

Public Sector
200 Schulz Drive
Red Bank, N.J. 07701
(800) 232-1309
(732) 219-5127 Fax
www.lifestyles.com/sexualhealth

January 13, 2009

State of West Virginia
Dept of Administration
Purchasing Division
Attn Roberta Wagner
2019 Washington Street East
Charleston WV 25305

RECEIVED . 2009 JAN 14 A 9:59

GCHASING DIVISION STATE OF WV

Dear Ms. Wagner:

Enclosed is Ansell's response to your Invitation to RFQ MCH9099. We will be bidding on our LifeStyles condoms.

All latex condoms manufactured by Ansell meet or excess the requirements set down by the latest revision of the American Society for Testing and Materials standards (ASTM), the Federal guidelines. We are in compliance with Good Manufacturing Practices regulations promulgated by the Food and Drug Administration.

With regards to Technical Documentation requirements, enclosed please find the following:

- 1. "How to Use a Condom" leaflet and Sexual Health Brochure
- 2. Statement of Product Information
- 3. Sample of Certificate of Conformance
- 4. Statement of Compliance/Conformance
- 5. Certificate of Registration
- 6. Certification Statement
- 7. Quality Assurance Procedures
- 8. Public Sector Price List
- 9. 510 (k) letter of authorization
- 10. Product Samples

Ansell's condoms are the same LifeStyles condoms sold in commercial marketplace. Per your bid requirements, we would supply a well-known condom brand to you. LifeStyles are available at the following retailers: CVS, Walgreens, Rite Aid, Kroger and Wal-Mart.

In order for a brand to have a retail presence, consumer acceptance and demand must be high. You can assume the product has a strong reputable company with experience supporting its product line. Our LifeStyles brand is a name people recognize.

Further, for questions or problems, we are the manufacturer with our headquarters office located in New Jersey.

Ansell's terms are Net 30 days. All orders are shipped F.O.B destination.

Thank you for the opportunity to participate in this offering. We hope our bid will be successful. Please do not hesitate to contact Christine Abel, Contract Sales Analyst, or myself if you have any problems or questions.

Sincerely,

Jan Warner Director Public Sector

JW: CA Enclosures

## GENERAL TERMS & CONDITIONS REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)

- 1. Awards will be made in the best interest of the State of West Virginia.
- 2. The State may accept or reject in part, or in whole, any bid
- 3. All quotations are governed by the West Virginia Code and the Legislative Rules of the Purchasing Division.
- 4. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required \$125 fee.
- 5. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods, this Purchase Order/Contract becomes void and of no effect after June 30.
- 6. Payment may only be made after the delivery and acceptance of goods or services.
- 7. Interest may be paid for late payment in accordance with the West Virginia Code
- 8. Vendor preference will be granted upon written request in accordance with the West Virginia Code
- 9. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.
- 10. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller.
- 11. The laws of the State of West Virginia and the *Legislative Rules* of the Purchasing Division shall govern all rights and duties under the Contract, including without limitation the validity of this Purchase Order/Contract.
- 12. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties
- 13. BANKRUPTCY: In the event the vendor/contractor files for bankruptcy protection, this Contract may be deemed null and void, and terminated without further order.
- 14. HIPAA BUSINESS ASSOCIATE ADDENDUM: The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, and available online at the Purchasing Division's web site (http://www.state.wv.us/admin/purchase/vrc/hipaa.htm) is hereby made part of the agreement. Provided that, the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.
- 15. WEST VIRGINIA ALCOHOL & DRUG-FREE WORKPLACE ACT: If this Contract constitutes a public improvement construction contract as set forth in Article 1D, Chapter 21 of the West Virginia Code ("The West Virginia Alcohol and Drug-Free Workplace Act"), then the following language shall hereby become part of this Contract: "The contractor and its subcontractors shall implement and maintain a written drug-free workplace policy in compliance with the West Virginia Alcohol and Drug-Free Workplace Act, as set forth in Article 1D, Chapter 21 of the West Virginia Code. The contractor and its subcontractors shall provide a sworn statement in writing, under the penalties of perjury, that they maintain a valid drug-free work place policy in compliance with the West Virginia and Drug-Free Workplace Act. It is understood and agreed that this Contract shall be cancelled by the awarding authority if the Contractor: 1) Fails to implement its drug-free workplace policy; 2) Fails to provide information regarding implementation of the contractor's drug-free workplace policy at the request of the public authority; or 3) Provides to the public authority false information regarding the contractor's drug-free workplace policy."

#### INSTRUCTIONS TO BIDDERS

- 1. Use the quotation forms provided by the Purchasing Division
- 2. SPECIFICATIONS: Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as EQUAL to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications.
- 3. Complete all sections of the quotation form.
- Unit prices shall prevail in case of discrepancy.
- 5. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation.
- 6. BID SUBMISSION: All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130



VENDOR

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

#### Request for Quotation

RFONUMBER MCH90099 PAGE 1

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

\*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

CHARLESTON, WV

25301 304-558-3417

DATE PRIN	TED TEP	IMS OF SALE	SHIP VIA	FOB	FREIGHT TERMS
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SIGNATURE	Warner	_	TELEPHONE 7.32 3	345 5338 DATE /	-13-09
Director.	Public Sector FEI	<sup>™</sup> 363/50			TO BE NOTED ABOVE



# Request for

RFQ NUMBER MCH90099 PAGE 2

ADDRESS CORRESPONDENCE TO ATTENTION OF:

304-558-3417

ROBERTA WAGNER B04-558-0067

25301

800-232-1309 \*709024704 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

SHIP VIA F.O.B. FREIGHT TERMS DATE PRINTED TERMS OF SALE 12/10/2008 BID OPENING DATE: 01:30PM 01/08/2009 BID OPENING TIME CAT UOP ITEM NUMBER UNITPRICE AMOUNT LINE QUANTITY NEUTRAL COLOR. (PRICE SHOULD INCLUDE FREIGHT). INDIVIDUALLY PACKAGED; 1000 PER CASE LIFESTYLE #5700 OR EQUAL. EXHIBIT 4 UNLESS THE VENDOR INDICATES LOCAL GOVERNMENT BODIES: IN THE BID HIS REFUSAL TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO COUNTY, SCHOOL, MUNICIPAL AND OTHER LOCAL GOVERNMENT BODIES, THE BID SHALL EXTEND TO POLITICAL SUBDIVISIONS OF THE STATE OF WEST IF THE VENDOR DOES NOT WISH TO EXTEND THE VIRGINIA. PRICES, TERMS, AND CONDITIONS OF THE BID TO ALL POLITICAL SUBDIVIBIONS OF THE STATE, THE VENDOR MUST CLEARLY INDICATE SUCH REFUSAL IN HIS BID. SUCH REFUSAL SHALL NOT PREJUDICE THE AWARD OF THIS CONTRACT IN ANY MANNER. REV. 3/88 INQUIRIES: written questions|shall be accepted through close of 12/22/2008... QUESTIONS MAY BE BUSINESS ON SENT VIA USPS, FAX, COURIER OR E-MAIL IN ORDER TO ASSURE NO VENDOR RECEIVES AN UNFAIR ADVANTAGE, NO SUBSTANTIVE QUESTIONS WILL BE ANSWERED ORALLY. IF POSSIBLE, E-MAIL QUESTIONS ARE PREFERRED. ADDRESS INOUIRIES TO! ROBERTA WAGNER DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION 2019 WASHINGTON STREET EAST CHARLESTON, WV 253 BEE REVERSE SIDE FOR TERMS AND CONDITIONS TELEPHONE 732 SIGNATURE ADDRESS CHANGES TO BE NOTED ABOVE 36 3152638



## Request for

RFQ NUMBER MCH90099

FREIGHT TERMS

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER B04-558-0067

\*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

SHIP VIA F.O.B. DATE PRINTED. TERMS OF SALE 12/10/2008 **BID OPENING DATE** 01:30PM RID OPENING TIME 01/08/2009 CAT UNIT PRICE AMOUNT UOP ITEM NUMBER QUANTITY. LINE NO: FAX: 304-558-4115 E-MAIL: ROBERTA A A WAGNER@WV GOV THIS CONTRACT BECOMES EFFECTIVE ON LIFE OF CONTRACT: FEBRUARY 1, 2009 AND EXTENDS FOR A PERLOD OF ONE (1) YEAR OR UNTIL SUCH "REASONABLE TIME" THEREAFTER AS IS NECESSARY TO OBTAIN A NEW CONTRACT OR RENEW THE DRIGINAL CONTRACT THE "REASONABLE TIME" PERIOD SHALL DURING THIS "REASONABLE NOT EXCEED TWELVE (12) MONTHS. TIME" THE VENDOR MAY TERMINATE THIS CONTRACT FOR ANY REASON UPON GIVING THE DIRECTOR OF PURCHASING 30 DAYS WRITTEN NOTICE UNLESS SPECIFIC PROVISTONS ARE STIPULATED ELSEWHERE IN THIS CONTRACT DOCUMENT, THE TERMS, CONDITIONS AND PRICING SET HEREIN ARE FIRM FOR THE LIFE OF THE CONTRACT .. RENEWAL: THIS CONTRACT MAY BE RENEWED UPON THE MUTUAL WRITTEN CONSENT OF THE SPENDING UNIT AND VENDOR, SUBMITTED TO THE DIRECTOR OF PURCHASING THIRTY (30) SUCH RENEWAL SHALL DAYS PRIOR TO THE EXPIRATION DATE. BE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE ORIGINAL CONTRACT AND SHALL BE LIMITED TO TWO (2) ONE (1) YEAR PERTODS. THE DIRECTOR OF PURCHASING RESERVES THE CANCELLATION! RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES SUPPLIED ARE OF AN INFERIOR QUALITY OR DO NOT CONFORM TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN. SEE REVERSE SIDE FOR TERMS AND CONDITIONS TELEPHONE SIGNATU -13-09 732345 5338 363152638 ADDRESS CHANGES TO BE NOTED ABOVE



## Request for

RFO NUMBER MCH90099 4

ADDRESS CORRESPONDENCE TO ATTENTION OF:

ROBERTA WAGNER 304-558-0067

\*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

FREIGHTTERMS DATE PRINTED TERMS OF SALE SHIP VIA FOR 12/10/2008 BID OPENING DATE: 01/08/2009 BID OPENING TIME 01:30PMQUANTITY AMOUNT. UOP ITEM NUMBER UNIT PRICE LINE PPEN MARKET CLAUSE: THE DIRECTOR OF PURCHASING MAY AUTHORIZE A SPENDING UNIT TO PURCHASE ON THE OPEN MARKET, WITHOUT THE FILING OF A REQUISITION OR COST ESTIMATE, ITEMS SPECIFIED ON THIS CONTRACT FOR IMMEDIATE DELIVERY IN EMERGENCIES DUE TO UNFORESEEN CAUSES (INCLUDING BUT NOT LIMITED TO DELAYS IN TRANS-PORTATION OR AN UNANTICIPATED INCREASE IN THE VOLUME OF WORK.) QUANTITIES: QUANTITIES LISTED IN THE REQUISITION ARE APPROXIMATIONS ONLY, BASED ON ESTIMATES SUPPLIED BY THE STATE SPENDING UNIT. IT IS UNDERSTOOD AND AGREED THAT THE CONTRACT SHALL COVER THE QUANTITIES ACTUALLY DRDERED FOR DELIVERY DURING THE TERM OF THE CONTRACT, WHETHER MORE OR LESS THAN THE QUANTITIES SHOWN. ORDERING PROCEDURE: SPENDING UNIT(S) SHALL ISSUE A WRITTEN STATE CONTRACT ORDER (FORM NUMBER WV-39) TO THE VENDOR FOR COMMODITIES COVERED BY THIS CONTRACT. THE ORIGINAL COPY OF THE WV-39 SHALL BE MAILED TO THE vendor as authorization for shipment, a second copy MAILED TO THE PURCHASING DIVISION, AND A THIRD COPY RETAINED BY THE SPENDING UNIT. IN THE EVENT THE VENDOR/CONTRACTOR FILES BANKRUPTCY: FOR BANKRUPTCY PROTECTION, THIS CONTRACT IS AUTOMATI-CALLY NULL AND VOID, AND IS TERMINATED WITHOUT FURTHER ORDER .. THE TERMS AND CONDITIONS CONTAINED IN THIS CONTRACT SHALL SUPERSEDE ANY AND ALL SUBSEQUENT TERMS AND CONDITIONS WHICH MAY APPEAR ON ANY ATTACHED PRINTED DOCUMENTS SUCH AS PRICE LISTS, ORDER FORMS, SALES AGREEMENTS OR MAINTENANCE AGREEMENTS, INCLUDING ANY ELECTRONIC MEDIUM SUCH AS CD-ROM. SEE REVERSE SIDE FOR TERMS AND CONDITIONS TELEPHONE SIGNATURE 1-13-09 ี*5*338 **フ**き之 ADDRESS CHANGES TO BE NOTED ABOVE 315 2638



## Request for Quotation

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MCH90099

PAGE

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

\*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

Director Pub Sector 363152638

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

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



# Request for Quotation

RFO NUMBER
MCH90099

PAGE 6

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 804-558-0067

\*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

25301 304-558-3417

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## Request for

MCH90099

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ADDRESS CORRESPONDENCE TO ATTENTION OF

304-558-3417

ROBERTA WAGNER 304-558-0067

25301

800-232-1309 \*709024704 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

FREIGHT TERMS FOB. SHIP VIA DATE PRINTED TERMS OF SALE 12/10/2008 01.30PM**BID OPENING DATE** OPENING TIME 01/08/2009 CAT NO. AMOUNT UNIT PRICE ITEM NUMBER LINE QUANTITY UOP 732 219 CONTACT PERSON (PLEASE PRINT CLEARLY): Abel 732 345 5338 Christine MCH90099 \*\*\*\*\* TOTAL: THIS IS THE END OF RFQ SEE REVERSE SIDE FOR TERMS AND CONDITIONS TELEPHONE 13-09 SIGNATURE 5338 ADDRESS CHANGES TO BE NOTED ABOVE 63152638

WV-36 (Rev 01/01/07)

#### STATE OF WEST VIRGINIA

#### **PURCHASE CONTINUATION SHEET**

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File:		Acct. No. SEE BE		
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Requisition / P.O. No:

P O. Date: Vendor: OMCFH/FAMILY PLANNING Unit Price Amount Description Quantity Item No. APPROX OPEN END CONTRACT TO PROVIDE THE FOLLOWING FAMILY **ANNUAL** PLANNING PRODUCTS: USAGE 1500 CS 1 CONDOMS, 100% LATEX LUBRICATED, RESERVOIR TIP, NEUTRAL COLOR, PACKAGING: 1000/CASE LIFESTYLES #5800 OR EQUAL 2 45 CS CONDOMS, 100% LATEX, NONLUBRICATED, RESERVOIR TIP, NEUTRAL COLOR, PACKAGING: 1000/CASE LIFESTYLE #5700 OR **EQUAL** SPECIFICATIONS: EACH INDIVIDUALLY PACKAGED CONDOM MUST BE LEGIBLY MARKED TO INCLUDE THE NAME OR TRADEMARK OF THE MANUFACTURER AND THE LOTS OR BATCH NUMBER. IN ADDITION, EACH INDIVIDUALLY PACKAGED CONDOM MUST INCLUDE THE PRINTED OR STAMPED EXPIRATION DATE. VENDOR MUST CLEARLY INDICATE THE MANUFACTURER'S NAME, BRAND AND PRODUCT NUMBER FOR EACH ITEM. IF THE LABEL OF THE PRODUCT TO BE SUPPLIED IDENTIFIES THE DISTRIBUTOR RATHER THAN THE MANUFACTURER, THE BIDDER MUST INDICATE BOTH THE DISTRIBUTOR AND MANUFACTURER'S NAME AND COUNTRY OR ORIGIN, IN ADDITION TO THE PRODUCT NUMBER. DURING THE TERM OF CONTRACT THE VENDOR IS TO DELIVERY ONLY THE PRODUCT SPECIFICALLY BID SAMPLES/DOCUMENTATION: SAMPLES OF PRODUCT TO BE SUPPLIED UNDER CONTRACT, AS WELL AS PRODUCT LITERATURE SHOULD ACCOMPANY BID FAILURE TO SUBMIT SAME DISQUALIFIES BID CONDOM SPECIFICATION FOR EACH STYLE AND TYPE OF CONDOM QUOTED SHOULD ACCOMPANY BID QUOTATION. CONDOM USAGE INSTRUCTIONS MUST BE INCLUDED WITH ALL **ORDERS** FDA AND OTHER REQUIREMENTS: VENDOR MUST CERTIFY THAT THE PRODUCT OFFERED MEETS ALL REQUIREMENTS OF THE AMERICAN SOCIETY FOR TESTING AND MATERIALS ASTM D-3492-97, STANDARD SPECIFICATIONS FOR RUBBER CONTRACEPTIVES (MALE CONDOMS), AND FOOD AND DRUG ADMINISTRATION (FDA) REQUIREMENTS FOR MEDICAL DEVICES 21 CFR, PART 801 A CERTIFICATE OF CONFORMANCE MUST BE PROVIDED FOR THE SAMPLES SUBMITTED AND FOR EACH BATCH OR LOT SUBMITTED UNDER THE CONTRACT. DOCUMENTATION/CERTIFICATIONS OF FDA 510 K PRODUCT REGISTRATION NUMBER AND FDA SITE REGISTRATION NUMBER FOR THE MANUFACTURING FACILITY IS REQUIRED.

WV-36 (Rev.01/01/07)

## STATE OF WEST VIRGINIA

## PURCHASE CONTINUATION SHEET

Page	of	Pages	Requisition / PO No: MCH90099	
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Item No.	Quantity		Description			Unit Price	Amount
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# COST SHEET FOR MCH90099

Item #	Apprx. Annual Usage	DESCRIPTION	BOIDD TINIT	TOTAL COST
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		Condoms, 100% Latex Lubricated, Reservoir Tip,		
		Neutral Packaging Lifestyples #5800 or Equal	•	ţ
_	1,500 Cases	1,500 Cases Pkg Size: 1000/cs Mfg: Lifestyles	34,20	52,440
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2	45 Cases	45 Cases Pkg Size: 1000/cs Mfg: LifeStyles	38,00	0171
		TOTAL COST		
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Contract may be awarded to multiple vendors based upon overall total cost per item which meets all requested specifications and requirements.

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.

#### STATE OF WEST VIRGINIA Purchasing Division

## **PURCHASING AFFIDAVIT**

#### **VENDOR OWING A DEBT TO THE STATE:**

West Virginia Code §5A-3-10a provides that: 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

#### PUBLIC IMPROVEMENT CONTRACTS & DRUG-FREE WORKPLACE ACT:

West Virginia Code §21-1D-5 provides that: Any solicitation for a public improvement construction contract shall require each vendor that submits a bid for the work to submit at the same time an affidavit that the vendor has a written plan for a drug-free workplace policy in compliance with Article 1D, Chapter 21 of the West Virginia Code. A public improvement construction contract may not be awarded to a vendor who does not have a written plan for a drug-free workplace policy in compliance with Article 1D, Chapter 21 of the West Virginia Code and who has not submitted that plan to the appropriate contracting authority in timely fashion For a vendor who is a subcontractor, compliance with Section 5, Article 1D, Chapter 21 of the West Virginia Code may take place before their work on the public improvement is begun.

#### **ANTITRUST:**

In submitting a bid to any agency for the state of West Virginia, the bidder offers and agrees that if the bid is accepted the bidder will convey, sell, assign or transfer to the state of West Virginia all rights, title and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the state of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the state of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to the bidder.

I certify that this bid is made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership or person or entity submitting a bid for the same materials, supplies, equipment or services and is in all respects fair and without collusion or fraud. I further certify that I am authorized to sign the certification on behalf of the bidder or this bid.

#### LICENSING:

Vendors must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agencies or political subdivision. Furthermore, the vendor must provide all necessary releases to obtain information to enable the Director or spending unit to verify that the vendor is licensed and in good standing with the above entities.

#### **CONFIDENTIALITY:**

The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures and rules. Vendors should visit <a href="https://www.state.wv.us/admin/purchase/privacy">www.state.wv.us/admin/purchase/privacy</a> for the Notice of Agency Confidentiality Policies.

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

Vendor's Name:		Ans	PH	. Healthcare	Produ	cts LC
Authorized Signature:	(F)	T	) 1	13/09	Date:	1-05-09
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Purchasing Affidavit (Revised 07/01/08)

### 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. ——		ontinuously in West Virginia for four (4) years immediately preced-
	business continuously in West Virginia for four (4) years ownership interest of Bidder is held by another individual, maintained its headquarters or principal place of businesseding the date of this certification: or.	t vendor and has maintained its headquarters or principal place of mmediately preceding the date of this certification; or 80% of the partnership, association or corporation resident vendor who has ess continuously in West Virginia for four (4) years immediately
	Bidder is a nonresident vendor which has an affiliate or sul and which has maintained its headquarters or principal p years immediately preceding the date of this certification	osidiary which employs a minimum of one hundred state residents lace of business within West Virginia continuously for the four (4); or,
2	working on the project being bid are residents of West Vir immediately preceding submission of this bid; or,	e life of the contract, on average at least 75% of the employees ginia who have resided in the state continuously for the two years
<b>3</b> .,	affiliate or subsidiary which maintains its headquarters minimum of one hundred state residents who certifies the	fone hundred state residents or is a nonresident vendor with an or principal place of business within West Virginia employing a lat, during the life of the contract, on average at least 75% of the sees are residents of West Virginia who have resided in the state
4.	Application is made for 5% resident vendor prefere Bidder meets either the requirement of both subdivisions	nce for the reason checked: (1) and (2) or subdivision (1) and (3) as stated above; <b>or,</b>
5.	Application is made for 3.5% resident vendor prefer Bidder is an individual resident vendor who is a veteran of and has resided in West Virginia continuously for the submitted; or,	rence who is a veteran for the reason checked: he United States armed forces, the reserves or the National Guard four years immediately preceding the date on which the bid is
6.	purposes of producing or distributing the commodities or	d States armed forces, the reserves or the National Guard, it, for completing the project which is the subject of the vendor's bid and age at least seventy-five percent of the vendor's employees are
requirer against or dedu	rements for such preference, the Secretary may order the D ist such Bidder in an amount not to exceed 5% of the bid am ducted from any unpaid balance on the contract or purchase	
authoriz the requ deemed	rizes the Department of Revenue to disclose to the Director o equired business taxes, provided that such information does ned by the Tax Commissioner to be confidential	easonably requested information to the Purchasing Division and f Purchasing appropriate information verifying that Bidder has paid not contain the amounts of taxes paid nor any other information
and acc	or penalty of law for false swearing (West Virginia Code accurate in all respects; and that if a contract is issued ges during the term of the contract, Bidder will notify t	, §61-5-3), Bidder hereby certifies that this certificate is true I to Bidder and if anything contained within this certificate the Purchasing Division in writing immediately.
Bidder:	er:Sign	ed:
Date:	Title	
	k any combination of preference consideration(s) indicated above wh	

bes Not apply to Ansell Heathcare

RFQ COPY



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

# Request for

MCH90099

ROBERTA WAGNER RO4-558-0067

**Ansell Healthcare Products** Public Sector - C. Abel 200 Schulz Drive Red Bank NJ 07701

TYPE NAME/ADDRESS HERE

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

SWYWWAEJORESSIE GRAFERFONDENGENJORAGIENJIJONEDERWE

DATE-PRINTED TERMS OF SALE SPIP VIA: 50'B FACISHE TERMS 01/05/2009 BID OPENING DATE: AMOUNT: UNITERICE TEM NUMBERS QUARTITY LINE X ADDENDUM NO. 1 TO MOVE THE BID OPENING DATE FROM 1/8/9 TO 1/15/9. 2. QUESTIONS AND ANSWERS ARE ATTACHED. . ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID. EXHIBIT 10 REQUISITION NO.: MCH90099 ADDENDUM ACKNOWLEDGEMENT HEREBY ACKNOWLEDGE RECEIPT OF THE FOILOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY PROPOSAL, PLANS AND/OR SPECIFICATION, ETC. ADDENDUM NO. 15: MO. 1 NO. 2 ..... NO. 3 ..... NO. 4 ..... MO, 5 ..... UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF THE ADDENDUM(S) MAY BE CAUSE FOR REJECTION OF BIDS. SEE REVERSEADE FOR TERMS AND CONDITIONS 1-13-09 5338 ADDRESS CHANGES TO BE NOTED ABOVE WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED VENDOR'

RFQ COPY



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

# Request for Quotation MCH90099

MCH90099

ROBERTA WAGNER 104-558-0067

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

TYPE NAME/ADDRESS HERE 25301 304-558-3417 

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WV-35 (Rev. 05/18/00)

## State of West Virginia Purchasing Division



# **PURCHASE REQUISITION**

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Requisition No	MCH90	0099	Buyer 22	La ratio to be a series of the					
Agency/Invalce	e To:		TEAM	WVFIMS DOCU	nent#				
WV DEPT. OF HEALTH & HUMA OMCFH/FAMILY PLANNING PRO 360 CAPITOL STREET, RM 427 CHARLESTON, WV 25301			VRESOURCES IGRAM	Suggested Vendors:  1. 2.					
Agency/Ship	To:	· · · · · · · · · · · · · · · · · · ·	TEAM	_					
WV DEPT, OF HEALTH & HUMA MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON, WV 25301				Additional Vendors on Reverse Side  PURCHASING DIVISION'S USE ONLY					
This Section Only For: Releases, Direct			urchases, Emergency Purchases a	and Agreements	Commodity Co	xde:			
Vendor Name	e and Addre	984;			Instructions:				
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Item No.	Quantity		Description ADDENDUM#1						
		REGARDING QUESTION: \ RFQ NOTED COMPETITIV RESPONSE: FROM THE L CONDOMS,	Type of Purchase DUM IS BEING SUBMITTED T THE ORIGINAL RFP SUBMIT WE ARE PREPARING TO SUE AND WANTED TO SEE IF YO E BID PRICING FROM THE P LISTED BELOW ARE THE PR AST CONTRACT.  100% LATEX, NON-LUBRICAT 100% LATEX LUBRICATED, F	TO ANSWER Q TED. BMIT A BID FOI DU CAN PROVI PREVIOUS BID? RODUCTS & PR TED, RESERVO	R ABOVE DE ? RICING DIR TIP \$38.00 CS				
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Public Sector
200 Schulz Drive
Red Bank, N.J. 07701
(800) 232-1309
(732) 219-5127 Fax
www.lifestyles.com/sexualhealth

January 13, 2009

State of West Virginia
Dept of Administration
Purchasing Division
Attn Roberta Wagner
2019 Washington Street East
Charleston WV 25305

Dear Ms. Wagner:

Enclosed is Ansell's response to your Invitation to RFQ MCH9099. We will be bidding on our LifeStyles condoms.

All latex condoms manufactured by Ansell meet or excess the requirements set down by the latest revision of the American Society for Testing and Materials standards (ASTM), the Federal guidelines. We are in compliance with Good Manufacturing Practices regulations promulgated by the Food and Drug Administration.

With regards to Technical Documentation requirements, enclosed please find the following:

- 1. "How to Use a Condom" leaflet and Sexual Health Brochure
- 2. Statement of Product Information
- 3. Sample of Certificate of Conformance
- 4. Statement of Compliance/Conformance
- 5. Certificate of Registration
- 6. Certification Statement
- 7. Quality Assurance Procedures
- 8. Public Sector Price List
- 9. 510 (k) letter of authorization
- 10. Product Samples

Ansell's condoms are the same LifeStyles condoms sold in commercial marketplace. Per your bid requirements, we would supply a well-known condom brand to you. LifeStyles are available at the following retailers: CVS, Walgreens, Rite Aid, Kroger and Wal-Mart.

In order for a brand to have a retail presence, consumer acceptance and demand must be high. You can assume the product has a strong reputable company with experience supporting its product line. Our LifeStyles brand is a name people recognize.

Further, for questions or problems, we are the manufacturer with our headquarters office located in New Jersey.

Ansell's terms are Net 30 days. All orders are shipped F.O.B destination.

Thank you for the opportunity to participate in this offering. We hope our bid will be successful. Please do not hesitate to contact Christine Abel, Contract Sales Analyst, or myself if you have any problems or questions.

Sincerely,

Jan Warner Director

**Public Sector** 

JW: CA Enclosures



\*709024704

ATTN: PUBLIC SECTOR

200 SCHULZ DRIVE

RED BANK NJ 07701

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

# Request for

MCH90099

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

800-232-1309 ANSELL HEALTHCARE PRODUCTS INC

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

CHARLESTON, WV 25301

304-558-3417

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Director	- Public Sector FEIN 363	3152638	ADDRESS CHANGES	TO BE NOTED ABOVE



# Request for

RFQ NUMBER MCH90099

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER B04-558-0067

\*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

FOB SHIP VIA FREIGHT TERMS TERMS OF SALE DATE PRINTED 12/10/2008 BID OPENING DATE 01:30PM BID OPENING TIME 01/08/2009 CAT AMOUNT QUANTITY UOP ITEM NUMBER UNIT PRICE LINE NEUTRAL COLOR. (PRICE SHOULD INCLUDE FREIGHT). INDIVIDUALLY PACKAGED; 1000 PER CASE. LIFESTYLE #5700 OR EQUAL. EXHIBIT 4 LOCAL GOVERNMENT BODIES: UNLESS THE VENDOR INDICATES IN THE BID HIS REFUSAL TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO COUNTY, SCHOOL, MUNICIPAL AND OTHER LOCAL GOVERNMENT BODIES, THE BID SHALL EXTEND TO POLITICAL SUBDIVISIONS OF THE STATE OF WEST IF THE VENDOR DOES NOT WISH TO EXTEND THE VIRGINIA. PRICES, TERMS, AND CONDITIONS OF THE BID TO ALL POLITICAL SUBDIVISIONS OF THE STATE, THE VENDOR MUST CLEARLY INDICATE SUCH REFUSAL IN HIS BID. SUCH REFUSAL SHALL NOT PREJUDICE THE AWARD OF THIS CONTRACT IN ANY MANNER .. REV. 3/88 INQUIRIES: WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF QUESTIONS MAY BE 12/22/2008 BUSINESS ON SENT VIA USPS, FAX, COURIER OR E-MAIL. IN ORDER TO ASSURE NO VENDOR RECEIVES AN UNFAIR ADVANTAGE, NO SUBSTANTIVE QUESTIONS WILL BE ANSWERED ORALLY. IF POSSIBLE, E-MAIL QUESTIONS ARE PREFERRED. ADDRESS INOUIRIES TO! ROBERTA WAGNÉR DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION 2019 WASHINGTON STREET EAST CHARLESTON, WW 253 DEFE REVERSE SIDE FOR TERMS AND CONDITIONS TELEPHONE SIGNATURE -13-09 732 <u>36</u>3152638 ADDRESS CHANGES TO BE NOTED ABOVE



800-232-1309

# Request for

RFQ NUMBER MCH90099

304-558-3417

-13-09

ADDRESS CHANGES TO BE NOTED ABOVE

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

25301

\*709024704 ANSELL HEALTHCARE PRODUCTS INC

Public Sector

ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

HEALTH AND HUMAN RESOURCES BPH - OMCFH MATERIALS MANAGEMENT 900 BULLITT STREET T CHARLESTON, WV

SHIP VIA FO.B. TERMS OF SALE FREIGHT TERMS DATE PRINTED <u> 12/10/2008</u> BID OPENING DATE: 01/08/2009 BID OPENING TIME 01:30PM QUANTITY UNIT PRICE AMOUNT LINE ITEM NUMBER FAX: 304-558-4115 E-MAIL: ROBERTA.A.WAGNER@WV.GOV THIS CONTRACT BECOMES EFFECTIVE ON LIFE OF CONTRACT: FEBRUARY 1, 2009 AND EXTENDS FOR A PERTOD OF ONE (1) YEAR OR UNTIL SUCH "REASONABLE TIME" THEREAFTER AS IS NECESSARY TO OBTAIN A NEW CONTRACT OR RENEW THE DRIGINAL CONTRACT THE "REASONABLE TIME" PERIOD SHALL NOT EXCEED TWELVE (12) MONTHS. DURING THIS "REASONABLE TIME" THE VENDOR MAY TERMINATE THIS CONTRACT FOR ANY REASON UPON GIVING THE DIRECTOR OF PURCHASING 30 DAYS WRITTEN NOTICE. UNLESS SPECIFIC PROVISIONS ARE STIPULATED ELSEWHERE IN THIS CONTRACT DOCUMENT, THE TERMS, CONDITIONS AND PRICING SET HEREIN ARE FIRM FOR THE LIFE OF THE CONTRACT. RENEWAL: THIS CONTRACT MAY BE RENEWED UPON THE MUTUAL WRITTEN CONSENT OF THE SPENDING UNIT AND VENDOR, SUBMITTED TO THE DIRECTOR OF PURCHASING THIRTY (30) DAYS PRIOR TO THE EXPIRATION DATE. SUCH RENEWAL SHALL BE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE original contract and shall be limited to two (2) one (1) YEAR PERIODS. CANCELLATION: THE DIRECTOR OF PURCHASING RESERVES THE RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES Supplied are of an inferior quality or do not conform TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN. SEE REVERSE SIDE FOR TERMS AND CONDITIONS

TELEPHONE

732345 5338



# Request for

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RFQ NUMBER MCH90099

ADDRESS CORRESPONDENCE TO ATTENTION OF:

ADDRESS CHANGES TO BE NOTED ABOVE

ROBERTA WAGNER B04-558-0067

\*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

FREIGHTTERMS DATE PRINTED TERMS OF SALE SHIP VIA F.O.B. 12/10/2008 BID OPENING DATE 01/08/2009 01:30PM BID OPENING TIME QUANTITY UOP AMOUNT. LINE ITEM NUMBER UNITPRICE DPEN MARKET CLAUSE: THE DIRECTOR OF PURCHASING MAY AUTHORIZE A SPENDING UNIT TO PURCHASE ON THE OPEN MARKET, WITHOUT THE FILING OF A REQUISITION OR COST ESTIMATE, ITEMS SPECIFIED ON THIS CONTRACT FOR IMMEDIATE DELIVERY IN EMERGENCIES DUE TO UNFORESEEN CAUSES (INCLUDING BUT NOT LIMITED TO DELAYS IN TRANS-PORTATION OR AN UNANTICIPATED INCREASE IN THE VOLUME OF WORK.) QUANTITIES: QUANTITIES LISTED IN THE REQUISITION ARE APPROXIMATIONS ONLY, BASED ON ESTIMATES SUPPLIED BY THE STATE SPENDING UNIT. IT IS UNDERSTOOD AND AGREED THAT THE CONTRACT SHALL COVER THE QUANTITIES ACTUALLY ORDERED FOR DELIVERY DURING THE TERM OF THE CONTRACT, WHETHER MORE OR LESS THAN THE QUANTITIES SHOWN. DRDERING PROCEDURE: SPENDING UNIT(S) SHALL ISSUE A WRITTEN STATE CONTRACT ORDER (FORM NUMBER WV-39) TO THE VENDOR FOR COMMODITIES COVERED BY THIS CONTRACT. THE ORIGINAL COPY OF THE WV-39 SHALL BE MAILED TO THE VENDOR AS AUTHORIZATION FOR SHIPMENT, A SECOND COPY MAILED TO THE PURCHASING DIVISION, AND A THIRD COPY RETAINED BY THE SPENDING UNIT. IN THE EVENT THE VENDOR/CONTRACTOR FILES BANKRUPTCY: FOR BANKRUPTCY PROTECTION, THIS CONTRACT IS AUTOMATI-CALLY NULL AND VOID, AND IS TERMINATED WITHOUT FURTHER ORDER. THE TERMS AND CONDITIONS CONTAINED IN THIS CONTRACT SHALL SUPERSEDE ANY AND ALL SUBSEQUENT TERMS AND CONDITIONS WHICH MAY APPEAR ON ANY ATTACHED PRINTED DOCUMENTS SUCH AS PRICE LISTS, ORDER FORMS, SALES AGREEMENTS OR MAINTENANCE AGREEMENTS, INCLUDING ANY ELECTRONIC MEDIUM SUCH AS CD-ROM. SEE REVERSE SIDE FOR TERMS AND CONDITIONS SIGNATURE TELEPHONE 1-13-09 5338



VENDOR

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

## Request for

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RFQ NUMBER MCH90099

ADDRESS CORRESPONDENCE TO ATTENTION OF:

ADDRESS CHANGES TO BE NOTED ABOVE

ROBERTA WAGNER 304-558-0067

\*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

TERMS OF SALE SHIP VIA FOB: FREIGHT TERMS DATE PRINTED 12/10/2008 BID OPENING DATE: 01:30PM 01/08/2009 BID OPENING TIME CAT NO AMOUNT QUANTITY UOP ITEM NUMBER UNIT PRICE LINE EXHIBIT 6 PRICE ADJUSTMENT PROVISION: THE STATE OF WEST VIRGINIA WILL CONSIDER PRICE ADJUSTMENTS AT THE TIME OF RENEWAL, PROVIDED THAT SUCH PRICE ADJUSTMENT COVERS BOTH UPWARD AND DOWNWARD THE COMMODITY PRICE, AND THAT ADJUSTMENT IS MOVEMENT OF BASED ON THE "PASS THROUGH" INCREASE OR DECREASE OF RAW MATERIALS AND/OR LABOR!, WHICH MAKE UP ALL OR A SUBSTANTIAL PART OF A PRODUCT. ADJUSTMENTS ARE TO BE BASED UPON AN ACTUAL DOLLAR FIGURE, NOT A PERCENTAGE. ALL PRICE ADJUSTMENT REQUESTS MUST BE \$UBSTANTIATED IN A MANNER ACCEPTABLE TO THE DIRECTOR PURCHASING, E.G. GOVERNMENTAL BENCH MARKS, GENERAL MARKET INCREASE, PUBLISHED PRICE LISTS. SUCH REQUESTS FOR AND INCREASE SHOULD BE RECEIVED IN WRITING BY THE DIRECTOR OF PURCHASING AT LEAST 30 DAYS IN ADVANCE OF THE EFFECTIVE DATE OF THE INCREASE. ANY TIME THE VENDOR REQUESTS A PRICE ADJUSTMENT, THE PURCHASING DIVISTON MAY EITHER ACCEPT THE PRICE ADJUSTMENT AND AMEND THE CONTRACT ACCORDINGLY OR REJECT THE ADUSTMENT IN ITS ENTIRETY AN CANCEL THE CONTRACT. THE MODEL/BRAND/SPECIFICATIONS NAMED HEREIN ESTABLISH THE ACCEPTABLE LEVEL OF QUALITY ONLY AND ARE NOT INTENDED TO REFLECT A PREFERENCE OR FAVOR ANY PARTICULAR BRAND OR VENDOR. VENDORS WHO ARE BIDDING ALTERNATES SHOULD SO STATE AND INCLUDE PERTINENT LITERATURE AND SPECIFICATIONS. FAILURE TO PROVIDE INFORMATION FOR ANY ALTERNATES MAY BE ¢ROUNDS FOR REJECTION OF THE BID. THE STATE RESERVES THE RIGHT 'O WAIVE MINOR IRREGULARITIES IN BIDS OR SPECIFICATION SEE REVERSE SIDE FOR TERMS AND CONDITIONS TELEPHONE SIGNATURE 13-09 5338 732

363152638



# Request for

RFQ NUMBER MCH90099 6

ADDRESS CORRESPONDENCE TO ATTENTION OF

304-558-3417

ADDRESS CHANGES TO BE NOTED ABOVE

ROBERTA WAGNER <u> 304-558-0067</u>

25301

\*709024704

800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN: PUBLIC SECTOR

200 SCHULZ DRIVE RED BANK NJ 07701

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

SHIP VIA F.O.B. DATE PRINTED TERMS OF SALE FREIGHT TERMS 12/10/2008 BID OPENING DATE: 01/08/2009 01:30PM BID OPENING TIME CAT AMOUNT LINE QUANTITY UOP ITEM NUMBER UNIT PRICE NO IN ACCORDANCE WITH SECTION 148-1-4(F) OF THE WEST VIRGINIA LEGISLATIVE RULES AND REGULATIONS. PURCHASING CARD ACCEPTANCE: THE STATE OF WEST VIRGINIA CURRENTLY UTILIZES A VISA PURCHASING CARD PROGRAM WHICH IS ISSUED THROUGH A BANK. THE SUCCESSFUL VENDOR MUST ACCEPT THE STATE OF WEST VIRGINIA VISA PURCHASING CARD FOR PAYMENT OF ALL ORDERS PLACED BY ANY STATE AGENCY AS A CONDITION OF AWARD. NOTICE AN ORIGINAL, SIGNED BID MUST BE SUBMITTED TO: DEPARTMENT OF ADMINISTRATION PURCHASING DIVISION BUILDING 15 2019 WASHINGTON STREET, EAST CHARLESTON, WV 25305-0130 PLEASE NOTE: A CONVENIENCE COPY WOULD BE APPRECIATED. BIDS MUST CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPES OR THE BIDS MAY NOT BE CONSIDERED: SEALED BID BUYER: RW-22 RFQ NO: MCH90099 BID OPENING DATE AND TIME 1/8/9 AT 1:30 PM PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID: SEE REVERSE SIDE FOR TERMS AND CONDITIONS TELEPHONE SIGNATURE



# Request for

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304-558-3417

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

25301

\*709024704

800-232-1309 ANSELL HEALTHCARE PRODUCTS INC

ATTN: PUBLIC SECTOR 200 SCHULZ DRIVE RED BANK NJ 07701

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

SHIP VIA FOB FREIGHT TERMS DATE PRINTED TERMS OF SALE 12/10/2008 BID OPENING DATÉ: BID OPENING TIME 01/08/2009 01:30PM LINE QUANTITY UOP ITEM NUMBER UNIT PRICE AMOUNT 732 219 5127 CONTACT PERSON (PLEASE PRINT CLEARLY): Christine Abel 732 345 5338 THIS IS THE END OF RFQ MCH90099 \*\*\*\*\* TOTAL: SEE REVERSE SIDE FOR TERMS AND CONDITIONS TELEPHONE SIGNATURE -13-09 345 5338 732 ADDRESS CHANGES TO BE NOTED ABOVE

Requisition / P.O. No: MCH90099

Pages

#### STATE OF WEST VIRGINIA

STATE OF WEST VIRGIN	Δ	Page		CH90099
	TINUATION SHEET	File: 22	Acct. No.: SEE BELOW	,
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Vendor:	HIST	P.O Date:	OMCFH/FAMIL	MILY PLANNING			
Item No.	Quantity	Description		Únit Price	Amount		
	APPROX ANNUAL USAGE	OPEN END CONTRACT TO PROVIDE THE FOLLOWING FAPLANNING PRODUCTS:	AMILY				
1	1500 CS.	CONDOMS, 100% LATEX LUBRICATED, RESERVOIR TIP, COLOR, PACKAGING: 1000/CASE. LIFESTYLES #5800 OF					
2.	45 CS.	CONDOMS, 100% LATEX, NONLUBRICATED, RESERVOIR NEUTRAL COLOR, PACKAGING: 1000/CASE. LIFESTYLE EQUAL.					
	:	SPECIFICATIONS:					
		EACH INDIVIDUALLY PACKAGED CONDOM MUST BE LEG MARKED TO INCLUDE THE NAME OR TRADEMARK OF THE MANUFACTURER AND THE LOTS OR BATCH NUMBER. IN ADDITION, EACH INDIVIDUALLY PACKAGED CONDOM MUST CLEARLY INDICATE THE MANUFACTURE NAME, BRAND AND PRODUCT NUMBER FOR EACH ITEM LABEL OF THE PRODUCT TO BE SUPPLIED IDENTIFIES TO DISTRIBUTOR RATHER THAN THE MANUFACTURER, THE MUST INDICATE BOTH THE DISTRIBUTOR AND MANUFACTURER, AND COUNTRY OR ORIGIN, IN ADDITION TO THE FOUND DELIVERY ONLY THE PRODUCT SPECIFICALLY BID	HE  JST  ER'S  IF THE  HE  BIDDER  CTURER'S  PRODUCT				
		SAMPLES/DOCUMENTATION:					
		SAMPLES OF PRODUCT TO BE SUPPLIED UNDER CONTR WELL AS PRODUCT LITERATURE SHOULD ACCOMPANY FAILURE TO SUBMIT SAME DISQUALIFIES BID					
		CONDOM SPECIFICATION FOR EACH STYLE AND TYPE CONDOM QUOTED SHOULD ACCOMPANY BID QUOTATION					
		CONDOM USAGE INSTRUCTIONS MUST BE INCLUDED WORDERS	TH ALL				
		FDA AND OTHER REQUIREMENTS:					
		VENDOR MUST CERTIFY THAT THE PRODUCT OFFERED ALL REQUIREMENTS OF THE AMERICAN SOCIETY FOR T AND MATERIALS ASTM D-3492-97, STANDARD SPECIFICATOR RUBBER CONTRACEPTIVES (MALE CONDOMS), AN AND DRUG ADMINISTRATION (FDA) REQUIREMENTS FOR MEDICAL DEVICES 21 CFR, PART 801	ESTING ATIONS D FOOD				
		A CERTIFICATE OF CONFORMANCE MUST BE PROVIDED THE SAMPLES SUBMITTED AND FOR EACH BATCH OR LO SUBMITTED UNDER THE CONTRACT					
		DOCUMENTATION/CERTIFICATIONS OF FDA 510 K PROD REGISTRATION NUMBER AND FDA SITE REGISTRATION I FOR THE MANUFACTURING FACILITY IS REQUIRED					

### STATE OF WEST VIRGINIA

## PURCHASE CONTINUATION SHEET

Page	of	Pages	Requisition / P.O. No : MCH90099
File: 22		Acct. No. SEE BE	
Spending		V PI ANNI	NG

Vendor:	An	se//	P O Date:	Spending Unit OMCFH/FAN	: MILY PLANNING	
Item No.	Quantity		Description		Unit Price	Amount
<del>,</del>		QUALITY ASS	URANCE:			
		RECALL THE	TOF SERIOUS PRODUCT COMP VENDOR/MANUFACTURER MUS TRACK EVERY SHIPMENT TO C IER.	ST HAVE THE ABILITY		
		CONTACT IND	ST PROVIDE A NAME AND PHON DIVIDUAL IN THE MANUFACTURI QUALITY ISSUES	E NUMBER OF A NG FACILITY	·	
		DOCUMENTAT ASSURANCE I	TON/CERTIFICATION OF MANUF PROCEDURES, IS REQUIRED	ACTURING QUALITY		
		MARKET AVAI				
		COUNTER AT	S BID MUST BE READILY AVAILA RETAIL OUTLETS IN WEST VIRO D STORES, MASS MERCHANDIS	SINIA , I E , DRUG		
		FREIGHT MUS	ST BE INCLUDED IN PRICE			
		NOTE: BIDS TO TO AWARD	O BE REVIEWED BY PROGRAM	DIRECTOR PRIOR		
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# COST SHEET FOR MCH90099

	A A			
#    2	Apprx. Annual Usage	DESCRIPTION	UNIT PRICE	TOTAL COST
	QUANTITY			1000
	<u> </u>	Condoms, 100% Latex Lubricated, Reservoir Tip.		
	ÝZ.	Neutral Packaging Lifestyples #5800 or Equal	,	
~	1,500 Cases Pkg	1,500 Cases Pkg Size: 1000/cs Mfg: Lifestyles	34.96	NA 446
	(			( ) ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
	<u> </u>	Condoms 100% Latex, Non-Lubricated, Reservoir Tip,		
	ΘN	Neutral Packaging, Lifestyle #5700 or Equal		-
2	45 Cases PK	45 Cases Pkg Size: 1000/cs Mfg: LifeStyles	77. 47	0,01
			00.00	22
	<u> </u>	TOTAL COST		() 1/2
				ー・シャン・

Contract may be awarded to multiple vendors based upon overall total cost per item which meets all requested specifications and requirements.

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.

#### STATE OF WEST VIRGINIA Purchasing Division

## PURCHASING AFFIDAVIT

#### **VENDOR OWING A DEBT TO THE STATE:**

West Virginia Code §5A-3-10a provides that: 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

## PUBLIC IMPROVEMENT CONTRACTS & DRUG-FREE WORKPLACE ACT:

West Virginia Code §21-1D-5 provides that: Any solicitation for a public improvement construction contract shall require each vendor that submits a bid for the work to submit at the same time an affidavit that the vendor has a written plan for a drug-free workplace policy in compliance with Article 1D, Chapter 21 of the West Virginia Code A public improvement construction contract may not be awarded to a vendor who does not have a written plan for a drug-free workplace policy in compliance with Article 1D, Chapter 21 of the West Virginia Code and who has not submitted that plan to the appropriate contracting authority in timely fashion For a vendor who is a subcontractor, compliance with Section 5, Article 1D, Chapter 21 of the West Virginia Code may take place before their work on the public improvement is begun

#### ANTITRUST:

In submitting a bid to any agency for the state of West Virginia, the bidder offers and agrees that if the bid is accepted the bidder will convey, sell, assign or transfer to the state of West Virginia all rights, title and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the state of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the state of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to the bidder.

I certify that this bid is made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership or person or entity submitting a bid for the same materials, supplies, equipment or services and is in all respects fair and without collusion or fraud I further certify that I am authorized to sign the certification on behalf of the bidder or this bid

#### LICENSING:

Vendors must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agencies or political subdivision Furthermore, the vendor must provide all necessary releases to obtain information to enable the Director or spending unit to verify that the vendor is licensed and in good standing with the above entities

#### CONFIDENTIALITY:

The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures and rules. Vendors should visit www.state.wv.us/admin/purchase/privacy for the Notice of Agency Confidentiality Policies

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

acknowledges the informe	^	11		
Maria da da Nama	Lincoll	Healthcare	Products LLC	_
Vendor's Name:		1 1001111		
Authorized Signature: 🙏	DD)	113/09	Date: /-05-09	
Authorized Signature: 🛆		1.510/		_

Purchasing Affidavit (Revised 07/01/08)

## 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,
<del></del>	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
	Bidder is a nonresident 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.
requirer against or dedu	understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the ments 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.
authoriz the requ deemed	nission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and tes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid uired 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
	penalty 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 as during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.
	Signed:
Date:_	Title:
*Check a	ny combination of preference consideration(s) indicated above which you are entitled to receive.

Not apply to Ansell Heathcare



RFQ COPY

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

ROBERTA WAGNER

STANDERS SECTION DENDERS TO A DESCRIPTION OF THE SECTION OF THE SE

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804-558-0067

HEALTH AND HUMAN RESOURCES

TYPE NAME/ADDRESS HERE BPH - OMCFH **Ansell Healthcare Products** MATERIALS MANAGEMENT 900 BULLITT STREET Public Sector - C. Abel CHARLESTON, WV 200 Schulz Drive 25301 304-558-3417 Red Bank NJ 07701

PATTERRINTED TERMS OF SALE SHIP YIA 50 GALE
01/05/2009
BID OPENING DATE: 01/15/2009 DTD OPENING TIME 01:30DM
ADDENDUM NO. 1
TO MOVE THE BID OPENING DATE FROM 1/8/9 TO 1/15/9.  2. QUESTIONS AND ANSWERS ARE ATTACHED.
ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT
should be signed and returned with your bid. Failure to
SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID.
EXHIBIT 10
DESCRIPTION AND A MOUDOGO
REQUISITION NO.: MCH90099
ADDENDUM ACKNOWLEDGEMENT
HEREBY ACKNOWLEDGE RECEIPT OF THE FOILOWING CHECKED
ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY
PROPOSAL, PLANS AND/OR SPECIFICATION, ETC.
ADDENDUM NO. S:
No. 1 .X
NO. 2
NO. 3
NO. 4
NO. 5
I UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF THE ADDENDUM(S) MAY BE CAUSE FOR REJECTION OF BIDS.
ADDENDUM(S) MAY BE CAUSE FOR REDECTION OF BIDD.
SEE REVERSE SIDE ROP TERMS AND CONDITIONS
SIGNATURE 10. DID 03 PATE /-13-09
ADDRESS CHANGES TO BE NOTED ABOVE
WHEN RESPONDING TO REQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

TYPE NAME/ADDRESS HERE



RFQ COPY

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

# Request for

MCH90099

MANAGORESSICORRESPONDENCE RICHARDENDION (USBRIDGE

ROBERTA WAGNER 304-558-0067

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

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WV-35 (Rev. 05/18/06)

# State of West Virginia Purchasing Division



# **PURCHASE REQUISITION**

Requisition No. MCH90099		0099	Buyer 22		Hequisition Pata 1/5/2008		
Agency/Invoice To:					WVFIMS Document#		
Agency/Invoice fo: WV DEPT, OF HEALTH & HUMA OMCFH/FAMILY PLANNING PRO 350 CAPITOL STREET, RM 427 CHARLESTON, WV 25301			N RESOURCES		Suggested Vendors:  1. 2.		
Aceney/Ship	Ta'		TEAM Code		<b></b>		
Agency/Ship To: WV DEPT, OF HEALTH & HUMA MATERIALS MANAGEMENT 900 BULLITT ST CHARLESTON, WV 25301					Additional Vendors on Reverse Side  PURCHASING DIVISION'S USEONLY		
This Section Vendor Name			Purchases, Emargancy Purchases a	end Agreements	Commodity Co	de:	
WVFIMS Ver	ndor#		TEAM Vendor #				
Terms -		- 10	FOB.			Unit Price	Amount
ltem No.	Quantity		Description		-	CHIL THOS	
	ļ		ADDENDUM #1 Type of Purchase		<del></del>		
		REGARDING QUESTION: V RFQ NOTED COMPETITIV RESPONSE: FROM THE L CONDOMS,	DUM IS BEING SUBMITTED ITHE ORIGINAL RFP SUBMIT WE ARE PREPARING TO SUE AND WANTED TO SEE IF YO E BID PRICING FROM THE P LISTED BELOW ARE THE PF AST CONTRACT.  100% LATEX, NON-LUBRICATED, F	TO ANSWER QUITED.  BMIT A BID FOR DU CAN PROVID PREVIOUS BID?  RODUCTS & PRITED, RESERVOI	ABOVE E CING IR TIP 538.00 CS		
Authorized Signature_	Ain		nev	Fotal Estimated of this Requisiti	d Value on:		
Title	pect		olk Sector.	Maximum Budi	geted Amount;		
Telephone_	732	345	5338		www.stat	iewv.us/admin/purch	as@



## STATEMENT OF PRODUCT INFORMATION

#### **Device Information**

<u>Description</u>	<u>510(k) Number</u>
LifeStyles Lubricated Lifestyles Non-Lubricated	K002393
Life Style S Nort-Lubricated	K053367

#### **Device Quality**

The products listed above are manufactured to meet the requirements of ASTM D3492 Standard Specification for Rubber contraceptives (Male Condoms). The product quality conforms to the Quality Inspection Requirements of ASTM D3492 as given below:

Characteristics	Inspection Level	<u>AQL (%)</u>
Dimensions	S-2	4.0
Air Burst Properties	1	1.5
Leakage	1	0.25
Package Integrity	S-3	2.5

ANSELL HEALTHCARE INC.

Lon D. McIlvain

Vice President, Regulatory Affairs

# **Ansell**

# ANSELL HEALTHCARE CERTIFICATE OF CONFORMANCE TO ASTM D3492

Ansell certifies that the product manufactured and packaged for this lot number was produced to current standard operating procedures and process specifications and will comply with the requirements of the standard for rubber contraceptives (condoms) for ASTM - D3492

PRODUCT: S53 CLEAR PRODUCT CODE: 600920 MFG DATE: 03/2007 LOT NUMBER: 07030276DT LOT SIZE: 1001.000 GROSS EXP DATE: 02/2012

SECT	<u>'ION</u>	DESCRIPTION	STANDARD	RESULT
3	Material		Natural Latex	Conforms
42	4.2 1.2	Length of Condom *Length of Condom (Large) Width of Condom *Width of Condom (Large) Wall Thickness of Condom	(min) 160mm (min) 180mm (max) 54mm (max) 58mm (min) 03mm	Conforms Conforms Conforms Conforms Conforms
4.4	Bursting V 4.4.1 4.4.2	Volume and Pressure Pressure Volume – 49mm Volume – 50/51mm Volume – 52mm Volume – 53/54mm Volume – 55mm Volume – 56mm	(min) 1.0 KPa (min) 14.0 Liters (min) 15.0 Liters (min) 16.0 Liters (min) 17.0 Liters (min) 18.0 Liters (min) 19.0 Liters	Conforms Conforms Conforms Conforms Conforms Conforms Conforms
4 5	Water Lea	kage	No Leakage	Conforms
5	Packaging 5 1 5 2	Packaging Packaging Integrity	As Required By Std 50 8 KPa	Conforms Conforms
60	Labelling		As Required By Std	Conforms
7.0	Storage		As Required By Std	Conforms
*Eva	entions decla	red in FDA 510(K)		

\*Exceptions declared in FDA 510(K)

Date: May 16, 2007 Form #0478-1/5 Diggs (Mood

**Quality Control Department** 

For and on behalf of Ansell Healthcare

NOTACONTROLLEDCOPY

# Ansell

# ANSELL HEALTHCARE CERTIFICATE OF CONFORMANCE TO ASTM D3492

Ansell certifies that the product manufactured and packaged for this lot number was produced to current standard operating procedures and process specifications and will comply with the requirements of the standard for rubber contraceptives (condoms) for ASTM - D3492.

PRODUCT: S53 THIN	LOT NUMBER: 07060332DT
PRODUCT CODE: 600893	LOT SIZE: 1043.000 GROSS
MFG. DATE: 06/2007	EXP. DATE: 05/2012

SECT	<u>'ION</u>	DESCRIPTION	STANDARD	RESULT
3	Material		Natural Latex	Conforms
4.2	Dimension 4.2.1.1 4.2.1.2 4.2.1.3	Length of Condom  *Length of Condom (Large)  Width of Condom  *Width of Condom (Large)  Wall Thickness of Condom	(min) 160mm (min) 180mm (max) 54mm (max) 58mm (min) 03mm	Conforms Conforms Conforms Conforms Conforms
4 4	Bursting V 4.4.1 4.4.2	Volume and Pressure Pressure Volume – 49mm Volume – 50/51mm Volume – 52mm Volume – 53/54mm Volume – 55mm Volume – 55mm Volume – 56mm	(min) 1.0 KPa (min) 14 0 Liters (min) 15 0 Liters (min) 16.0 Liters (min) 17.0 Liters (min) 18 0 Liters (min) 19 0 Liters	Conforms Conforms Conforms Conforms Conforms Conforms Conforms
4.5	Water Lea	kage	No Leakage	Conforms
5	Packaging 5.1 5.2	Packaging Packaging Integrity	As Required By Std. 50 8 KPa	Conforms Conforms
6 0	Labelling		As Required By Std	Conforms
7 0	Storage		As Required By Std	Conforms
*Exce	eptions decla	red in FDA 510(K)	For and an hahalf of Angall Heal	theara

Date: August 6, 2007

Form #0478-1/5

For and on behalf of Ansell Healthcare

**Quality Control Department** 



# STATEMENT OF COMPLIANCE / CONFORMANCE

Products manufactured by Ansell Healthcare Products Inc. for distribution under the provisions of this contract conform to the requirements of ASTM D3492 Standard Specifications for Rubber Contraceptives (Condoms) and meet or exceed the minimum specifications therein.

Packaged condoms, including dressing materials and compounding ingredients, are manufactured in compliance with the applicable FDA regulations in force at the time of manufacture.

Lon D. McIlvain

Vice President, Regulatory Affairs

**Date** 

# **Certificate of Registration**

**QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003** 

This is to certify that:

Ansell Healthcare Products LLC 1635 Industrial Road Dothan Alabama 36303 USA

Holds Certificate No. FM 76779

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

The packaging & distribution of latex condoms. For the legal manufacture of condoms, medical gloves & liquid personal lubricants for distribution into Canada.

For and on behalf of BSI:

President, BSI Management Systems America, Inc.

Originally registered: 10/17/2003

Latest Issue: 12/05/2007

Expiry Date: 12/04/2010

BSI



CMDCAS Recognized Registrar

Page: 1 of 1



Management Systems

This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated <u>online</u> Printed copies can be validated at www bsi-global com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.



### **CERTIFICATION STATEMENT**

To Whom It May Concern:

Ansell Healthcare is a manufacturer/distributor of latex condoms which are, by definition, medical devices. As a manufacturer/distributor of medical devices, Ansell is regulated by the United States Food and Drug Administration. The US FDA performs periodic site inspections to ensure compliance.

Condoms manufactured and distributed by Ansell meet or exceed the requirements set down by the American Society for Testing and Materials Standard D3492-08, International Standard Organization 4074 (ISO) and European Standard (EN600).

Ansell Healthcare in Dothan, Alabama, is registered under the FDA Registration of Medical Device Establishment Number 1019632

Tammy McGriff

**Quality Assurance Manager** 

Data

12-5-08



# ANSELL/SURETEX QUALITY ASSURANCE PROCEDURES

#### I. RAW MATERIAL

Each lot of raw materials is quarantined upon arrival and sampled for incoming inspection. The tests performed on these samples range from infrared and ultraviolet chemical analysis to visual and physical tests. Certificates of analysis from the vendors are reviewed against purchase specifications. A written specification exists for each raw material used in the product. When the raw material is accepted, it is released from quarantine for use. If it fails to meet the specification, it is rejected and returned to the vendor or reviewed by Material Review Board for final disposition.

#### II. LATEX COMPOUND

Liquid latex is mixed with vulcanization and processing chemicals to create the condom latex compound. Each batch of compound is assigned a lot number; the raw materials which go into the compound are listed by their own lot numbers to assure traceability. As each compound lot is finished, it is tested against specified parameters (pH, total solids, chemical and mechanical stability, degree of vulcanization, etc.)

#### III. DIPPING OF CONDOMS

As the condoms are being produced from the latex compound, various Statistical Process Control (SPC) checks are performed in-process to monitor the quality and to provide feedback to the manufacturing operations. Samples are taken from each product line and are tested by filling with 300 ml of water and examined for both visual and functional defects. Dimensional tests for thickness, length, weight are also conducted on samples from each machine. Data from all of the in-process tests are placed on hard copies (forms).

Samples of the latex compound from the dipping tanks are collected daily and checked for pH, total solids, and degree of vulcanization in order to maintain a consistent latex mix on the dipping lines.

Products are formed into lots at the dipping operation to ensure that traceability is maintained throughout the manufacturing processes

After each lot comes off the production line, the condoms are powdered and dried. Samples are taken from each lot to be tested for strength and dimensions.

#### IV. ELECTRONIC TESTING

All condoms are electronically tested for pinholes in the manufacturing area. This is accomplished by subjecting them to a high voltage test which rejects individual condoms with which, due to pinholes, allow current to be conducted across the rubber film.

Each electronic testing machine is validated prior to being put into service. In addition the equipment is continuously checked by examining statistically selected samples from each machine and utilizing the water test method throughout the production day.

# <u>Ansell</u>

If a machine is found to be malfunctioning, it is shut down and examined by the engineering staff and is not restarted until the problem is corrected. Product found to have failed testing by established statistical process control procedures is destroyed or is subjected to electronic testing again.

#### V, **PACKAGING**

Product that is released from electronic testing is packaged into various packaging configurations. Each of these packaging operations is monitored by a Statistical Process Control Procedure which involves the selection of product from the packaging line and testing for lubrication quantity, a water test for pinholes, the verification of lot number and expiry dating (which is stamped onto each individual condom pack or consumer pack) and for a vacuum test for package integrity.

#### VI. FINAL TESTING

In addition to the various tests listed above, condoms are also routinely tested for resistance to aging (by oven conditioning at elevated temperatures).

The U. S. Food and Drug Administration performs routine G.M.P. inspections.

Other tasks pertaining to ISO and QSR Regulations are also routinely carried out. These include, but are not necessarily limited to, calibration of equipment, self and vendor audits, validations, and investigation of complaints.

QA Manager

<u>//- 19-08</u> Date



8900

Strips of 1000's

# Ansell Public Sector- Price List

Issue Date: April 15, 2008

\$63.00

		FULL CASE		
CODE	PACK	QUANTITY	PRICE PER GROSS	PRICE PER CASE
4541	Strips of 1000's	1,000 Condoms		\$63.00
			49mm in width when laid flat	
The conventional condom r 5200	Strips of 1000's	1,000 Condoms	ser iit.	\$63.00
3240		1,000 0011001113		ψοσ.σσ
ifeStyles® Assorted Col	ors: Is produced in three o	colors: green, red, & ye	ellow. The pigments are in th	e latex itself and will
ot rub off. They are lubrica	ited, non-irritant and harm	less to the latex and u	ser. Popular with teens.	
5300	Strips of 1000's	1,000 Condoms		\$63.00
5303	Three Packs	12 gross	\$14.00	\$168.00
_ifeStyles® Ultra-Sensitiv			g heightened sensitivity.	
5400	Strips of 1000's	1,000 Condoms		\$63.00
ifoCtuloo@ Dibbod: Lubric				
.ifeStyles® Ribbed: Lubric Preferred by many women.	cated and designed with a	specially ribbed surface	ce to ennance sensation.	
5600	Strips of 1000's	1,000 Condoms		\$63.00
3000	Othps of 1000 s	1,000 Condoms		<u> </u> φου.υυ
ifeStyles® Lubricated: Is	the original lubricated cor	ndom-silky smooth lub	rication for a natural feeling.	Our Bost Seller
5800	Strips of 1000's	1,000 Condoms		\$60.00
5803	Three Packs	12 gross	\$14.00	\$168.00
5812	Twelve Packs	12 gross	\$12.75	\$153.00
5844	Strips of 144's	20 gross	\$11.00	\$220.00
· · · · · · · · · · · · · · · · · · ·				<u> </u>
ifeStyles® Extra Strength			-	
5900	Strips of 1000's	1,000 Condoms		\$63.00
5944	Strips of 144's	20 gross	\$11.00	\$220.00
ifeStyles® Tuxedo: Is a lu	thricated candom calared	in a midnight chada. A	V LifeCtules Evaluaine I	
6200	Strips of 1000's	1,000 Condoms	T LITESTYLES EXCLUSIVE !	\$63.00
0200	T Strips of 1000's	1,000 Condoms		<u> </u>
ifeStyles® Ultra-Thin: Thi	is is the thinnest LifeStyles	s condom available. A	lubricated condom, it offers	all the strength
f a traditional LifeStyles co	ndom.	o donadin arasabio. 7	rabilitation bottlebilit, it billion	an the strength
6400	Strips of 1000's	1,000 Condoms		\$63.00
				400.00
ifeStyles® Dual Pleasure	: A lubricated condom witl	n an oversized tip that	has an exclusive shape des	igned to
nhance friction, delivering h	neightened stimulation for	both partners.	·	•
6600	Strips of 1000's	1,000 Condoms		\$63.00
	, ,	•	ho prefer a more relaxed fit.	
feStyles XLarge measures			sures 52 mm.	
6700	Strips of 1000's	1,000 Condoms		\$63.00
itaChdaa@ Acaastad Elec	ava. A lubukasa da da ee	and the state of t	(I	
			ous flavors: Tropical Banana	ι,
/ild Strawberry, and Senuo 6800				<b>#00.00</b>
0000	Strips of 1000's	1,000 Condoms	11.00 th	\$63.00
ifeStyles® His N' Her Plea	asure: Special shape prov	ides mutual pleasure		
or Him: Proprietary Baggy		•	staned cancitivity	
ropilotally baggy		1 000 Condome	ACTION SCHOLLIVILY	¢62.00

1,000 Condoms

# Ansell

### Public Sector- Price List

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#### **NON - LUBRICATED CONDOMS**

LifeStyles® Kiss of Mint®: Is a non-lubricated condom scented with mint. For those seeking something different.

			PRICE
			DED DDICE DED
CODE	PACK	FULL CASE QUANTITY	GROSS CASE
5100	Strips of 1000's	1,000 Condoms	\$59.00

LifeStyles® Non-Lubricated Ultra Sensitive: Is a dry condom with a soft and pleasant finish.

For couples who prefer condoms without lubrication.

5700	Strips of 1000's	1,000 Condoms	\$59.00

#### SPERMICIDALLY LUBRICATED CONDOMS

LifeStyles® Spermicidally Lubricated with Nonoxynol-9: Contains Nonoxynol-9, the preferred spermicide, in the

lubricated shaped condom.

5500	Strips of 1000's	1,000 Condoms		\$63.00
5503	Three Packs	12 gross	\$14.00	\$168.00

#### **NON - LATEX CONDOMS**

**LifeStyles® SKYN**: The only condom made from a revolutionary **non-latex** material called polyisoprene. Delivers the strength of Premium Latex, with the sensitivity of an Ultra-Thin condom. Flexible material means extra comfort.

Available January 2009

7300	Strips of 1000's	1,000 Condoms	\$330.00

#### PERSONAL LUBRICANT

**LifeStyles® Liquid Personal Lubricant**: Is formulated with both Aloe Vera and Vitamin E to provide that smooth, silky sensation and help restore moisture to the skin Each easy open, single packet contains an ample supply of lubricant. Safe to use with latex condoms. Packets are convenient for travel and everyday use. Each sachet is 4.5 grams (0.158 oz)

7000	Strips of 1000's	1,000 Condoms	\$80.00

#### **ANSELL MEDICAL GLOVES**

Medi-Touch® Powder Free Exam Gloves - Latex Disposables: Powder free, beaded cuff, ambidextrous latex exam

glove that eliminates powder sensitivity complaints and powder related issues.

14-0070 - Small	50 gloves per box, 24 bx per CS	1,200 gloves per case	\$54.00
14-0080 - Medium	50 gloves per box, 24 bx per CS	1,200 gloves per case	\$54.00
14-0090 - Large	50 gloves per box, 24 bx per CS	1,200 gloves per case	\$54.00
50-9808 - One Size Fits All	100 gloves per box 12 bx per CS	1,200 gloves per case	\$48.00

Vinyl-Touch® Latex Free Synthetic Vinyl: Latex-Free - prevents the possibility of allergic reactions to latex proteins.

Medical quality, beaded cuff. Meets United States ASTM Quality Standards.

15-0181- One Size Fits All	50 gloves per box,	1,200 gloves per case	\$57.60
	24 bx per CS		

# Ansell Public Sector- Price List

### PROMOTIONAL/EDUCATIONAL ITEMS

ITEM	CODE	PRICE
Wooden Penis Educational Demo Model	5000	\$6.00 each
Discreet Condom Carrying Case:	5003	\$12.00 box
Holds 2-4 condoms, 75 Wallets per Box (20 bx per CS)		<u>                                     </u>
"How to Use" Instruction Leaflet: Easy to read, illustrated,	5007	\$18 00 box
English with Spanish Translation, 500 per box (50 per pack, 10 packs per box)		
New Teaching Sex Ed 101 MANUAL: Designed to help young people and adults feel more confident and competent dealing with sexual and social issues Each lesson contains objectives, rationales, recommended materials and step-by-step procedures.	5005	\$18 00 each
Sex Ed 101 KIT: Kit includes Easy-to-use Carry/Display Case; Teaching manual focused on safer sex education entitled Sex Ed 101: A Collection of Sex Education Lessons, LifeStyles® Brand Condoms T-Shirt (One Size Fits All); Penis Demo Model, 50 "How to Use" Leaflets; Lifestyles® Non-lubricated Condoms and a supply of brochures.	5006	\$50.00

Issue Date: April 15, 2008

#### **Quality Assurance**

Condoms are classified as a Class II Medical Device. All Ansell condoms are produced to the strictest standards established by the FDA. Every condom is electronically tested and rigorous quality control measures are enforced LifeStyles condoms are also in full compliance with the regulations set by numerous international standards organizations. Ansell, a world leader in latex technology, maintains worldwide manufacturing facilities, and uses the most modern technical facilities and expertise to manufacture condoms and medical gloves - both surgical & exam.

### **Storage Information**

Protect condoms against exposure to extreme low or high temperatures, moisture, direct sunlight and fluorescent light. Rotate condom inventory - use FIFO (first in, first out)

THE DATE STAMPED ON THE PACKAGE OR STRIPS IS THE EXPIRATION DATE

#### Additional Information

All Ansell condoms are made of latex, are transparent, and have a reservoir end

For our lubricated condoms, a natural feeling, silky lubricant is used. The lubricant is silicone based so it is non-irritating. If additional lubrication is desired, do not use oil-based lubricants (such as mineral oil, creams, or petroleum jelly) with latex condoms as this will result in deterioration of the product. We recommend LifeStyles Liquid Personal Lubricant or other water based or silicone lubricants.

Products containing natural rubber latex may cause allergic reactions.

Proper use and storage instructions included with all products.

#### Case Information

Strips 1,000's	Case dimensions: 12.50 L x 11.0 H x 9.50 W	Case Weight: 6.45lbs Case Cube: 0.738	
Strips 144's	Case dimensions: 12.25 L x 21.0 H x 14.5 W	Case Weight: 31.20 lbs Case Cube: 2.160	
3 packs	Case dimensions: 12.50 L x 11.0 H x 9.5 W	Case Weight: 18.20 lbs Case Cube: 1.584	

### A Variety of Packaging

Three Packs Selling Unit: 1 gross, 48 packages of 3, display box Twelve Packs Selling Unit: 1 gross, 12 packages of 12, display box Strips 144's Selling Unit: 1 gross, 48 strips of 3, plain white box

Strips 1,000's Selling Unit: 1,000 condoms, bulk packed in corrugated carton

Public Sector - Price List Issue Date: April 15, 2008

#### Ways to Order

Call Toll Free: 1-800-327-8659, Order by Fax: 1-800-722-8155

Order by Email: psinfo@ansell.com. Include Account #, Contact Name, & Phone # with your order

Send Written orders to: Ansell Public Sector, 200 Schulz Drive, Red Bank, NJ 07701

#### **Payment Terms**

Open Account - 30 days

Remit all payments to: Dept CH 17373, Palatine IL 60055-7373

Cash in advance - please send order and payment to Public Sector Red Bank address

VISA & MASTERCARD cards accepted

# **Shipping Policy for Condoms, Lubricants & Medical Gloves**

1. Minimum order requirement: \$175.00

- 2. FOB Destination
- 3. Ground freight prepaid if delivery is within continental US. Shipping charges added to all other orders
- 4. Selection of freight carrier shall be made by Ansell Healthcare Products LLC.
- 5. Truckers are required to make deliveries to an inside, street level area immediately adjacent to the entrance. If delivery elsewhere in the building is required, this will be arranged upon request with order and the customer will be invoiced for the additional *inside delivery* charges.

#### **Return Goods Policy**

- 1. All sales are final. No returned product will be accepted without prior written authorization.
- 2. We will investigate any product complaints by requesting written documentation of the complaint along with the return of samples for testing. If, as a result of this examination, defects in workmanship or materials are indicated or any doubt remains after testing, return of the production lots in question will be authorized and appropriate adjustments made to the account. Please direct any questions to Ansell Public Sector Customer Service. **Call 1-800-327-8659**
- 3. Customer errors in ordering subject to a 10% restocking fee. Unopened boxes accepted within 30 days of purchase. Prior authorization from Customer Service is required.

### **Customer Service & Inquiries**

- 1. Please address correspondence concerning deliveries, damaged merchandise or other matters related to your order to: Ansell Public Sector- Customer Service, 200 Schulz Drive, Red Bank, NJ 07701 1-800-327-8659
- 2. General Correspondence should be directed to:

Ansell Public Sector, 200 Schulz Drive, Red Bank, NJ 07701 Attn:Public Sector OR email psinfo@ansell.com

3. For general questions not pertaining to individual orders, please call: 1-800-232-1309 Ext 5338 Visit us at www.lifestyles.com/sexualhealth

#### Important Delivery Receipt Requirements

Proper care must be taken by the customer upon delivery of the product. Customer *must* count and inspect for shortages or damage. Any discrepancy *must* be noted on the delivery receipt and promptly reported to Customer Service at 1-800-327-8659

Where required, Ansell will charge the appropriate state & local sales tax. If your organization has a sales tax exemption certificate, please photocopy and submit to Customer Service along with contact name and phone number. In states where we are required to collect sales tax, we must have a copy of the sales tax exemption certificate on file or we must charge the appropriate tax.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

AUG 1 9 1999

Suretex Prophylactics (India) LTD.
c/o Mr. Lon D. McIlvain
Quality Assurance/Regulatory Manager
Ansell Healthcare Products Inc.
1500 Industrial Road
Post Office Box 1252
Dothan, Alabama 36302

Re: K992081

LifeStyles® and Tuxedo® Black Color Male Latex Condoms

Dated: June 18, 1999 Received: June 21, 1999 Regulatory Class: II

21 CFR §884 5300/Procode: 85 HIS

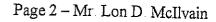
Dear Mr. McIlvain:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895 A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations





This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR 884 5300 and 884 5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR 801 435. Therefore, an expiration date, supported by test data developed under the conditions specified in 801 435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, 801 435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, 801 435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in 801 435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616 Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807 97) Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number: (800) 638-2041 or (301) 443-6597, or at its Internet address: "http://www.fda.gov/cdrh/dsma/dsmamain.html"

Sincerely yours,

CAPT Daniel G Schultz, M D.

Acting Director, Division of Reproductive,

Abdominal, Ear, Nose and Throat,

and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health



**(1)**