water. FDA regulations for bottled water include Good Manufacturing Practices (GMP's), standards of identity, and labeling requirements. These regulations are posted in the Code of Federal Register and are enforced at the state level.

The following is to give a brief overview of information which regulators may request for licensing purposes and bottled water labeling requirements.

## **Licensing and Applications:**

In order to sell bottled water in the U.S., bottlers must meet FDA regulations as well as additional regulatory requirements of the states in which their finished product water is sold. While some states only focus on regulating bottled water produced in their state, 26 states currently require some sort of application process for out of state bottlers as well. The amount of information required to be submitted varies from state to state and can include:

- A formal application
- Source water and finished product analysis results
- Source hydrogeological and engineering reports (if the source is not from a municipality)
- Engineering reports, drawings, and pictures of the bottling plant
- Samples of bottles, caps, and labels
- Copies of inspection permits and/or licenses issued by the state in which the plant is located
- Bottling plant Standard Operating Procedures (SOP's) and or Hazard Analysis Critical Control Points (HAACP) documents
- Contaminated product recall plan.

In addition to requiring information, many states impose licensing fees. The fees imposed vary greatly from no licensing fee for bottlers selling in Georgia to an initial licensing fee of \$1,100 for bottlers wishing to sell product in New Jersey. While the state of New York currently does not have a bottling fee, bottlers wishing to sell in New York City will need to pay a fee of \$695. (NYC is the only city in the US which has its own bottled water licensing program).

The time it takes to get licensed varies greatly from a couple of weeks to over six months depending on the state and the bottler. Some states, such as NY, are very specific about the type of information they require and closely scrutinize every application. Bottlers will be required to make modifications and/or submit new documentation if: they fail to provide all of the proper documentation; or if the plants are not designed or configured in a manner to meet the state's regulations. The most cost effective and time saving method to obtain licenses is to contact the regulators of each state in which product will be sold very early in the process to discuss their regulatory requirements. It is much easier to change a blue print design prior to the building the plant and installing the equipment than to try to correct deficiencies in these areas later.

## Labeling

Many new bottled water companies make the mistake of spending a lot of money on the design and printing of their bottled water labels only to find out that they can not use them because they do not comply with FDA or state regulations. These mistakes can also be avoided by careful attention to FDA labeling requirements and any special labeling requirements of states in which the bottler wants to be licensed.

FDA regulations for bottled water labeling include but are not limited to the following:

- Principal display and information panels should be large enough to accommodate all the mandatory labeling information and meet minimum size requirements.
- The statement of identity (type of water: spring, drinking, purified, etc) should be printed prominently and conspicuously on the principal display panel.
- An ingredient list must be included if minerals (including fluoride) are added.
- The label must contain the name and place of business of the manufacturer, packer, or distributor.
- The label should include the serving size (typically defined as 8oz.) and the number of servings in the container.
- The net quantity of contents, in terms of weight, measure or numerical count should appear in the bottom 30% of the principal panel in the proper font size.
- Nutrition labels need to appear on labels making nutritional claims such as sodium free. (Nutrition label regulations are very specific regarding font type, size, and layout)
- No claim regarding the term “healthy” may be used or implied unless the water contains at least 10 percent of the reference daily intake (RDI) per serving size of vitamin A, vitamin C, calcium, iron, protein, or fiber and meets all other low fat, sodium, and cholesterol requirements.

States may have their own labeling requirements in addition to those of the FDA. Some states require identification and location of the source as well as bottle deposit and return information. States such as Connecticut and New York even require the bottlers license number to appear on the bottle which means that no labels can be printed for product to be distributed to that state until the application has been approved.

Obtaining licenses in multiple states can be an expensive, confusing, and time consuming process; however, no product should be distributed in a state without proper approval. Regulators are unsympathetic toward bottlers whose products are found in their state without proper licensing. Having a well developed marketing plan on initial states to be targeted for distribution and gathering information up front on the licensing and labeling regulations of those states can save time, money and frustration in the end.