



CHURCH & DWIGHT CO., INC.

ARMKEL, LLC

An affiliate of Church & Dwight Co., Inc.
and Kelso Company

469 North Harrison Street, Princeton, NJ 08543

May 3, 2002

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

Re: Docket № 02D-0103
Draft Revised Compliance Policy Guide
Male Condom Defects (CPG 7124.21)

Dear Sirs:

Church & Dwight Co., Inc. is the manufacturer and marketer of TROJAN® brand condoms, America's #1 brand of condoms. We thank and commend the Agency for agreeing with our comment to the draft "Recidivist Policy" [Docket № 00D-1383] and deciding to revise the above referenced CPG to update the water leak test acceptable quality level from 0.4 to 0.25 in conformance with ASTM D3492-97 and ISO 4074-1, the two latex condom voluntary standards recognized by the Agency.

Another revision incorporated into the draft CPG included the addition of air burst testing with an AQL of 1.0 (*q.v.*, Regulatory Action Guidance section B, page 6; Attachment B, page 10; a reference also appears on page 5, first full paragraph). Both the ASTM and ISO standards include air burst testing requirements. The ASTM D3492-97 air burst test requirement calls for an AQL of 1.5 (*q.v.*, Section 4.1.1, Table 1 -Quality Inspections Requirements). Similarly, the ISO 4074:2002(E) air burst test requirement also call for an AQL of 1.5 (*q.v.*, Section 6.1, page 4). We believe that the CPG should be consistent with the two voluntary standards recognized by the Agency, and therefore, the draft CPG should be revised to provide for an AQL of 1.5 for the air burst test.

The revised CPG also makes reference to ISO 2859 Part 1, "Sampling Procedures and Tables for Inspection by Attributes." We believe that, as an agency of the United States, the Agency should reference ANSI/ASQC Z1.4, "Sampling Procedures and Tables for Inspection by Attributes," the US equivalent.

02D-0103

Sincerely,



Stephen C. Kolakowsky
Director, Regulatory Affairs



CHURCH & DWIGHT CO., INC.

ARMKEL, LLC

An affiliate of Church & Dwight Co., Inc.
and Kelso Company

469 North Harrison Street, Princeton, NJ 08543

May 3, 2002

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

Re: Docket № 02D-0103
Draft Revised Compliance Policy Guide
Male Condom Defects (CPG 7124.21)

Dear Sirs:

Church & Dwight Co., Inc. is the manufacturer and marketer of TROJAN® brand condoms, America's #1 brand of condoms. We thank and commend the Agency for agreeing with our comment to the draft "Recidivist Policy" [Docket № 00D-1383] and deciding to revise the above referenced CPG to update the water leak test acceptable quality level from 0.4 to 0.25 in conformance with ASTM D3492-97 and ISO 4074-1, the two latex condom voluntary standards recognized by the Agency.

Another revision incorporated into the draft CPG included the addition of air burst testing with an AQL of 1.0 (*q.v.*, Regulatory Action Guidance section B, page 6; Attachment B, page 10; a reference also appears on page 5, first full paragraph). Both the ASTM and ISO standards include air burst testing requirements. The ASTM D3492-97 air burst test requirement calls for an AQL of 1.5 (*q.v.*, Section 4.1.1, Table 1 -Quality Inspections Requirements). Similarly, the ISO 4074:2002(E) air burst test requirement also call for an AQL of 1.5 (*q.v.*, Section 6.1, page 4). We believe that the CPG should be consistent with the two voluntary standards recognized by the Agency, and therefore, the draft CPG should be revised to provide for an AQL of 1.5 for the air burst test.

The revised CPG also makes reference to ISO 2859 Part 1, "Sampling Procedures and Tables for Inspection by Attributes." We believe that, as an agency of the United States, the Agency should reference ANSI/ASQC Z1.4, "Sampling Procedures and Tables for Inspection by Attributes," the US equivalent.

02D-0103

Sincerely,



Stephen C. Kolakowsky
Director, Regulatory Affairs

KILMER P&D
FM
03 MAY 88
2002
WINNETON
PEMETER
7038326 U.S. POSTAGE

