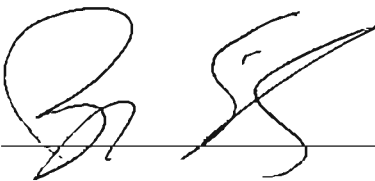


# Prescription Drug Marketing Act Pedigree/Authorized Distributor of Record Policy

Document Number	Effective Date	Supersede Date	Revision
CP-POL-004	DECEMBER 1, 2006	N/A	00

### Approvals:

Initiator:  Date: 11/15/06

Department Head: Stephen M. Robinson Date: 11/16/06

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**Governing Department:** Finance

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### Revision History

REVISION	DATE EFFECTIVE	INITIATOR	MAJOR CHANGES
00	12/1/06	Brent G. Eilefson	New Policy

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**I. PURPOSE/SCOPE**

The Prescription Drug Marketing Act of 1987 (“PDMA”), as modified by the Prescription Drug Amendments of 1992, requires USL to identify each authorized distributor of record (“ADR”) of USL prescription drug products, and to maintain a list of its ADRs (“ADR List”). Pursuant to the PDMA, an ADR must have a written agreement in place with USL to purchase USL product(s) in order to be designated an ADR. The ADR List must be updated on a continuing basis, and USL is required to make the ADR List available on request to the public for inspection.

The intent of the PDMA is to protect the integrity of the prescription drug wholesale distribution network. It is USL’s position that its ADR List is highly confidential competitive information, and because of this, along with the fact that the PDMA does not require website posting, USL will not publish its ADR List on its website. Rather, USL will make its ADR List available to third-parties as set forth herein.

**II. FREQUENCY**

N/A

**III. ATTACHMENTS**

N/A

**IV. REFERENCES**

A. 21 CFR Part 203

B. 21 USC § 503

**V. RESPONSIBILITIES**

A. Anyone within the organization who receives a request from a third party: (i) to be designated a USL ADR, (ii) to verify a party’s ADR status, or (iii) to view USL’s ADR List, should forward the request to National Contract Sales (Annamarie Lee).

B. National Contract Sales (Annamarie Lee), together with Industry Relations (Mike McBride), have primary responsibility for maintaining USL’s ADR List, responding to requests for ADR designation or verification, and responding to third-party requests to inspect USL’s ADR List.

**VI. DEFINITIONS**

N/A

**VII. SAFETY CONSIDERATIONS**

N/A

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## VIII. PROCEDURE

### A. Creating and Maintaining USL's ADR List.

1. Prior to December 1, 2006, and on an as-needed, continuing basis thereafter, USL shall generate an ADR List which shall contain the names of approved USL ADRs. ADR status shall not be conferred upon third-parties who purchase only USL over-the-counter products.
2. USL's ADR List shall reside with National Contract Sales (Annamarie Lee).

### B. Responding to ADR Designation or ADR Verification Requests.

1. Third-party requests to be designated a USL ADR, or to verify a party's ADR status, shall be made in writing and forwarded to National Contract Sales (Annamarie Lee).
2. National Contract Sales, together with Industry Relations (Mike McBride), shall assess whether the requestor or identified third party has a written agreement in place with USL to purchase USL product(s).
3. National Contract Sales shall respond to each requestor seeking to be designated a USL ADR using the appropriate template response letter. For ADR verification requests, National Contract Sales shall respond to the requestor in the manner best deemed appropriate.
4. Where a requestor requires use of its own ADR response form, National Contract Sales shall forward the proposed form to Legal for review prior to completing and returning the form to the requestor.
5. In the event a requestor has a written agreement in place with USL to purchase USL product(s), and USL desires to approve the requestor as an ADR, National Contract Sales shall add the requestor to USL's ADR List.
6. In the event a requestor does not have a written agreement in place with USL to purchase USL product(s), National Contract Sales shall track that the request to be designated a USL ADR has been denied.

### C. Responding to Requests for USL's ADR List.

1. Requests from Government Agencies.
  - a. Upon written request, National Contract Sales shall provide USL's ADR List in its entirety to government regulators or enforcement agencies.
  - b. National Contract Sales shall provide the requesting agency a hardcopy of USL's current ADR List, marking each page "Confidential" and including a cover page which identifies the

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enclosed ADR List as “USL Confidential Competitive Information—Not For Public Dissemination”.

2. Requests from Third-Parties.
  - a. All third-party requests to inspect USL’s current ADR List shall be submitted to USL in writing and forwarded to National Contract Sales.
  - b. National Contract Sales shall work with Legal to assess the merits of the request. USL may require additional information from requesting parties at USL’s discretion.
  - c. If a third-party request is deemed by USL to be appropriate and not made for purposes of competitive disadvantage to USL, USL shall make its current ADR List available to the requesting party for inspection.
  - d. Prior to making USL’s ADR List available to any third-party, each page thereof shall be marked “Confidential” and a cover page shall be included which identifies the ADR List as “USL Confidential Competitive Information—Not for Public Dissemination”.
  - e. USL may require the requesting party to inspect USL’s ADR List on-site at USL’s discretion.