DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-683/S-028

Allendale Pharmaceuticals, Incorporated
Attention: Dr. Robert Staub, Ph.D.
Chief Scientific Officer
73 Franklin Turnpike
Allendale, NJ 07401

Dear Dr. Staab:

Please refer to your supplemental new drug application dated October 14, 1999, received October 19, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for. Today® (1 gram nonoxynol-9 vaginal contraceptive) Sponge.

We also refer to your submissions dated October 14, 1999, February 29, 2000, January 12, 2001, January 23 and October 31, 2003, and April 30, May 26, July 26 and October 3, 2004.

Your submission of April 30, 2004, constituted a complete response to our May 3, 2004 action letter.

This supplemental new drug application provides for revised labeling for the 3-count, 6-count, and 12-count package sizes.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted draft labeling (consumer information leaflet submitted on October 3, 2004, carton labeling for the 3-count package size submitted on September July 26, 2004, carton labeling for 6 and 12-count package sizes submitted on October 3, 2004, and pouch labeling submitted on July 26, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-683/S-028." Approval of this submission by FDA is not required before the labeling is used.

We wish to inform you that we will soon require new labeling warning statements for all over-the-counter (OTC) vaginal contraceptive drug products containing nonoxynol-9. Refer to FDA's January 16, 2003 proposed rule for OTC vaginal contraceptive drug products containing nonoxynol-9 for more information about these upcoming labeling requirements. Based on comments submitted to the proposed rule and other available information, these labeling statements may change when the final rule is published.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). We also remind you that you cannot begin marketing this product until you have received approval for Supplement 030.

If you have any questions, call Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

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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