DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-676

Berlex, Inc.
Attention: Nancy Velez
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Velez:

Please refer to your new drug application (NDA) dated October 16, 2004, received October 17, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for YAZ (drospirenone 3 mg / ethinyl estradiol 0.02 mg) Tablets.

We acknowledge receipt of your submissions dated November 18, 25, December 4, 2003, January 29, February 18, March 18, April 8, 16 (2), 19, 21(2), 23, 26, 28, May 6, 14, 21, 26, 27, June 9, 10, 11, 24, 29, 30, July 1, 8, 9, 22, August 3, 4, 6(2), 11, 13, 17, 23, September 8, 24, October 7, 21, November 4 (4), 8, 11, December 27, 2004, February 28, March 31, May 9, 10, 17, June 7, 15, 23, 24, August 18, September 12, October 28 (2), November 1, 3, 10, 11, 17, 22, 30, December 2, 6, 9, 13, 2005, January 10 (2), February 28, March 2, 3, 9 (3), 10, 14, 15, and 16 (2), 2006.

The June 15, 2005 submission constituted a complete response to our November 17, 2005 action letter.

We have completed our review of this application, and it is approved. It 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 enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels) and/or submitted labeling (package insert and patient package insert submitted **March 16, 2006**, immediate container and carton labels submitted **November 30, 2005**). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-676**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitment in your submission dated August 18, 2005 entitled "International Active Surveillance Study of Women taking Oral Contraceptives (INAS OC)."

Protocol Submission:	August 18, 2005
Study Start: (YAZ Component)	First Day of Launch of YAZ in the U.S.
Final Report Submission:	5.5 years following the launch of YAZ in the U.S.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Reproductive and Urologic Products and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Charlene Williamson, Regulatory Project Manager, at (301) 796-1025.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure