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State of West Virginia Department of Administration Purchasing Division

NOTICE

Due to the size of this bid, it was impractical to scan every page for online viewing. We have made an attempt to scan and publish all pertinent bid information. However, it is important to note that some pages were necessarily omitted.

If you would like to review the bid in its entirety, please contact the buyer. Thank you.



RFQ COPY

Remedy Repack

TYPE NAME/ADDRESS HERE

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130 Charleston, WV 25305-0130

Request for Quotation

MCH10072

ADDRESS CORRESPONDENCE TO ATTENTION OF:

ROBERTA WAGNER 304-558-0067

HEALTH AND HUMAN RESOURCES BPH - OMCFH MATERIALS MANAGEMENT 900 BULLITT STREET

655 Kolter Drive Indiana PA 15701 CHARLESTON, WV 25301 304-558-3417 Attn: Cathleen Zilner DATE PRINTED TERMS OF SALE SHIP VIA FREIGHT TERMS

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WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'



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25301

304-558-3417

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Remedy Repack 655 Kolter Drive Indiana PA 15701

Attn: Cathleen Zilner

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State of West Virginia Department of Administration **Purchasing Division** 2019 Washington Street East Post Office Box 50130 Charleston, WV 25305-0130

TERMS OF SALE

Request for Quotation

SHIP VIA

RFQ NUMBER MCH10072

FREIGHT TERMS

ROBERTA WAGNER

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RFONUMBER MCH10072 PAGE 4

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BPH - OMCFH
MATERIALS MANAGEMENT
900 BULLITT STREET
CHARLESTON, WV

TERMS OF SALE DATE PRINTED SHIP VIA FOB: FREIGHTTERMS 01/14/2010 BID OPENING DATE: 02/02/2010 BID OPENING TIME 01:30PM CAT. LINE QUANTITY UOP ITEM NUMBER UNIT PRICE AMOUNT

REV. 05/26/2009 NOTICE A SIGNED BID MUST BE SUBMITTED TO: DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION BUILDING 15 2019 WASHINGTON STREET, EAST CHARLESTON, WV 25305-0130 THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED: SEALED BID BUYER: RW-22 RFQ. NO.: MCH10072 02/02/2010 BID OPENING DATE: BID OPENING TIME: 1:30PM PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID:

Fax: 866-307-9744

SEE BEVERSE SIDE FOR TERMS AND CONDITIONS

TELEPHONE 866-845-3791 x1068 Feb 8, 2010

Director of Operations | FEIN 20-4037334 ADDRESS C

ADDRESS CHANGES TO BE NOTED ABOVE



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State of West Virginia Department of Administration Purchasing Division 2019 Washington Street East Post Office Box 50130 Charleston, WV 25305-0130

TERMS OF SALE

Request for REQUIRER Quotation

SHIP VIA

MCH10072

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FREIGHT TERMS

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Packing Slip



RemedyRepack 655 Kolter Drive Indiana, Pa 15701

Contact: Matthew Heller

Phone Number:

655 Kolter DR.

Indiana,PA15701

(724) 349-1111 ext. 1095

Fax:

Ship from RemedyRepack

(724) 349-2636

Ship to:

Dept of Admin Purchasing Divion

2019 Washington Street East

Building 15

Charleston, WV 25305-0130

(304) 558-0067

Customer ID	Reference Number	Payment Terms
Customer Contact	Shipping Method	Ship Date: 2/8/2010 Due Date:
Robert Wagner	Priority Overnight	

Item	Order Qty.	Description / NDC #	Comments
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February 8, 2010

655 Kolter Drive Indiana, PA 15701

724.465.8762 1.866.845.3791 1.866.307.9744 fax www.remedyrepack.com

Department of Administration Purchasing Division Building 15 2019 Washington Street, East Charleston, WV 25305-0130

Attn: Roberta Wagner

Dear Ms. Wagner:

Please find enclosed our quotation for your RFQ MCH10072. We appreciate this opportunity to quote on the pharmaceutical repackaging for your Family Planning Program Services.

Remedy Repack is a FDA Registered Drug Repacker and is also registered with the DEA (certificates of registration enclosed). In business since 2006, we are the sole drug repacker to Diamond Pharmacy Services, the nation's largest correctional pharmacy. We also provide medication repackaging services to the PA Department of Health for a contract very similar to yours. This contract has been recently renewed.

We emphasize customer service and reliability through our extensive quality systems and our seasoned staff. We were audited by the DEA in June 2008 and by the FDA last May. Having passed both audits, we were also asked by the FDA to speak at the AFDO Conference (Association of Food and Drug Officials) in Pittsburgh regarding our quality systems.

Please feel free to contact me with any questions or to schedule a visit to our facility in Western PA. I can be reached at 1.866.845.3791 ext. 1068 or on my cell at 412.719.0276.

Sincerely,

ni iliyaf Ososationa

Director of Operations

RFQ# MCH10072

Part 1 PURPOSE

1.1 PURPOSE

The purpose of this Request for Quotation (RFQ) is to engage the services of a vendor to provide pharmaceutical repackaging for selected prescription drugs for the Office of Maternal, Child and Family Health, Family Planning Program located at 350 Capitol Street, Room 427, Charleston, West Virginia.

1.2 BACKGROUND

Within the West Virginia Department of Health and Human Resources (WVDHHR), Bureau for Public Health, the Office of Maternal, Child and Family Health (OMCFH) offers preventive health care and screening services through a community-based network of health care providers throughout the State. The Family Planning Program (FPP) provides comprehensive reproductive health care, medical services, counseling and education, contraceptive methods, and laboratory services. Family Planning Program services are offered through a statewide network of 151 participating provider agencies.

Part 2 CONTRACTUAL SERVICES

2.1 REQUIRED SERVICES

The vendor will be responsible for the repackaging of pharmaceuticals dispensed at the 151 Family Planning Program clinic sites throughout the State. The vendor will purchase all pharmaceuticals. Generic drugs will be purchased unless the Family Planning Program requests the purchase of specific brand name drugs. Family Planning Program is requesting pharmaceutical repackaging for the following prescription drugs. Strengths, packaging requirements and estimated annual usage are also listed.

	Approx. Annual
	Usage
Doxycycline 100 mg 14 tabs/vial	2500 vials
Tetracycline 500 mg 28 tabs/vial	500 vials
Flagyl 500 mg 14 tabs/vial	3500 vials
Ciprofloxacin 500mg 1 tab/vial	25 vials
Fluconazole 150mg 1 tab/vial	1000 vials

The vendor will supply medication in unit-of-use doses. Vendor will supply tamper-proof, plastic, amber or opaque prescription vials. Vendor will supply and affix labels for repackaged drugs to include:

- a. Name of drug
- b. Strength of drug

- c. Quantity of drug
- d. Expiration date
- e. Space for date and patient name
- f. Full directions for use
- g. Name of manufacturer (generic drugs)
- h. Lot number
- i. Auxiliary labels (as indicated for appropriate drugs)

2.2 ADMINISTRATIVE AND OPERATIONAL REQUIREMENTS

Vendor must supply two (2) double tab peel off labels for record keeping. One shall be marked for application to the patient chart and one will be marked for the purpose of lot number tracking and inventory control.

Vendor must supply medications with minimum expiration dates of one year. Vendor must have no minimum order requirements. Vendor must inform the Family Planning Program immediately when any purchased drugs are recalled.

Vendor must ship pharmaceutical supplies by express delivery service, i.e. United Parcel Service, Federal Express, etc. within 7 days (excluding holidays) after receipt of order. Vendor must ship supplies to DHHR Materials Management with freight prepaid by vendor. A shipping invoice must accompany each shipment.

PART 3 GENERAL TERMS AND CONDITIONS

3.1 REJECTION OF QUOTATION/BIDS

The State reserves the right to accept any or all quotations/bids if it is determined to be in the State's best interests. The Department may withdraw this RFQ at any time for any reason. Receipt of a quotation confers no rights upon the bidder. A contract based upon this RFQ may or may not be awarded. Then, said contract must be approved as to form by the Attorney General's Office.

3.2 SUBCONTRACTS PROHIBITED

The successful vendor will be solely responsible for all work performed under the contract. The vendor shall not enter into written or oral subcontracts for performance of work under the contract without written permission of the agency.

3.3 COMPLIANCE WITH LAW AND REGULATIONS

The vendor shall pay any sales, use, and personal property taxes arising out of this contract and the transactions contemplated thereby. Any other taxes levied upon this contract, the transaction, or the equipment, or services delivered pursuant hereto shall be borne by the vendor.

The vendor shall comply with all applicable laws, rules and regulations including, but not limited to those relating to hospital licensure, State and Federal labor laws and laws, rules and policies related to the WVDHHR.

The vendor shall be responsible for compliance with all workplace safety requirements, including, but not limited to compliance with applicable OSHA and all other applicable environmental agency requirements for storage, labeling, handling and disposal of all items used in the performance of duties associated with cytology services. The vendor shall appropriately train its employees in proper workplace safety requirements.

3.4 RECORD RETENTION AND CONFIDENTIALITY

The vendor will maintain financial records pertaining to the contract for five (5) years following the end of the State fiscal year during which the contract is terminated or State and Federal audits of the contract have been completed, whichever is later. If questions about accounting records arise during an audit, the accounting records pertaining to the contract shall be retained until resolution of all pending audit questions and for one (1) year following the termination of any litigation relating to the contract if the litigation has not terminated within the above five (5) year period. Accounting records and procedures shall be subject to State and Federal approval.

3.5 CHANGES IN SCOPE

Formal contract amendments and/or change orders will be negotiated by the Department with the vendor, whenever necessary, to address changes to the terms and conditions, costs of, or scope of work included under the contract. An approved contract amendment/change order means one approved by the WV Department of Health and Human Resources, the WV Department of Administration, and all other applicable State agencies prior to the effective date of such amendment/change order. An approved contract amendment/change order is required whenever the change affects the payment provision and the scope of work performed by the vendor. Vendor shall not change the scope of services to be conducted without the approval of the State As soon as possible after receipt of a written change request, but in no event more than thirty (30) days thereafter, the vendor shall provide the State a

written statement that the change has no price impact on the contract or if there is a price impact, provide a description of the price increase or decrease involved in implementing the change.

3.6 TERMINATION OF THE CONTRACT

The Department may terminate a contract resulting from this RFQ at any time that the vendor fails to carry out its responsibilities under the terms of any contract resulting from this RFQ to satisfaction of the Department, Bureau or Office of Maternal, Child and Family Health.

The Department shall provide the vendor with notice of conditions endangering performance. If after such notice the vendor fails to remedy this conditions contained in this notice, within the time period contained in the notice, the Department shall issue the vendor an order to stop all work immediately. The Department shall be obligated only for services rendered and accepted prior to the date of the notice of termination.

The contract may also be terminated upon mutual agreement of the parties with thirty (30) days prior notice.

3.7 INVOICE AND PAYMENTS

The vendor shall submit invoices, in arrears to the Office of Maternal, Child and Family Health, Family Planning Program for all services provided pursuant to the terms of the contract. The invoices shall be in a format approved by the Department. The vendor must submit an original itemized invoice for each order placed against this contract. Payment will be made in arrears after receipt of each completed order.

3.8 TERM OF CONTRACT

Contract shall be for a period of one year with the option of two (2), one (1) year renewal periods.

Remedy Repack

COST SHEET FOR MCH10072

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Award will be made to the vendor with the lowest overall cost who meets specifications.

Vendor must submit an original itemized invoice for each order. Payment will be made in arrears after receipt of each completed order. Orders will be placed on an as needed basis.

Rev. 09/08

State of West Virginia

VENDOR PREFERENCE CERTIFICATE

Certification and application* is hereby made for Preference in accordance with **West Virginia Code**, §5A-3-37 (Does not apply to construction contracts). **West Virginia Code**, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the **West Virginia Code** This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Resident Vendor Preference, if applicable.

1.	Application is made for 2.5% resident vendor preference for the reason checked: Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; or, Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or, Bidder is a honresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; or,
2.	Application is made for 2.5% resident vendor preference for the reason checked: Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,
3.	Application is made for 2.5% resident vendor preference for the reason checked: Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,
4.	Application is made for 5% resident vendor preference for the reason checked: Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; or,
5.	Application is made for 3.5% resident vendor preference who is a veteran for the reason checked: Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; or,
6.	Application is made for 3.5% resident vendor preference who is a veteran for the reason checked: Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.
requiren against	understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the nents for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency cted from any unpaid balance on the contract or purchase order
authorize the requ	nission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and es the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid ired business taxes, provided that such information does not contain the amounts of taxes paid nor any other information by the Tax Commissioner to be confidential.
and acc	nenalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true curate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate is during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.
Bidder:_	Remedy Repack Signed:
Date:	February 8, 2010 Title: Director of Operations

*Check any combination of preference consideration(s) indicated above, which you are entitled to receive.

RFQ No. 1	CH10072
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STATE OF WEST VIRGINIA Purchasing Division

PURCHASING AFFIDAVIT

West Virginia Code §5A-3-10a states: No contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and the debt owed is an amount greater than one thousand dollars in the aggregate

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Debtor" means any individual, corporation, partnership, association, limited liability company or any other form or business association owing a debt to the state or any of its political subdivisions. "Political subdivision" means any county commission; municipality; county board of education; any instrumentality established by a county or municipality; any separate corporation or instrumentality established by one or more counties or municipalities, as permitted by law; or any public body charged by law with the performance of a government function or whose jurisdiction is coextensive with one or more counties or municipalities "Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

EXCEPTION: The prohibition of this section does not apply where a vendor has contested any tax administered pursuant to chapter eleven of this code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

Under penalty of law for false swearing (West Virginia Code §61-5-3), it is hereby certified that the vendor affirms and acknowledges the information in this affidavit and is in compliance with the requirements as stated.

Vendor's Name: Cathleen Zilner Authorized Signature: Date: February 8, 2010 State of Pennsylvania County of Indiana, to-wit: Taken, subscribed, and sworn to before me this 8 day of February, 2010. My Commission expires February 11, 2011. AFFIX SEAL HERE NOTARY PUBLIC DEVIAN ACCOUNTS.

COMMONWEALTH OF PENNSYLVANIA

WITNESS THE FOLLOWING SIGNATURE

Notarial Seal Deborah L. Rodgers, Notary Public Indiana Boro, Indiana County My Commission Expires Feb. 11, 2011

Member, Pennsylvania Association of Notaries

Purchasing Affidavit (Revised 12/15/09)



State of West Virginia Request for Department of Administration Quotation Purchasing Division 2019 Washington Street East Post Office Box 50130 Charleston, WV 25305-0130

Request for Edward Burnsen 1993

MCH10072

WAR PAGE NOW

ROBERTA WAGNER 804-558-0067

RFQ COPY TYPE NAME/ADDRESS HERE Remedy Repack Cathleen Zilner 655 Kolter Drive Indiana PA 15701

HEALTH AND HUMAN RESOURCES BPH - OMCFH MATERIALS MANAGEMENT 900 BULLITT STREET CHARLESTON, WV 25301 304-558-3417

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State of West Virginia Department of Administration Quotation Purchasing Division 2019 Washington Street East Post Office Box 50130 Charleston, WV 25305-0130

Request for The Telephone Republic Telephone Republ MCH10072

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ROBERTA WAGNER 804-558-0067

HEALTH AND HUMAN RESOURCES BPH - OMCFH MATERIALS MANAGEMENT 900 BULLITT STREET CHARLESTON, WV 304-558-3417 25301

Remedy Repack Cathleen Zilner 655 Kolter Drive Indiana PA 15701

TYPE NAME/ADDRESS HERE

REO COPY

Secretary Terms DATERRINTED TERMS OF SALE SHIPAGA C.O.B. 01/27/2010 BID OPENING DATE: BID OPENING TIME 02/10/2010 UNE (September 1 DINTPRICE QUANTITY & ORAL DISCUSSION HELD BETWEEN VENDOR'S REPRESENTATIVES AND ANY STATE PERSONNEL IS NOT BINDING ONLY THE INFORMATION ISSUED IN WRITING AND ADDED TO THE SPECIFICATIONS BY AN OFFICIAL ADDENDUM IS BINDING. SIGNATURE Z Remedy Replack ... COMPANY February 8, 2010 DATE HOTE: THIS ADDENDOM ACKNOWLEDGEMENT SHOULD BE SUBMITTED WITH THE BID REV. 09/21/2009 END OF ADDENDUM NO. 1 SOUSEE HEVERGE SIDE FOR TERMS AND CONDITIONS ‴Feb 8, 2010 866-845-3791 ADDRESS CHANGESTO BE NOTED ABOVE 20-4037334 Director of Operations WHEN RESPONDING TO REGUNGERY WAVE AND ADDRESS IN SPACE ABOVE LABELED VENDOR



February 9, 2010

655 Kolter Drive Indiana, PA 15701

724.465.8762 1.866.845.3791 1.866.307.9744 fax www.remedyrepack.com

Department of Administration

Purchasing Division

Building 15

2019 Washington Street, East

Charleston, WV 25305-0130

Attn: Roberta Wagner

Re: RFQ MCH10072

Dear Ms. Wagner:

Please accept my apologies as I believe these documents may have been omitted from our bid package which shipped to you yesterday. Please add the enclosed FDA and DEA certificates of registration to our package.

Thank you,

Cathleen I. Zilner

Director of Operations

RECEIVED

2010 FEB 10 A 10: 17:

PURCHASING DIVISION STATE OF WV

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Form Approved: OMB No. 0910-0045. Expiration Date: December 31 See OMB Statement on Reverse. FDA USE ONLY DEPARTMENT OF HEALTH AND HUMAN SERVICES RE 84,370 FOOD AND DRUG ADMINISTRATION REGISTRATION OF DRUG ESTABLISHMENT/ LABELER CODE ASSIGNMENT anatralay 20 (In accordance with Public Law 92-387) NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not LABELER CODE more than one year or a fine of not more than \$1,000, or both. (FD&C Act, Section 303). REGISTRATION NUMBER 24236 /49349 3005841768 SECTION A - SITE INFORMATION STATE OF INC. REPORTING FIRM NAME RemedyRepack SITE TELEPHONE NUMBER SITE ADDRESS (No P.O. Box) (724) 465-8762 655 Kolter Dr. ZIP CODE COUNTRY BUSINESS CATEGORY: STATE CITY 15701 US Z HUMAN VETERINARY PA Indiana SITE MAILING ADDRESS (If different from site address) COUNTRY SITE INTERNET/EMAIL ADDRESS ZIP CODE CITY STATE Kathleen Zilner DOING BUSINESS AS (DBA) NAME OF FIRM (If applicable) PARENT COMPANY NAME TYPE OF OWNERSHIP PERSON SUBMITTING DATA AND TELEPHONE REASON(s) FOR SUBMISSION Firm Registration Address Change . Sole Proprietorship BUSINESS TYPE Registration of Merger/Buyoul Partnership Distributor* Additional Site Reentry into Business ne-Registration Coop. Assn. Manufacturer Foreign Country with Same Name Repacker LC Assignment Corporation Analytical Lab Out of Business Relabeler Name Change Other _ Other SECTION B - FIRM COMPLIANCE MAILING ADDRESS for Annual Listing Report and/or Firm Correspondence NUMBER AND STREET AND/OR P.O. BOX and ATTENTION LINE and/or internal Mail Code TELEPHONE NUMBER (724) 465-8762 655 Kolter Dr. STATE ZIP CODE COUNTRY COMPLIANCE INTERNET/EMAIL CITY 15701 PA US Indiana phays@remedyrepack.com SECTION C - ADDITIONAL FIRM AND SITE INFORMATION POSITION NAME OF OWNER, PARTNERS OR OFFICERS TITLE RECEIVED President Kathleen Zilner Į. Vice President Mark Zilner Joan Zilner Secretary m MAY 18 2019 Treasurer LouAnn Bowser 22 DRIS OTHER FIRMS DOING BUSINESS AT THIS SITE FIRM NAME LABELER CODE FIRM NAME LABELER CODE **SECTION D - SIGNATURE** SIGNATURE OF AUTHORIZING OFFICIAL , TITLE DATE President DISTRIBUTOR'S CERTIFICATION: As a, Distributor, I am submitting product listing information to the FDA on my own behalf. I have provided a copy of this certification (Form FDA 2656)46 The registered manufacturer(s). My signature and phone number are listed below. SIGNATURE OF DISTRIBUTOR **RETURN THIS FORM TO:** FOOD AND DRUG ADMINISTRATION CDER/DRUG REGISTRATION AND LISTING (HFD-337) DISTRIBUTOR'S TELEPHONE NUMBER 5600 FISHERS LANE ROCKVILLE, MD 20857 INTERNET: DRLS@FDA.HHS.GOV

FORM FDA 2656 (8/07) (FRONT)

NOTE: Validation of this form is not to be construed as FDA approval of the establishment or its products.