



Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

September 13, 1993

TO: Manufacturers of Menstrual Tampons

RE: FDA's Position on Eight Hours/Overnight Use of Menstrual Tampons

It has come to our attention that some menstrual tampon manufacturers are promoting overnight use of menstrual tampons. In response to this promotion, the Food and Drug Administration (FDA) provides the following information:

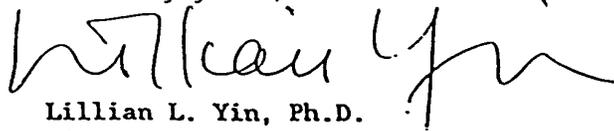
1. Changes in the labeling and promotional materials for overnight use of menstrual tampons, up to eight (8) hours, does not require 510(k) premarket notification. Questions concerning your proposed labeling and promotional materials should be directed to Bryon Tart of the Promotion and Advertising Policy Staff, Office of Compliance, at (301) 427-1342.
2. Based on current epidemiologic evidence, FDA does not believe that overnight use of tampons for up to 8 hours, *per se*, will increase the risk of menstrual Toxic Shock Syndrome (TSS). The incidence of menstrual TSS is estimated at 1 case per 100,000 menstrual women.¹ Moreover it is estimated that the incidence of menstrual TSS has decreased ten-fold since the recognition of the association of TSS with tampon use in 1980.²

Epidemiologic studies indicate that, after adjusting for tampon absorbency, the risk of TSS does not increase significantly when the tampon is used overnight for up to eight (8) hours.³

3. It should be recognized that epidemiological data show that continuous use of tampons was associated with higher risk of TSS than intermittent use. Labeling and promotional materials that have been changed to include a recommendation for overnight use must include the following information:
 - a. The risk of TSS may be reduced through the intermittent use of tampons. Tampons use should be alternated with menstrual pad use.
 - b. Claims for overnight use must include the phrase "up to 8 hours" to indicate length of time implied by overnight.

If you have any further questions, you may contact Mr. Colin M. Pollard at (301) 427-1180.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian Yin".

Lillian L. Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat, and
Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

- 1.Rev Infect Dis 11:S28-S34(1989)
- 2.MMWR 39:(25)421-423(1990)
- 3.Rev Infect Dis 11:S35-S42(1989)