This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

>WPMAIL -DEC -ECHO
MAIL ALL-FIELD ORA-ORO 'Condoms'

Subject: Condoms
To: All Regional Directors
All District Directors
All Directors of Investigators Branches
All Directors of Laboratories
WPMAIL VERSION 001.5b

All Directors of Compliance
Director of Regional Operations ORA-ORO
From: Director, Division of Compliance OperatPrepare your diskette/cassette and begin sending.
ions
CDRH, HFZ-320

Condoms: 1)Inspection of and Sampling at Domestic Manufacturers
2)Inspection of and Sampling of all Repackers
3)Sampling from all Importers

See Below

BACKGROUND

The question of the effectiveness of condoms in the prevention of Acquired Immune Deficency Syndrome (AIDS) and other sexually transmitted disease's (STDs) is gaining attention at a rapid rate.

Meetings were held between the Commissioner and his immediate staff to determine what measures CDRH would take to evaluate condoms in light of the increased use by individuals attempting to prevent the spread of STDs. As a result of these meetings a decision was made to provide a letter of guidance to all known manufacturers, repackers and importers (Appendix A); increase attention to consumer education regarding condom use and disease prevention, initiate a major effort at industry surveillance by all field offices, and revise the current CPG7124.21 "Prophylactics-Adulteration; Defects (10/01/80)."

INSPECTION

A. Manufacturers

All district's whose inventory includes condom manufacturers are requested to conduct complete GMP inspections at each manufacturer as soon as possible. Known manufacturers are listed in Appendix B. Special emphasis should be placed on a complete description of manufacturing, complaint file review, quality control testing criteria and release procedures, calibration of test equipment, and validation performed to establish the adequacy of the tests. In addition, please determine the number of batches produced since the last inspection and the release/quarantine status of batches that had more than four defective condoms per thousand. Submit as exhibits, one complete batch record, randomly selected from each week's production going back twenty (20) weeks from the time of inspection (a total of 20 complete batch records). Submit current labels and labeling.

their products for the prevention of STDs including AIDS. If they intend to promote their product for use in the prevention of STDs, including AIDS determine what testing they have done or plan to do to support their claims. If a manufacturer produces both latex and "natural" condoms, report the information for each of the two separately. Be sure to report the firm's coding procedure and breakdown.

In addition, please determine the history of bulk sale to repackers for the last six months and forward a list of consignees and amounts to the respective districts for follow up in the event that there are new firms not in the respective districts files.

B. Repackers

All districts with repackers please inspect each one with special emphasis on product handling, finished product testing if any, and complaint file review. Please obtain labels and labeling in current use and determine any changes management intends to make in light of the STDs problem as previously described. If batch testing records are maintained, collect at least five (5) complete batch records.

C. Importers

Sample each entry from receipt of the assignment through May 22, 1987 or up to a minimum of six (samples) per foreign manufacturer.

D. Correspondence

Lastly, if the attached letter has not been received by the manufacturer, repacker,or importer, please provide a copy.

SAMPLE COLLECTION

Collect only latex condoms unless the "natural" condoms are promoted for use in the prevention of STD's. Collect three samples of each type of latex condom (ex. ripple end, ribbed etc.) on a surveillance basis. Collect additional samples if warranted by the inspection.

For repackers, collect three surveillance samples per repacker unless additional samples are warranted.

Refer to Appendix C for sample sizes.

Laboratory Analysis

Analysis of samples should be done by the Home District or Servicing Laboratory. Testing procedures should be in accordance with current water test methodology.

A copy of all EIR's, laboratory records, etc. should be sent to Frank Pipari, HFZ-323, 8757 Georgia Avenue, Silver Spring, Maryland 20910. Use a one day delivery service. Frank will also be available to answer any questions at 8-427-8040.

This assignment has concurrence of ORO.

If a lot of condoms is rejected using the criteria in this assignment, please contact Frank Pipari, HFZ-323, at 427-8040 for guidance until a revised CPG is issued.

ORO contact for investigational questions, call 8-443-3340.
ORO contact for scientific questions, call 8-443-3007.

Please note: A signed copy of the letter to "All U.S. Condom Manufacturers, Importers and Repackagers" which was mailed on April 7, 1987 will be sent under seperate cover.

William H. Damaska

Attachments

PC:	85
Priority:	High
PAC:	82Z002
Est. Comp. Time:	8 hours per inspection 4 hours per sample collections
Est. Comp. Date:	June 5, 1987 for all EIR laboratory test results etc.

Addressees: All Regional Directors
All District Directors

cc: All Directors of Investigators Branches
All Directors of Laboratories
All Directors of Compliance
Director of Regional Operations ORA-ORO

Appendix B

Known Domestic Condom Manufacturers

Ansell, Inc.
Henderson Highway
Troy, Alabama 36081

Apex Medical Corporation
807 West 106th Street
Bloomington, Minnesota 55420

Carter-Wallace, Inc.
310 Enterprise Avenue
Trenton, New Jersey 08638

Circle Rubber Corporation
408 Frelinghuysen Avenue
Newark, New Jersey 07114

Dean Rubber Company, Inc.
1601 Iron Street
North Kansas City, Missouri 64116

HDC Corporation
2531 Casey Avenue
Mountain View, California 94043

National Sanitary Laboratories, Inc.
7150 N. Ridgeway
Lincolnwood, Illinois 60645

Ortho Pharmaceutical Corporation
Route 202
Raritan, New Jersey 08869

Schmid Laboratories, Inc.
U.S. Highway #29 South, RFD #6
Anderson, South Carolina 29622

and

Route 40 West
Little Falls, New Jersey 07424

Mentor Corporation
2700 Freeway Boulevard
Suite 750
Brooklyn Center, Minnesota 55430

Orox Corporation
8175 Kroger Farm Road
Cincinnati, Ohio 45243

Appendix C
Sampling Inspection Plan

1. Sample Collection

Each sample consists of one lot per code number

Lot Size	Number of Condoms/Sample
Up to 35,000 Condoms (69 - 242 Gross)	576 (4 Gross)
35,001 - 150,000 Condoms (242 - 1035 Gross)	1008 (7 Gross)
150,001 - 500,000 Condoms (1035 - 3450 Gross)	1440 (10 Gross)

Collect the condoms randomly and representatively across the lot. All sample sizes above consist of more condoms than the maximum number of condoms to be tested under the sample examination plans below. The additional condoms are included as an acommodation to the industry's quantitative packaging practices.

2. Sample Examination

Single and multiple sampling plans are presented below for the various lot sizes. The laboratory may determine which option to select. Examination may cease after information is sufficient to determine the accept/reject status of the lot.

Lot Size up to 35,000

Single Sampling Plan	Sample Size	No. of Defective Units	
		Accept	Reject
	Up to 315	3	4

Multiple Sampling Plan		(cumlative)		
Sample	1st 80	80	*	3
	2nd 80	160	0	3
	3rd 80	240	1	4
	4th 80	320	2	5
	5th 80	400	3	6
	6th 80	480	4	6
	7th 80	560	6	7

* acceptance is not possible at this stage

Lot size 35,001 to 150,000

Single Sampling Plan	Sample Size	No. of Defective Units	
		Accept	Reject
	Up to 500	5	6
Multiple Sampling Plan	**(cumlative)**		
Sample 1st 125	125	*	4
2nd 125	250	1	5
3rd 125	375	2	6
4th 125	500	3	7
5th 125	625	5	8
6th 125	750	7	9
7th 125	875	9	10

* acceptance is not possible at this stage

Lot Size 150,001 to 500,000

Single Sampling Plan	Sample Size	No. of Defective Units	
		Accept	Reject
	Up to 800	7	8
Multiple Sampling Plan	**(cumlative)**		
Sample 1st 200	200	0	4
2nd 200	400	1	6
3rd 200	600	3	8
4th 200	800	5	10
5th 200	1000	7	11
6th 200	1200	10	12
7th 200	1400	13	14

Clearance Record
Prep:FPipari:3/4/87
dt:dde:3/4/87
Rev:CBender:HFC-230:3/9/87
Rev:TJohnson:HFC-133:3/9/87
Init:JABittenbender:3/24/87
rd:dde:3/24/87
Rev:CBender:3/25/87
Init:JABittenbender:3/25/87
rd:dde:3/25/87
Init:WGundaker:HFZ-300:3/25/87
Concur:PBWhite:HFZ-80:3/27/87
Rev:TRJohnson:HFC-133:3/31/87
Rev:MHeller:GCF-1:4/1/87
Concur:LHorton:GCF-1:4/1/87
rd:CBender:HFC-230:4/2/87 (DCP#87-345)
tp:imr:HFC-230:4/2/87
Concur:WDamaska:HFC-320:4/3/87
cc:
HFZ-80 (White)
HFZ-323 (FP, RF)
HFZ-320
HFZ-300
HFC-200
HFC-210
HFC-220 (Howard)
HFC-102
HFC-133 (Johnson)
GCF-1 (Horton)
HFA-224