

October 18, 2010

## IF YOU INTEND TO MARKET DRUG PRODUCTS IN THE UNITED STATES, BE AWARE:

- U.S. FDA procedures have changed and now require annual drug establishment registrations and listings to be submitted to FDA electronically. Drug establishments must have a DUNS number. Drug labels must be cataloged using extensible markup language (XML) and be submitted in SPL format.
- These requirements apply to all drugs including: Over-the-Counter Drugs, Active Pharmaceutical Ingredients, Prescription Drugs, Homeopathic Drugs, Animal Drug Products and Medical Gases.
- Companies typically spend more than 12 weeks trying to complete the registration process. Improper U.S. FDA registration and listings may result in detentions.



Example of Certificate of Registration issued by Registar Corp

**Registar Corp's team of Regulatory Specialists can complete the entire process for you in less than a week.**

***For assistance, fax this completed form to +1-757-224-0179***

<p><b>Option 1</b></p> <p><input type="checkbox"/> We need to know if these regulations apply to our products.</p> <p><b>Option 2</b></p> <p><input type="checkbox"/> We need assistance with electronic establishment registration and/or drug listings.</p> <p><b>Option 3</b></p> <p><input type="checkbox"/> We have products currently detained by U.S. FDA and need immediate assistance.</p>	<p>Company Name: _____</p> <p>Contact Name: _____</p> <p>Job Title: _____</p> <p>Phone: _____ Ext.: _____</p> <p>Fax: _____</p> <p>E-Mail: _____</p> <p>Business Function (<i>select all that apply</i>):</p> <table style="width: 100%;"> <tr> <td><input type="checkbox"/> Manufacturer</td> <td><input type="checkbox"/> Distributor</td> </tr> <tr> <td><input type="checkbox"/> Repacker</td> <td><input type="checkbox"/> Analytical Lab</td> </tr> <tr> <td><input type="checkbox"/> Relabeler</td> <td><input type="checkbox"/> Other</td> </tr> </table>	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Distributor	<input type="checkbox"/> Repacker	<input type="checkbox"/> Analytical Lab	<input type="checkbox"/> Relabeler	<input type="checkbox"/> Other
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Registar Corp assists businesses with Drug, Medical Device, Cosmetic, Food, Beverage, and Dietary Supplement regulatory requirements. Certificates of Registration issued by Registar Corp provide confirmation to industry that you are fulfilling registration requirements. Registar Corp is not affiliated with the U.S. Food and Drug Administration. FDA does not issue or recognize Certificates of Registration.