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Talk Paper

TODAY SPONGE

FDA has been receiving inquiries regarding the decision of Whitehall-Robins Healthcare to stop manufacturing Today Sponge, a contraceptive for women. The following can be used to answer questions:

Today Sponge has been in short supply since the firm stopped production after FDA's inspection in March 1994 of the only facility manufacturing the contraceptive.

The comprehensive inspection of the firm's plant in Hammonton, N.J., disclosed bacterial contamination of the water used to make the Today Sponge as well as other products manufactured in the facility, including nasal sprays, ointments and suppositories.

FDA investigators also established that the firm had neglected to validate its microbiological test methods, thereby raising questions about their reliability. Still other problems were found in the firm's equipment sanitization.

Recently, after weighing the cost of modifications that would be necessary to bring the Hammonton plant up to acceptable

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manufacturing standards, as well as the likely loss of Today Sponge's market share by the time the upgrading would be completed, the firm announced its decision to stop making the contraceptive.

The agency did not object to continued production of Today Sponge under appropriate manufacturing and hygienic conditions. Long-standing public health standards, however, do not allow the marketing of contaminated products that present a potential risk of disease transmission.

Consumers should be aware that Today Sponge is only one of many OTC contraceptives for women that are on the market, including a female condom and spermicides. Available prescription contraceptives for women include IUD, injection, implant, diphragm and cervical cap with spermicide, and various birth control pills.

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