DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-683/S-030

Allendale Pharmaceuticals
Attention: Robert Staab, Ph.D.
Chairman, Chief Scientific Officer
73 Franklin Turnpike
Allendale, NJ 07401

Dear Dr. Staab:

Please refer to your supplemental new drug application dated March 10, 2004, received March 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Today (1 gram nonoxynol-9 vaginal contraceptive) Sponge.

We acknowledge receipt of your submission dated October 13, 2004.

Your submission of October 13, 2004 constituted a complete response to our July 9, 2004 action letter.

This supplemental new drug application provides for new manufacturing and testing facilities, a new source for the (b)(4) used in the manufacture of the sponge, and a modification of the acceptance criterion for (b)(4).

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call the Regulatory Project Manager, at (301) 827-2222.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Charles Ganley
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