DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-676/S-009 **SUPPLEMENT APPROVAL**

Novartis Consumer Health, Inc.
Attention: Karen A. Costa-Strachan, Ph.D.
Associate Director, Regulatory Affairs
200 Kimball Drive
Parsippany, New Jersey 07054

Dear Dr. Costa-Strachan:

Please refer to your supplemental new drug application dated March 19, 2009, received March 20, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vagistat-1 Vaginal Ointment (300 mg, 6.5%, tioconazole) and 1-Day Ointment (300 mg, 6.5% tioconazole.

This "Changes Being Effected" supplemental new drug application provides for an additional warning to the Drug Facts labeling in response to FDA's supplement request letter dated December 8, 2006. This letter requested that the following statement be added under "When using this product" state: "If you do not get complete relief ask a doctor before using another product".

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

The final printed labeling must be identical to the enclosed labeling (for Vagistat-1 ointment and 1-Day ointment cartons, pouch labels and educational brochures submitted March 19, 2009) with the inclusion of the following changes agreed to via facsimile on September 11, 2009.

Vagistat-1 and 1-Day

A. Carton

1. In accordance with 21 CFR 201.66(d)(2), the bullet size should be 5pt. Revise labeling to be in accordance with the regulation.
2. Under Drug Facts under "Do not use", bold the entire warning statement.
3. Under Drug Facts under "When using this product", delete the comma in the 4th bulleted statement "if you do not get complete relief…."
4. Under Drug Facts under "Other information", revise the statements in the first bullet by deleting the semicolon between the first two phrases and replacing it with a period. The first bulleted statements should then read as follows: "this product is a 1-dose treatment. Most women do not experience complete relief of their symptoms in just one day. Most women experience some relief within one day and complete relief of symptoms within 7 days."

B. Pouch Label

1. Under Drug Facts under "Do not use", bold the entire warning statement to be consistent with carton labeling.
2. Under Drug Facts under "When using this product", delete the comma in the 4th bulleted statement "if you do not get complete relief…..".
3. Under Drug Facts under "Other information", revise the first bulleted statement by deleting the semicolon between the first two phrases and replacing it with a period to be consistent with carton labeling.

C. Educational Brochure

1. Under Part 4 Warnings:
   - Bold the entire "Do not use" warning to be consistent with carton labeling.
   - Under "When using this product", delete the comma in the 4th bulleted statement "if you do not get complete relief…." to be consistent with carton labeling.

You have agreed to make changes A, B, and C within 180 days or at the time of next printing, whichever comes first.

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 20-676/S-009**." Approval of this submission by FDA is not required before the labeling is used.

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, Regulatory Project Manager, at (301) 796-0941.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure:

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20676	SUPPL-9	NOVARTIS CONSUMER HEALTH INC	VAGISTAT-1 (TIOCONAZOLE 6.5%) VAGINAL OI

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

/s/

JOEL SCHIFFENBAUER
09/15/2009