

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Date: June 12, 2000

From: Charles J. Ganley, M.D., _____
Director, Division of Over the Counter Drug Products

Subject: July 12, 2000 Today® Sponge Advisory Committee Discussion

Today® Sponge is a barrier contraceptive containing the spermicide, nonoxynol 9. The New Drug Application (NDA # 18-683) was approved in 1983 and marketed by Vorhauer Laboratories. In 1987, the NDA was transferred to Whitehall Robins. Whitehall Robins continued marketing the product until they voluntarily withdrew it from the market in January 1995 for reasons unrelated to efficacy or safety. In March 1999, the NDA was transferred to Allendale Pharmaceuticals, Inc. Allendale Pharmaceuticals, Inc. intends to resume marketing.

Because Allendale Pharmaceuticals has changed the manufacturing facility for the finished drug product, they were required under federal regulations to submit a chemistry supplement to the NDA. Allendale has provided this information. Labeling revisions were also requested to update the package carton and package insert. Currently, there are chemistry issues that have to be resolved by the sponsor before marketing can be resumed. The agency hopes to obtain comments from the advisory committee on the adequacy of the proposed revised labeling.

In order to focus the discussion during this meeting, there are several things to keep in mind:

- NDA # 18-683 is an approved NDA.
- The efficacy of this product was established by clinical trials conducted by the original sponsor of this application. The agency is not currently seeking additional advice regarding the efficacy of this product; but the agency is interested in discussion of how the product should be labeled so that consumers will be adequately apprised of the effectiveness of the product. Any discussion of efficacy should focus on whether the consumer will be adequately apprised of the effectiveness of the product.
- Toxic Shock Syndrome (TSS) was reported with use of the product dating back to 1983. The agency made the determination, after receiving these early reports, that TSS was a rare occurrence and the overall benefit risk assessment favored keeping the product on the market with appropriate warnings. During the meeting, the agency will provide an overview of the serious adverse events reported to the safety database, particularly the reports of TSS or TSS-like adverse events. The agency hopes to obtain feedback on the adequacy of the proposed labeling to provide consumers with information that will warn them of the risk for these events and also describe the symptoms associated with these conditions (should they develop once the consumer chooses and uses the product).
- When marketing is resumed, there are likely to be rare reports of TSS or TSS-like symptoms or other serious events associated with the use of the Today® Sponge. The agency seeks discussion on the types of measures the sponsor should take in the reporting of these events (e.g. information to be collected, analyses to be performed, diligence of follow-up for certain events) and the type of follow-up necessary for reports of difficult sponge removal.

The information in this package includes safety reviews, current approved labeling and the proposed labeling. Also included are Citizen Petitions submitted to the agency in 1983, 1984 and 1992 and the agency's response to these petitions. The agency received another Citizen Petition on April 24, 2000. This petition relates to the safety of the Today® Sponge and other products that contain the nonoxynol 9 ingredient. This petition is currently under review by the agency. The agency has provided this petition for informational purposes in the event that some of the issues included in the petition are raised during the public comment period. During the meeting, the agency does not plan to comment on the issues raised in the April 24 petition because the agency has not completed its review of the petition.