



## DRUG ESTABLISHMENT REGISTRATION AND LISTINGS

**The U.S. Food and Drug Administration (FDA)** requires companies that manufacture, prepare, propagate, compound, or process drugs to register their establishments with FDA and list their products. Registrar Corp's team of Regulatory Specialists will:

- ★ Register your establishment and list your drug products with FDA
- ★ Index your drug labels using extensible markup language (XML) and submit them to FDA in SPL format
- ★ Provide a Certificate of Registration issued by Registrar Corp to assure your customers that you have a valid FDA registration

## U.S. AGENT AND REGISTRANT CONTACT SERVICES

**FDA registered Drug establishments** are required to designate a Registrant Contact. In addition, non-U.S. drug establishments must designate a U.S. Agent for FDA communications. As your U.S. Agent and Registrant Contact, Registrar Corp will:

- ★ Obtain your establishment's DUNs number
- ★ Electronically register, renew and update your registration and drug listings with FDA as required
- ★ Facilitate communications with FDA, including scheduling of FDA inspections and detention assistance

## DRUG MASTER FILE SUBMISSIONS

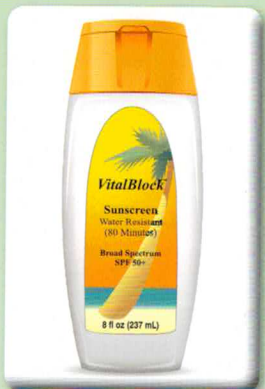
**Drug Master File (DMF)** submissions are used to provide confidential information about establishments, processes, or articles used in the manufacturing, processing, packaging, and storing of human drugs. DMFs allow a party other than the holder of the DMF to reference material without disclosing to that party the contents of the file. Companies wishing to submit a DMF must designate an Agent for FDA communications, such as Registrar Corp.

**Electronic Common Technical Documents (eCTD)** format will be required by FDA for all DMF submissions beginning May 5, 2017. This includes all DMF amendments, letters of authorization, annual reports, etc. Registrar Corp's team of Regulatory Specialists will help convert and submit your DMFs to FDA in eCTD format.

## DRUG LABEL AND INGREDIENT REVIEW

**Registrar Corp** helps companies determine their drug's likely classification and applicable labeling requirements. Registrar Corp's team of Regulatory Specialists will:

- ★ Prepare and send you a detailed report (typically 40-50 pages) after reviewing each element of your labeling
- ★ Provide a print-ready graphic file of your revised label incorporating our recommended changes
- ★ Provide additional reports and revisions for the same label within 90 days at no extra cost



**Registrar Corp** ★

144 Research Drive ★ Hampton, Virginia 23666 USA

Phone: +1-757-224-0177 ★ Fax +1-757-224-0179 ★ Email: [info@registrarcorp.com](mailto:info@registrarcorp.com) ★ [www.registrarcorp.com](http://www.registrarcorp.com)



## COSMETIC ESTABLISHMENT REGISTRATION

Registrar Corp assists cosmetic companies with reporting required by the California Safe Cosmetics Program, as well as voluntary U.S. FDA registration (VCRP) and Cosmetic Product Ingredient Statement (CPIS) filings. Registrar Corp's team of Regulatory Specialists will:

- ✦ Register your cosmetic establishment and ingredients with FDA
- ✦ Report your products to the State of California as required
- ✦ Provide a Certificate of Registration issued by Registrar Corp for your registration and each CPIS filing. The certificates may be used to assure your customers that you have a valid FDA registration and CPIS filing as well as prevent the accidental loss of your critical information.



## COSMETIC-DRUG PRODUCTS

**Many common cosmetics** are regulated by FDA as drugs. Examples include sun screen lotions, antiperspirants, and anticavity toothpastes. Registrar Corp assists in determining how FDA may likely regulate your product and provides FDA Drug Establishment Registration and product listing assistance if needed.



## LABEL AND INGREDIENT REVIEW

**Registrar Corp** helps companies comply with FDA's extensive labeling requirements by researching your cosmetic labeling against thousands of pages within the Code of Federal Regulations as well as the Federal Register, Guidance Documents, Labeling Guides, and Warning Letters issued by FDA. Registrar Corp's team of Regulatory Specialists will:

- ✦ Prepare and send you a detailed report (typically 40-50 pages) after reviewing each element of your labeling, including the ingredients and product claims
- ✦ Provide a print-ready graphic file of your revised label incorporating our recommended changes
- ✦ Provide additional reports and revisions for the same label within 90 days at no extra cost



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Email: [info@registrarcorp.com](mailto:info@registrarcorp.com) ★ [www.registrarcorp.com](http://www.registrarcorp.com)



## MEDICAL DEVICE ESTABLISHMENT REGISTRATION AND LISTINGS

The **U.S. Food and Drug Administration (FDA)** requires companies that manufacture, prepare, propagate, compound, assemble, process, or import medical devices to register their establishments and list their devices with FDA.

Registrar Corp assists companies in properly registering their medical device establishments and listing their devices with FDA. Registrar Corp's team of Regulatory Specialists will:

- ✦ File for and obtain your FDA Owner/Operator and Establishment Registration Numbers
- ✦ Submit and obtain your FDA Medical Device Listing Numbers
- ✦ Provide you with a Certificate of Registration issued by Registrar Corp



## U.S. AGENT AND OFFICIAL CORRESPONDENT

**FDA Registered Medical Device establishments** are required to designate an Official Correspondent for FDA communications. In addition, Non-U.S. establishments must designate a U.S. Agent for FDA communications. As your Official Correspondent and U.S. Agent, Registrar Corp's team of Regulatory Specialists will:

- ✦ Update your registration and listing information with FDA as required
- ✦ Facilitate communications with FDA, including scheduling of FDA inspections and detention assistance

## 510(K) ADMINISTRATIVE REVIEW

**FDA requires** Premarket Notification (510(k)) for certain devices before they may be marketed in the United States. To avoid delays and incomplete submissions, Registrar Corp provides a 510(k) Administrative Review Service, which includes:

- ✦ A determination of how FDA will likely classify your product as well as a review of your product labeling
- ✦ Verification of the structure, format and content of your 510(k)
- ✦ Submission of the 510(k) and follow-up correspondence with FDA



## UDI AND GUDID

**FDA requires** device labelers to include a Unique Device Identifier (UDI) on device labels and packages. Device labelers must also submit information about each device to FDA's Global Unique Device Identification Database (GUDID). Compliance dates for UDI and GUDID requirements depend on the class of the device. Registrar Corp's Regulatory Specialists will:

- ✦ Determine how FDA's UDI requirements apply to your medical device
- ✦ Submit your device data to the GUDID per FDA requirements
- ✦ Serve as your FDA Regulatory Contact for your GUDID submissions

## LABEL REVIEW

**Registrar Corp** helps companies comply with FDA's extensive medical device labeling requirements. Registrar Corp's team of Regulatory Specialists will provide:

- ✦ A detailed report (typically 40-50 pages) of how FDA regulations apply to your product labeling
- ✦ A print-ready file of your revised label incorporating our recommended changes



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