DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018683/S-034 **SUPPLEMENT APPROVAL**

PAV Nova, Inc.
Attention: Gregory M. Torre, Ph.D., Esq.
Vice President, Regulatory Affairs
9 Campus Drive, 3rd Floor
Parsippany, NJ 07054

Dear Dr. Torre:

Please refer to your Supplemental New Drug Application (sNDA) dated April 15, 2009, received April 16, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Today (1 gram nonoxynol-9 vaginal contraceptive) Sponge.

We acknowledge receipt of your submission dated May 20, 2010. The November 20, 2009, submission constituted a complete response to our October 15, 2009 action letter.

This "Changes Being Effected" supplemental new drug application provides for changes in name and address of the manufacturer, of the drug product; the inclusion of the FDA-required language from the Federal Register Notice of December 10, 2007, regarding nonoxynol-9, and the associated labeling changes.

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

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed (3-count carton submitted November 20, 2009, and consumer information leaflet (CIL) submitted May 20, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. The e-mail correspondence from you dated, May 17, 2010, notified us that the 3-count label is intended to serve as a representative package size. Any changes approved for the 3-count label will be incorporated onto the labels of the 6- and 12-count package sizes, which must be identical to the 3-count label with the exception of the count size. FPL must be submitted for all the referenced count sizes. Representative labeling will not be acceptable in the FPL submission.

Though no revisions were made to the immediate container (pouch), you should submit the immediate container (pouch) label as part of the FPL for this supplement to maintain a record of complete labeling for these count sizes and packaging configurations.

The final printed labeling should be submitted electronically according to the guidance for industry titled "*Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 018683/S-034**." Approval of this submission by FDA is not required before the labeling is used.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Mary Lewis, Senior Regulatory Project Manager, at (301) 796-0941.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosures:

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18683	SUPPL-34	PAV NOVA INC	TODAY VAGINAL CONTRACEPTIVE SPONGE

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

/s/

ANDREA LEONARD SEGAL
05/27/2010