

CPG Sec. 345.100 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 The direct reference seizure authority was rescinded on October 1, 1980, in the Compliance Policy Guide 7124.21 (See Sec. 310.100), "Prophylactics - Adulteration; Defects" when the Bureau of Medical Devices chose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 manufacturers 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 *or* 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."

Attachment A 7124.21

Sampling Inspection Plan

1. Sample Collection

Sample Size

Minimum # Maximum

*Lot Size of Condoms of Condoms

0-500 32 36 (1/4 Gross)

501 - 3,200 125 144 (1 Gross)

3,201 - 10,000 350 432 (3 Gross)

10,001 - 35,000 560 576 (4 Gross)

35,001 - 150,000 875 1008 (7 Gross)

150,001 - 500,000 1400 1440 (10 Gross)

500,001 - Over 2205 2304 (16 Gross)*

Collect the condoms randomly and representatively across the lots. *All sample sizes listed above under the column headed "Maximum Number of Condoms/Samples" 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.

Single Sample Plan for Lot Size 0 - 500

Exam Number of Defective Condoms

Condoms Accept Rejected

32 0 1

Single Sample Plan for Lot Size 501 to 3,200

Exam Number of Defective Condoms

Condoms Accept Rejected

125 1 2

Multiple Sample Plan for Lot Size 3,201 to 10,000

Exam Number of Defective Condoms

Condoms Cumulative Accept Rejected

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*

Multiple Sample Plan for Lot Size 10,001 to 35,000

Exam Number of Defective Condoms

Condoms Cumulative Accept Rejected

1st 80 80 @ 3

2nd 80 160 0 3

3rd 80 240 1 45

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*

Multiple Sample Plan for Lot Size 35,001 to 150,000

Exam Number of Defective Condoms
Condoms Cumulative Accept Rejected

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*

Multiple Sample Plan for Lot Size 150,001 to 500,000

Exam Number of Defective Condoms
Condoms Cumulative Accept Rejected

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

Multiple Sample Plan for Lot Size 500,001 and Greater

Exam Number of Defective Condoms
Condoms Cumulative Accept Rejected

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

Issued: 01/01/73

Revised: 12/30/87, 3/95

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