



SPL Registration Program - Terms, Conditions and Fees Medical Gas Manufacturers

1) Description of Reg-E-Stration Services

Reg-E-Stration LLC, in accordance with Appendix A of this document (Schedule of Fees), agrees to provide the following services:

- a. Facility Registration** - Reg-E-Stration LLC will complete your SPL facility registration on FDA's electronic form(s), and document each of your sites with the required information, including an individual DUNS number for each facility.
- b. NDC Labeler Code Request** - Reg-E-Stration LLC will complete your SPL NDC Labeler Code application on FDA's electronic form for each of your drug products, entering all required information, including individual package sizes for each product
- c. Drug Listing** - Reg-E-Stration LLC will complete the SPL Drug Listing on FDA's electronic form for your drug labels. In addition to adding the required information, we also code each label into the xHTML format and embed a scanned image of the label into the form.
- d. Web Portal Setup and SPL Document Submission** - Reg-E-Stration LLC will establish a secure web portal for your data into FDA, and obtain the required computer security certificates. Reg-E-Stration LLC will submit the SPL forms through the gateway in the proper order, and verify your registration forms are correctly received and filed with FDA.
- e. Additional Electronic Document Submission** – Reg-E-Stration will file any additional electronic document submissions required, including but not limited to, eMDR reports and eMedwatch reports as FDA phases those requirement into effect.
- f. Annual Re-Registration, Updates, & Web Portal Maintenance** - Reg-E-Stration LLC will annually re-submit your registration documents, file any changes to your information, and maintain the web portal, including the required security certificates.

2) Acceptance

If you desire the FDA SPL Registration Services from Reg-E-Stration LLC described above, please indicate your acceptance by signing and returning a copy of this Agreement. Reg-E-Stration LLC will return an executed copy for your records. Send signed agreements to the address listed in section #3 below.

3) Term Of Agreement

The term of this Agreement shall commence on the later date of acceptance set forth below and shall continue for three years from that date. The agreement will automatically renew as an annual agreement thereafter unless terminated by either party by prior written notice a minimum of ninety (90) days in advance of the agreement expiration date. Upon cancellation you agree to pay for all activities conducted and administrative and other expenses incurred in connection with reasonable obligations undertaken by Reg-E-Stration in accordance with the agreement up to the date of cancellation. Cancellation notices shall be deemed sufficient when sent by first class U.S. Mail, faxes, or emailed to Reg-E-Stration at the following address:

Reg-E-Stration LLC
P.O. Box 20603
Lehigh Valley, PA 18002
Email: bob.yeoman@reg-e-stration.com
FAX – (610) 868-7185

4) Price

Services under this agreement shall be in accordance with the pricing sheet included as **Appendix A** with this agreement. Unless otherwise stated, all fees are exclusive of state and local use, sales, value added, or similar taxes. Such taxes, when applicable, will appear as separate items on the invoice. The Reg-E-Stration LLC fees for services provided under this agreement are a firm price for the first 24 calendar months of this agreement. After the first 24 months of the initial term of the agreement, the service fees are subject to change, to reflect the current Reg-



E-Stration LLC schedule of fees in effect at that time.

5) Delivery

All SPL registrations made on your behalf will be made based on information and documents provided by you. We assume no liability for any errors in SPL submissions based on inaccurate information provided to Reg-E-Stration LLC. Reg-E-Stration LLC shall not be held liable for any delays in meeting agreed deadlines which are due to labor difficulties, fire, civil riots, wars, insurrections, acts of God, internet service interruptions, or causes beyond the control of Reg-E-Stration LLC, including your failure to provide any required registration information. Any delivery dates quoted are best estimates and Reg-E-Stration LLC shall have the right to make reasonable changes to schedules with the prior agreement by the customer. Said customer agreement shall not be unreasonably withheld. Electronic forms prepared and submitted to FDA, as well as any security certificates purchased by Reg-E-Stration LLC to facilitate that process shall remain the property of Reg-E-Stration LLC. Non editable copies of these forms can be provided in accordance with the schedule of fees.

6) Confidentiality

Both parties shall undertake all reasonable care in safeguarding information deemed proprietary, commercially sensitive, or confidential. The care taken by each party of the information in their possession shall be no less than the activities either party would undertake to protect their own confidential information. Reg-E-Stration LLC shall maintain a secure backup of all electronic SPL documentation created under this agreement.

7) Terms of Payment

Payment for program fees & implementation fees must be received before Reg-E-Stration will submit any documents to FDA on your behalf. All Reg-E-Stration LLC renewal invoices are due on receipt, and payment must be received before any annual registration renewal activities occur.

Miscellaneous

8) You agree to select an employee from your firm to act as the interface between Reg-E-Stration and your company on all SPL registration issues, and to provide contact information for that individual. You agree to notify Reg-E-Stration when that individual changes.

9) To facilitate Reg-E-Stration establishing a secure gateway account for your business, you agrees to approve a letter of non repudiation acknowledging your acceptance of electronic signatures, and naming Reg-E-Stration LLC as your agent, as required by 21 CFR §11.100. Reg-E-Stration will draft the letter for you.

10) In no event shall Reg-E-Stration LLC be responsible for any penalties or fines levied against customer by any governmental agency for failure to comply with all applicable laws and regulations. In addition, you agree that you understand these covenants and agree that Reg-E-Stration LLC shall be released from, and have no responsibility or obligation for consequential damages.

11) The services provided under this agreement reflect applicable federal regulatory compliance requirements. The services under this agreement do not constitute legal advice and the Company is advised to consult competent legal counsel if such counsel is required.

12) If any provision of this agreement is deemed to be illegal, or otherwise void, invalid, or unenforceable, such provision(s) shall be disregarded and the remainder of this agreement without such provision shall not be affected and shall remain in full force and effect.

13) This Agreement shall be construed and enforced in accordance with the laws of the State of Pennsylvania.



Acceptance Section
SPL Registration Program - Medical Gases

Offered By:

Accepted by Customer:

Reg-E-Stration LLC

(Customer)

BY: J. Robert Yeoman
(Name)

BY: _____
(Name)

BY: _____
(Signature)

BY: _____
(Signature)

ITS: President & CEO
(Title)

ITS: _____
(Title)

Date: _____

Date: _____

Enter the Following Information

_____ Number of Facilities Filling Medical Gases

_____ Enter the number of labels, including any certificates of Analysis

Contact email address: _____



Appendix A – Schedule of Fees

Medical Gases - Annual Program Fees		
Program & Web Portal Maintenance – Annual Fees For Each Company With 1 Secure Web Portal		
# Sites	Yearly Fee	What Reg-E-Stration Provides
1	\$350	We monitor the FDA SPL regulations and stay abreast of any changes in requirements. We ensure your electronic registration meets current regulatory requirements and stays in compliance with future changes in FDA SPL regulations. Annually we confirm / solicit for any changes in registration information with each of your registered facilities. We annually re-file your company's registration, and provide an update service for your facility listings and drug label information as needed in accordance with the fees listed below. We make sure your registration is properly filed with FDA and in their electronic database. We maintain your secure web portal, and annually obtain new computer Security Certificates. We maintain a secure electronic data archive & backup of your information. Reg-E-Stration will also electronically file any med watch or adverse event reports for you once that requirement becomes effective.
2	\$425	
3-10	\$495 + \$75 each additional site over 3	
11-20	\$1,100 + \$70 each additional site over 11	
21-30	\$1,800 + \$65 each additional site over 21	
31 +	\$2,450 + \$60 each additional site over 31	

Medical Gases – First Year - One Time Implementation Fees		
Activity	Fee	What Reg-E-Stration Provides
Facility Registration	\$75 Each Initial & Add/ Remove	Complete your SPL facility registration electronically, and register each manufacturing site, including looking up and documenting DUNS number for each site registered.
NDC Labeler Code & Drug Listing	\$100 Each	Complete SPL NDC Labeler Code Request electronically & for each medical gas drug label. Enter all package sizes for each cylinder. Code each label into the xHTML format and also embed a scanned image of each label.
Setup Web Portal & Submit Documents	\$250 Each Portal Setup	Establish secure web trader account with FDA. Submit your SPL forms through this gateway in the proper order. Assure registration forms are correctly received and filed with FDA.

Medical Gases – Administrative and Other Fees – As Required		
Activity	Fee	What Reg-E-Stration Provides
Obtain New DUNS Number	\$40 Each If Required	Apply for and obtain new manufacturing facility DUNS Number if needed.
Correct Label Information	\$100 Each If Required	Provide input and recommended changes to labels that do not meet the current CGA & FDA requirements for medical gas labels.
Update SPL Documents	\$30 Per Form If Required	Make changes or updates to an SPL submission form. Limit of 10 individual changes per each form. Hourly SPL admin charges assessed for more than 10 changes on single form. If changes performed at time of annual renewal this fee includes submitting documents to FDA.
Maintain Additional Web Portal	\$75 Each Annual Fee	Maintain any additional web portals created for your company if needed. Includes annual security certificate.
Submit Documents	\$30 Per Form If Required	File new or changed SPL documents when not part of the annual registration renewal process. File other electronic communications with FDA as requested by customer
SPL Administrative Services	\$95 Per Hour If Required	Administrative charges related to your SPL submission not included in the annual renewal or initial implementation fees.
Add New Drug label Listing	\$100 Each	Complete new drug label SPL. Enter all package sizes for each cylinder. Code each label into the xHTML format and also embed a scanned image of each label.