

Nonprescription Drugs Advisory Committee

July 12, 2000

Food and Drug Administration, Center for Drug Evaluation and Research
Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD

Today Sponge ®, Allendale Pharmaceuticals

Allendale Pharmaceuticals plans to resume marketing of the Today Sponge®. The agency has requested that the sponsor revise the currently approved carton label so that it conforms to the Drug Facts format. The agency has also proposed revisions to the package insert. The information provided to the committee included the currently approved labeling (designated 1991 labeling) and the proposed revised labeling (designated 2000 labeling).

1. Given the material provided in your briefing packages and presented today, does the revised labeling adequately convey the risks associated with the use of the product?
2. The current carton label does not include information on the efficacy of this product. Should the carton label include efficacy information so that the consumer will have this information available at the point of purchase?
 - a. If yes, should this kind of information be required of all OTC contraceptive products?
3. Are there other aspects of the labeling that should be revised?
4. Please provide comments on the type of post-marketing surveillance for adverse events the sponsor should conduct (e.g. active collection, follow-up reporting and analysis of cases of difficult sponge removal, provisions in place to facilitate adequate adverse event reporting)?