*Lot Size 150,001 to 500,000

Multiple Sampling Plan	No. of Condoms to be Examined (Cumulative)	No. of Defective Condoms Accept	Reject
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

Lot Size 500,001 and Greater

Multiple Sampling Plan	No. of Condoms to be Examined (Cumulative)	No. of Defective Condoms Accept	Reject
Sample 1st 315	315	0	5
2nd 315	630	3	8
3rd 315	945	6	10
4th 315	1260	8	13
5th 315	1575	11	15
6th 315	1890	14	17
7th 315	2205	18	19*

Material between asterisks is new or revised

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CHAPTER 24 - DEVICES

SUBJECT: *Condoms; Defects - Criteria for Direct Reference Seizure*

BACKGROUND:

The FDA has had a long history of seizure actions against condoms because of defects. On June 4, 1968, FDA issued a plan for the sampling and examination of condoms which provided the basic criteria for direct reference seizures of defective condoms in the Administrative Guideline 7424.03, published January 1, 1973. *The direct reference seizure authority was rescinded on October 1, 1980, in the Compliance Policy Guide 7124.21, "Prophylactics - Adulteration; Defects" when the Bureau of Medical Devices chose to review the FDA inspection sampling criteria as well as sampling criteria set forth in other specifications and standards used to determine the acceptability of lots of condoms.*

*After completing its review of the inspection sampling criteria, FDA altered its position to bring it more in line with the American Society for Testing Materials (ASTM) "Standard Specification for Rubber Contraceptives (Condoms)". "Designation: D3492-83". This is the voluntary standard that is available to domestic latex condom manufactures to assess the quality of their medical devices. *According to this voluntary standard, the Acceptable Quality Level (AQL) for leakage is at 0.4%, or not to exceed 4 leaking condoms per 1000 condoms.

For purposes of FDA's sampling inspection plan, the AQL of 0.4% is the value of the maximum percent defective for leakage that will be considered satisfactory as a process average. *In this regard, the sampling inspection plan used by FDA emphasizes protection against the rejection of lots where the percent defective is less than or equal to 0.4%.*

The sampling inspection plan used by FDA has been extracted from MIL-STD-105D, (the military standard for "Sampling Procedures and Tables for Inspection by Attributes"), based on an AQL of 0.4%, inspection level II, and normal inspection. Single sampling will be used for lots less than or equal to 3200. For lots greater than 3200, multiple sampling will be used. The FDA plan is described in Attachment A - Sampling Inspection Plan.

REGULATORY ACTION GUIDANCE:

Lots of condoms that are rejected based on the criteria in Attachment A - Sampling Inspection Plan are subject to direct reference seizure. Districts should forward seizure recommendations to the Division of Compliance Management and Operations (HFC-210).

SPECIMEN CHARGES:

*Note: Charges for seizure of devices do not include allegations of shipment in interstate commerce because allegations of interstate commerce are not required to support seizure of devices [see section 304(a)(2)] and FDA's jurisdiction to bring enforcement actions involving devices is presumed under section 709 of the Federal Food, Drug, and Cosmetic Act (the Act).

1. For lots that exceed an AQL of 0.4%, charge:

   "That the article of device is adulterated within the meaning of the Act, 21 U.S.C. 351(c), in that it is not subject to 21 U.S.C. 351(b) and its quality falls below that which it purports or is represented to possess in that the devices contain defects/holes."

2. If the condoms are labeled for the prevention of disease, also charge:

   "That the article of device is misbranded within the meaning of the Act, 21 U.S.C. 352(a), in that its labeling 'for the prevention of disease' is false and misleading, because the article contains holes."

3. If the lot to be seized was repacked by the dealer, and it is believed that holes may have occurred during repacking, add a statement to the examination paragraph of the complaint similar to the following:

   "(Insert name of firm) repacked the article of device from bulk stock after receipt in interstate commerce."*

Sampling Inspection Plan

1. Sample Collection

*Lot Size

	Sample Size	
	Minimum Number of Condoms/Sample	Maximum Number of Condoms/Sample
0 - 500 Condoms	32	36 (1/4 Gross)
501 - 3,200 Condoms	125	144 (1 Gross)
3,201 - 10,000 Condoms	350	432 (3 Gross)
10,001 - 35,000 Condoms	560	576 (4 Gross)
35,001 - 150,000 Condoms	875	1008 (7 Gross)
150,001 - 500,000 Condoms	1400	1440 (10 Gross)
500,001 Condoms or Over	2205	2305 (16 Gross)*

Collect the condoms randomly and representatively across the lots. *All sample sizes listed above under the column headed "Maximum Number of Condoms/Sample" are included as an accommodation to the industry's quantitative packaging practices, and consist of more condoms than will be tested under the sample examination plan below.*

2. Sample Examination

Two single and five multiple sample examination plans are presented below for various lot sizes. Examination may cease when a lot is determined to be violative.

Material between asterisks is new or revised

*Lot Size 0 to 500			
Single Sampling Plan	No. of Condoms to be Examined	No. of Defective Condoms Accept	Reject
	32	0	1

Lot Size 501 – 3,200			
Single Sampling Plan	No. of Condoms to be Examined	No. of Defective Condoms Accept	Reject
	125	1	2

Lot Size 3,201 to 10,000			
Multiple Sampling Plan	No. of Condoms to be Examined (Cumulative)	No. of Defective Condoms Accept	Reject
Sample 1st 50	50	#	2
2nd 50	100	0	3
3rd 50	150	0	3
4th 50	200	1	4
5th 50	250	2	4
6th 50	300	3	5
7th 50	350	4	5

#Acceptance is not possible at this stage*

Material between asterisks is new or revised

*Lot Size 10,001 to 35,000

Multiple Sampling Plan	No. of Condoms to be Examined (Cumulative)	No. of Defective Condoms Accept	Reject
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

Multiple Sampling Plan	No. of Condoms to be Examined (Cumulative)	No. of Defective Condoms Accept	Reject
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*

Material between asterisks is new or revised