STATE OF LOUISIANA
DEPARTMENT OF HEALTH AND HOSPITALS

Dear Prospective Bottled Water Manufacturer:

I am pleased to provide you with the attached documents as a guideline to the steps necessary in order to obtain a Permit to Operate as a bottled-water manufacturer in the state of Louisiana. Please read the following information carefully, and if you have any questions immediately after reviewing it, please contact your district sanitarian.

1. Water Sources: Your first step in obtaining a Permit to Operate for your new facility is to ensure that your water source will be approved for this use. If you will be tying into an existing Public Water Supply, indicate this information on your FD-1B FDU Plans Review Questionnaire document. If this supply is in good standing with Louisiana's Safe Drinking Water Program, you may request a document from the supply's certified operator indicating that the supply is compliant with the requirements of the National Primary Drinking Water Regulations (40 CFR 141). If the supply is not in good standing, you may contact its certified operator or call the Safe Drinking Water Program at (225) 342-7499 to obtain a list of deficiencies.

Engineering Review of Well Plans: If you are utilizing a private water supply, you must submit your well plans for review and approval to OPH's Engineering Services section. Plans must be sent to Jake Causey, Engineer 5 at jcausey@dhh.la.gov or by regular mail at Bin # 3, P.O. Box 4489, Baton Rouge, LA 70821- 4489. Mr. Causey may be reached at (225) 342-7273. **Do not begin construction on your well or your facility until well plans have been approved!** Failure to wait until you receive a **written** approval document may result in expensive changes being required to bring your site up to code.

DOTD Registration of New Water Well: Please also note that any new water well drilled/dug/jetted in the state of Louisiana must be registered with the Louisiana Department of Transportation and Development's Water Resources Section. More information regarding proper water well registration may be found at the following website: http://www.dotd.louisiana.gov/intermodal/wells/rules_regs_and_standards.asp. DOTD will not register a new well for drinking water use unless its plans have been approved by DHH (see above).

Submission of Hydrogeological Report on Source to Program Manager: Once well plans have been approved and construction is complete, you must submit a hydrogeological report for any new private water supply that you intend to put into service for bottling water. The report is to be submitted to the Sanitarian Program Manager for Bottled Water for review at (225) 342-7672 [fax] or regular mail at Bin # 14, P.O. Box 4489, Baton Rouge, LA 70821- 4489. The report must include the following items (at a minimum) and it must be signed and certified by a credentialed professional geologist or hydrogeologist:

a) a report on the regional geology and the specific site geology of the source area, including a description of the vertical and horizontal extent of the source aquifer using

existing data;

b) a report detailing the development of the source, the method of construction including spring design, well installation, surface catchment and intake structures, and transmission facilities as appropriate;

c) a watershed survey of the recharge area or zone of influence of subject source that identifies and evaluates actual and potential sources of contamination;

d) and, based on the findings of Section (c) above, a plan for special monitoring of any significant contaminant source and for taking restrictive preventive or corrective measures as appropriate to protect the source and product water.

2. Facility Plans: Your next step will be to submit plans for your physical facility (e.g., everything excluding the well and catchment materials) to your district sanitarian for review and approval. Review the attached **Basic Requirements for Prospective Food Manufacturers, Processors, Packers, and Repackers** document for basic requirements. In addition, study the attached sections 1, 3, and 9 from **Part VI of Title 51 of the Louisiana Administrative Code**; this is the set of regulations from which the previous document is derived, and it contains more detailed information. Once you have read these documents, you may submit a set of professionally-drawn blueprints or *neatly* hand-drawn plans, to scale. These plans must include plumbing, mechanical, HVAC, electrical, equipment, and floor, wall, and ceiling finish schedules; also provide documentation regarding mold-blowing, bottle-washing, or bottle-filling equipment, as well as ozonators, UV emitters, or other specialized equipment used in your process. Please note that filling, washing, or crowning containers manually contravenes the provisions of **Part VI of Title 51**. In addition to the materials indicated above, please provide a process diagram that shows the flow of water from the catchment equipment to the final product capping line, including all steps and intervening equipment, as well as filters and purification methods. Finally, include a completed copy of the attached **FD-1B Plans Review Questionnaire** document.

Multi-Service Containers: If your operation intends to reuse containers, you must obtain a **Secondhand Container Permit** from this office. Please see the attached **Secondhand Container Packet** and submit an **FD-4 Application for a License to Use Secondhand Containers** in addition to your other plans paperwork. Note that **all multi-service (secondhand) containers are required to be washed, rinsed, sanitized, and visually inspected prior to filling**. The wash, rinse, and sanitize steps in this process must be performed by a mechanical container-washing device; hand washing in a 3-compartment sink or by any other means is not permitted. It is **highly recommended** that all single-service containers also be washed, rinsed, sanitized, and visually inspected prior to filling.

Unit Production Code Requirements: State and federal regulations require that you provide a production code that distinguishes each unique lot of water product. Note that for the purposes of this section, a **lot** is a group of primary containers [usually] or unit packages of the same type, size, and style produced under conditions as nearly uniform as possible and designated by a common container code or marking. For practical purposes, this typically translates into a single continuous

production run on a single fill line. Codes must specify a unique lot number and also incorporate information on the date of processing for that lot number. Codes may be printed onto the containers using indelible ink or imprinted into the container in such a way that the structural integrity is not compromised. A key or explanation of the code must be provided to the department.

Approval of Private Sewer Treatment Systems: Contact your parish utility office to find out whether a community sewer system is available at your proposed site; if so, document the name and the operator of the system on your plans. If not, you will need to install an onsite wastewater treatment and disposal system. Contact your local parish health unit about the size and design of said system. If appropriate, you may provide the parish official with the attached **FD-1E Parish Utility Letter** to complete and provide to your district sanitarian.
Depending upon the size of your facility, the parish may direct you to the OPH regional office in your area for the design of your onsite sewer system. If this should occur, attach a copy of the plans approval letter for your sewer system provided by the Regional Engineer with your plans packet.

3. Product Registration: Your non-bulk products (any sizes below 3 gallons) must be registered with the Central Office. Therefore, you must submit proofs or specimen copies of labels containing all of the basic information provided in and meeting the criteria outlined in the **Basic Requirements for Prospective Food Manufacturers, Processors, Packers, and Repackers** document. Labels must be submitted to the Program Manager for Product Registration, currently Brian R. Warren, at (225) 342-7672 [fax] or regular mail at Bin # 14, P.O. Box 4489, Baton Rouge, LA 70821- 4489. Once the program manager advises you that the labels are suitable for registration, you may assemble a registration packet consisting of the attached **FD-9(N) Application for a New Product Registration Form**, a check or money order for $20 per distinct product, and specimens or proofs of each label. **Hold this packet** until your facility is ready for inspection. At that time, you may provide it to your district sanitarian as proof that you have completed the registration process; the sanitarian **will not issue a Permit to Operate without this packet**.

Clarification of "Distinct Product" and What It Means in the Bottled Water Industry: An additional note on registration: the term "distinct product" as it applies to bottled water may mean several things. If your firm will manufacture a distilled water product and a spring water product, these are two distinct products. However, if your firm will produce a Brand X distilled water and a Brand Y distilled water, these are also two distinct products. So, the rule of thumb to follow here is this: if the water conforms to a different standard of identity as specified in **21 CFR 165.110 (Bottled water)** and **LSA R.S. 40: 732 (of the Bottled Water Quality Law)**, it is a distinct product, and if you manufacture said product under different brand names or private labels, each of those constitutes a separate product as well. You **must** register each product that your firm manufactures, but the registration fee is capped at 10 products or $200.

4. Food Facility FDA Registration: Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires that existing food facilities be registered with the Food and Drug Administration no later than December 12, 2003 and that new facilities register prior to beginning to process, manufacture, pack, or distribute food products.

Online Registration: The easiest way to register your facility is to go to an FDA website and enter the required information. You may visit either http://www.cfsan.fda.gov/~furls/ovffreg.html or http://www.access.fda.gov/. Computers with internet access are available at public libraries throughout the state, if you do not have one at your home or office. The registration website is available 24 hours a day and online help is also available. Please note that whether you choose to complete the registration process on- or offline, FDA **does not charge a fee** to register your facility. However, there are various websites that will offer to register your facility with FDA for fees that may exceed several hundred dollars. If you wish to register your facility online, please visit only one of the above two links for that purpose.

Offline Registration: Alternatively, you may register your facility offline by obtaining a copy of Registration Form 3537 and sending to FDA by mail or facsimile. The attached **Form 3537 DHHS/FDA – Food Facility Registration Form** may be printed out and filled in or it may be completed by using a computer with the latest version of Adobe Acrobat Reader software (which may be downloaded free of charge here: http://www.adobe.com/products/acrobat/readstep2.html). Completed forms may be submitted to FDA at the above address by mail or by facsimile at (301) 210-0247. A duplicate Form 3537 may be requested by calling FDA at 1-800-216-7331 between 6:30 am and 10:00 pm CST or you may request a form in writing by sending your request to US Food and Drug Administration, HFS-681, 5600 Fishers Lane, Rockville, MD 20857.

5. Source And Product Water Monitoring: Once construction is complete on your well, if you are relying on a private water supply, you will need to perform tests on a sample taken from your sample tap. The required testing and monitoring regimen is outlined in the attached **Testing Requirements for Bottled Water – Source and Product** document; also relevant is the **Notice to Bottled Water Manufacturers** dated October 12, 2006, which provides the schedule on which results are to be submitted on a routine basis to the Bottled Water Program Manager for review and archiving. If your water source is an approved Public Water Supply, the document specified in Section 1, above, will suffice to attest to the adequate quality of the source water.

Once a source sample is collected (according to the guidelines of and using the sample container provided by the testing laboratory), you may submit the sample for analysis to one of the laboratories found in the attached **DHH List of Certified Laboratories – Drinking Water Chemistry** for the performance of annual, quadrennial, and triennial testing and/or a laboratory on the attached **DHH List of Certified Laboratories – Drinking Water Microbiology** for the coliform testing. Once your facility is constructed, you may use an in-house laboratory to conduct the routine weekly microbiological testing, but annual tests must be performed by a laboratory on the **Drinking Water Chemistry** lab list.

Results Review: As soon as you receive test results back from the laboratory, submit those results by fax, email, or regular mail to the Sanitarian Program Manager for Bottled Water at Food and Drug Unit, Bin # 14, P.O. Box 4489, Baton Rouge, LA 70821- 4489 or (225) 342-7672. Contact the Food and Drug Unit's Central Office staff for an email address for the current Program Manager. The Program Manager will review the results and provide you with information on which (if any) items

exceed tolerances permitted under EPA/FDA/FDU rules and regulations. These are items that you will want to pay special attention to when you receive your product testing results.

Requirements for Crown/Container Testing: In addition to water testing, **21 CFR 129.80** requires that your facility conduct quarterly testing on your containers and crowns. Specifically, a swab or rinse test for coliform bacteria must be conducted of at least four containers and crowns pulled from the fill line just prior to filling and the test must be conducted either by an in-house or approved **Drinking Water Microbiology** laboratory. Results of this testing must be submitted to the Sanitarian Program Manager for Bottled Water along with the quarterly water testing.

Product Water Testing Requirements: Once your facility plans have been approved by the district sanitarian and construction is complete, you must test a sample of your product water and test it in accordance with the information provided in the attached **Testing Requirements for Bottled Water – Source and Product** document. These test results must be reviewed by the Sanitarian Program Manager for Bottled Water. If the product water exceeds the maximum contaminant levels shown in the document above for one or more tested contaminants, the water may be a) retested as is or b) corrective actions may be taken, such as the addition of extra carbon filters or extra processing steps, and the water then retested. However, please be aware that **no product water will be approved and no Permit to Operate will be issued for your facility until and unless subsequent rounds of testing indicate that the water meets the standard of identity requirements outlined in 21 CFR 165.110.**

Inspection and Permitting: Once the district sanitarian has received notice that your product water meets all requirements, (s)he will contact you to schedule a pre-operational inspection of your facility. At that time, your compliance with the guidelines in the **Basic Requirements for Prospective Food Manufacturers, Processors, Packers, and Repackers** document and adherence to the approved plans will be verified. If there are any problems observed during the inspection, the sanitarian will document these items on the inspection report and schedule a follow-up inspection. Once any issues have been addressed and a follow-up inspection completed, the sanitarian will assist you in completing an **LHS-31 Application for Permit to Operate** form, which will serve as a temporary **Permit to Operate** until receipt of the official document, an approximately 3.75” x 8.5” light blue LHS-16B form. Post your LHS-31 (and later your LHS-16B) in a conspicuous place along with similar permit and license documents; your sanitarian will request to see it during subsequent inspections.

Record-Keeping: A key part of subsequent inspections of your facility will be a records review conducted by your district sanitarian. By state and federal law, you are required to maintain all required records at the facility for at least two years. Your sanitarian will be checking for the following records during his/her site visit: 1) records of testing of product water [and, if applicable, source water] for contaminants as described above, 2) records of container/crown testing as described above, 3) records of equipment maintenance and cleaning, and 4) records of cleaning/sanitizing solution testing.

Attachments: PLEASE FIND THE FOLLOWING DOCUMENTS ATTACHED TO THIS GUIDE

BASIC REQUIREMENTS FOR FOOD MANUFACTURERS, PROCESSORS, PACKERS, AND REPACKERS
FD-1B PLANS REVIEW QUESTIONNAIRE FORM
FD-1E PARISH UTILITY LETTER FORM
FD-4 APPLICATION FOR A LICENSE TO USE SECONDHAND CONTAINERS
FD-9(N) APPLICATION FOR A NEW PRODUCT REGISTRATION FORM
FORM 3537 – DHHS/FDA FOOD FACILITY REGISTRATION FORM
21 CFR 129 GOOD MANUFACTURING PRACTICES FOR BOTTLED WATER
21 CFR 165.110 STANDARD OF IDENTITY FOR BOTTLED WATER
LSA R.S. 40: 681 – 695 (SECONDHAND CONTAINER LAW)
LSA R.S. 40: 731 – 741 (LOUISIANA BOTTLED WATER QUALITY LAW)
PART VI, TITLE 51, LOUISIANA ADMINISTRATIVE CODE (MANUFACTURING, PROCESSING, PACKING, AND HOLDING OF FOOD, DRUGS, AND COSMETICS), SECTIONS 1, 3, AND 9
TESTING REQUIREMENTS FOR BOTTLED WATER – SOURCE AND PRODUCT
DHH LIST OF CERTIFIED LABORATORIES – DRINKING WATER MICROBIOLOGY
DHH LIST OF CERTIFIED LABORATORIES – DRINKING WATER CHEMISTRY
NOTICE TO BOTTLED WATER MANUFACTURERS (OCTOBER 12, 2006)