Ansell

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May 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02D-0103
Draft Revised Compliance Policy Guide; Male Condom Defects

Dear Sir or Madam:

Ansell Healthcare Inc. ("Ansell"), a major manufacturer of condoms for the United States and international markets, submits these comments on the above-referenced Draft Revised Compliance Policy Guide, notice of which was published in the Federal Register of March 29, 2002 (67 Fed. Reg. 15213). Ansell Healthcare Inc. is the manufacturer and marketer of LifeStyles® and other brands of latex condoms.

Lowering the AQL on Imported Condoms to 0.25

Ansell concurs with the proposal to lower the AQL on imported condoms to 0.25 and to introduce air burst testing under the circumstances described in the draft. The world's major condom standards have contained these requirements and Ansell and most other manufacturers have been complying with them for years.

Serious Concern with the "Recidivist Policy"

However, with the lowering of the AQL for holes, we now have a serious concern with the "Recidivist Policy", which prescribes a three-level progression of detention, the final consequence being a Warning Letter and cessation of shipments to the USA for the offending firm. Progression up the detention ladder is halted only by a firm suffering no failure of an incoming condom shipment for two years.

The root of our concern lies in the "producer's risk", which is inherent in the sampling plans of ISO 2859-1 (or its American equivalent ANSI/ASQC Z1.4-1993). Briefly, this is the risk that a test of a sample can yield a "fail" disposition, although the population from which the sample came actually meets the quality requirement. Most sampling plans are designed nominally to accept lots which just meet the AQL about 95% of the time. Conversely, about 5% of the time, or 1 lot in 20, lots just meeting the required AQL are rejected. This is the "producer's risk".

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The effect of this is that a condom importing firm who ships 20 or more shipments over two years, whose manufacturing process average for holes is near the AQL, 0.25% defective, who has a QSR-compliant quality system, still faces a statistical certainty that it will have a lot rejected and be put on detention due to the producer's risk, while meeting the required quality standard. The following illustrates how this comes about.

In 2001, a large factory made 161 condom shipments to the USA, and thus far in 2002, it has made 73 shipments. Given the frequency of these shipments, please consider the effect of the three sampling plans FDA commonly uses for condom shipments: SSCL's N, P, and Q, "Multiple sampling plans for normal inspection". At the proposed 0.25 AQL, the 95% acceptance levels of these plans are 0.273, 0.327, and 0.318. True, these levels are marginally above 0.25. However, with 300 to 400 shipments over two years, a shipper must be superior to 99% acceptance limits, not 95%, to avoid a "fail". The 99% acceptance limits for these three sampling plans are 0.165, 0.223, and 0.232. In other words, a condom importing firm which makes 100 or more condom shipments over two years, whose manufacturing process average for holes is superior to the 0.25 AQL but in excess of 0.165% defective, and which has a QSR-compliant quality system, is statistically certain to go on detention due to the producer's risk, while making superior quality condoms.

Assume further that a particular shipper will make 300 to 400 shipments over the next two years. In this case, the shipper's process average must be somewhere below 0.10% defective consistently, to have an assurance of avoiding rejected lots and the ensuing detention. This is simply not technologically feasible at the present time using the best available condom manufacturing technology.

A final example concerns a particular shipper's shipments to date in 2002. We recently received through FOI, FDA test results on the shipments over the first quarter. FDA's data shows a commendable 0.14% defective overall. However, if the incoming AQL were now 0.25, instead of 0.40, one of these shipments would have failed, and this shipper would now be facing the next level of detention, assuming it has been less than two years since its last detention.

One possibility for adding flexibility to the Recidivist Policy is to incorporate a system similar to that employed by the French government, which recognizes the potential of "producer's risk". The French require testing of each condom lot which enters their country. Briefly, their policy is that if more than 5% of a given firm's condoms fail the French testing over a year's time, then that firm may not ship product to France until corrective and preventive action is demonstrated. Alternatively, FDA could review its own recent testing history of a firm's product in the event of a failure, and not put the firm on detention unless that history revealed an average above 0.25% defective. Other

suitable changes could also be made, but it is very important that coincident with lowering the AQL for holes, consideration be given to the effect of the Recidivist Policy on manufacturers making many shipments into the United States every year.

Introduction of Air Burst Testing

Concerning the introduction of air burst testing, we recommend that FDA pattern the AQL and dispositioning criteria after the new ISO 4074:2002. The AQL is 1.5 and volume failures, pressure failures, and volume/pressure failures are counted together. Quoting from the Standard, "A non-conforming condom is defined as a condom that fails the requirement for volume, pressure, or both…" Regarding a condom that leaks during the air burst, we agree with the existing "Note 3" of the draft CPG.

If you have any questions or require clarification of any of these comments, please telephone me at (334) 615-2562, or e-mail to lmcilvai@ansell.com, or you may write to me at our Alabama address.

Respectfully submitted,

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Quality Assurance/Regulatory Manager

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cc: John Farnham

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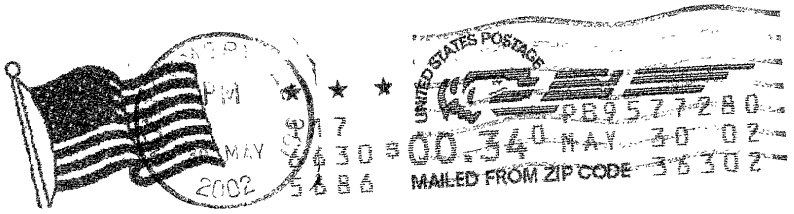

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