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November 10, 2000

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

Re: FDA Draft "Guidance for Industry on Surveillance
and Detention Without Physical Examination of
Condoms" (Recidivist Policy)
[Docket No. 00D-1383]

Dear Sir or Madam:

On Monday, August 14, 2000, the US Food and Drug Administration (FDA) published a notice announcing the availability for comment of FDA's Draft "Guidance for Industry on Surveillance and Detention Without Physical Examination of Condoms", also referred to as FDA's Recidivist Policy. [*Federal Register*, Vol. 65, No. 157, pp. 49585-49586.]

We support FDA's initiative to detain without physical examination the shipment of inferior quality condoms into the United States from recidivist foreign manufacturers/shippers who repeatedly violate FDA standards for condoms. However, we strongly object to the obsolete standard of quality that FDA would rely upon as part of the draft guidance. FDA must insist on the use of a water leak quality standard at least as stringent as that imposed on U.S. manufacturers. Therefore, the water leak acceptance level for foreign exports to the USA should be changed from 0.4 AQL to 0.25 AQL.

The *Federal Register* notice states that, "This draft guidance is intended to provide guidance to FDA staff and industry about a recidivist policy for firms that repeatedly attempt to import condoms that violate quality requirements." [Background, p. 49585.] "Many foreign manufacturers and shippers of condoms have consistently failed to provide condoms of adequate quality for distribution in the United States, which presents a potentially serious hazard to health for users." [Summary, p. 49585.]

The *Recidivist Policy* on page 1 notes correctly that, "Consumers rely on condoms for protection from HIV (AIDS) and other sexually transmitted diseases (STDs), as well as for contraception."

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Carter-Wallace, Inc. is the manufacturer and marketer of TROJAN[®] brand condoms, America's #1 condom, trusted for over 80 years, and made in the USA. Carter-Wallace recognizes its responsibility and is committed to providing the USA consumer with only high quality condoms that are safe and effective for their intended uses. We believe that USA consumers should demand and receive no less. It is for this reason that Carter-Wallace must comment on what we believe are the short comings of FDA's draft Recidivist Policy, namely, FDA's surveillance testing of condoms as defined in its Compliance Policy Guide CPG 7124.21 *Condoms; Defects - Criteria for Direct Reference Seizure*. [*Recidivist Policy*, Level 1 Detention; see also, *Import Alert #85-02*, Sampling.]

CPG 7124.21 states the following...

"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."

FDA's Compliance Policy Guide CPG 7124.21 was last revised in March 1995.

FDA was granted authority under Section 206 of the FDA Modernization Act of 1997 (FDAMA) [FFD&C Act Sec. 514] to recognize consensus standards established by international and national standards development organizations that may be used to satisfy identified portions of device premarket review submissions or other requirements. [63 *Fed Reg* No. 37, p. 9561, Feb 25, 1998 at p. 9562, part I; and 63 *Fed Reg* No. 200, Oct 16, 1998, p.55617, Part I.]

Effective Nov 16, 1998, for the purpose of Premarket Notifications (510(k)s), Premarket Approval Applications (PMAs), Investigational Device Exemptions (IDEs), Product Development Protocols (PDPs), Humanitarian-Use Device Exemptions (HDEs), and Design Control Input, FDA recognized the ASTM D-3492-96 Standard Specifications for Rubber Contraceptives (Male Condoms) — except, *inter alia*, the quality inspection requirements for air burst properties and water leakage as stated in Table 1 of the Section 4 *Requirements*. [Ibid, *Fed Reg* Oct 16, 1998.] Instead FDA noted it would "recognize an acceptable quality level (AQL) for air burst properties at 1.0 and an AQL

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for leakage at 0.25.” Therefore, for 510(k)s, PMAs, IDEs, PDPs, HDEs, and Design Control Input, FDA requires a 0.25 AQL for water leakage — but this is not the case with CPG 7124.21.

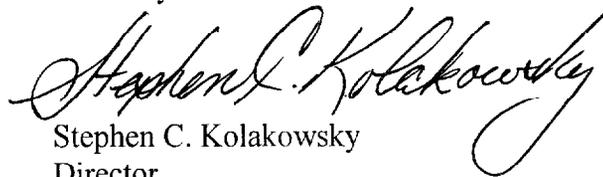
For compliance purposes in examining imported latex condoms, FDA continues to allow foreign condoms imported into the USA to only meet the 0.4 AQL level. (Note, in March 1998, seven months before the above *Federal Register* Notice, the American Society for Testing and Materials (ASTM) published D-3492-97, which was revised Aug 10, 1997, adopting the 0.25 AQL leakage limit requirement.)

In the October 1998 *Federal Register*, FDA recognized the International Standards Organization standard for condoms (ISO 4074:1996 Rubber Condoms Part 1: Requirements) limit for holes of 0.25 AQL, which as noted is the same as that of the ASTM standard. [Ibid, Oct 16, 1998 at p.55628.] Thus, FDA recognized the same standard recognized worldwide for water leakage — 0.25 AQL. However, as noted above CPG 7124.21 remains at 0.4 AQL, and therefore, latex condoms imported into the USA do not have to meet the world standard of 0.25 AQL. Foreign condom manufactures that fail to meet the standard recognized by the rest of the world may still export their condoms — with as many as 4 leaking condoms per 1000 — into the USA.

Latex condom manufacturers in the USA produce condoms to meet the 0.25 AQL standard. FDA, however, under the existing CPG requirement would continue to allow foreign condoms into the USA that do not meet this same quality standard. The continued acceptance of the 0.4% quality limit for the water leakage requirement is not in the best interest of the public health and should be revised to 0.25AQL.

We strongly encourage FDA to revise CPG 7124.21 to be consistent with the USA and ISO standard of 0.25 AQL for leakage.

Sincerely



Stephen C. Kolakowsky
Director
Regulatory Affairs

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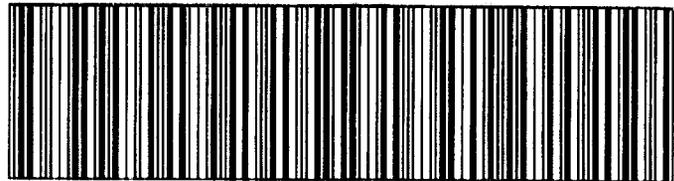
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