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APPROVAL PACKAGE

APPLICATION NUMBER(S)

21-371

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-371

Novavax Inc.
Attention: Joan Brisker
VP Regulatory Affairs and Quality Assurance
12111 Parklawn Drive
Rockville MD 20852

Dear Ms. Brisker:

Please refer to your new drug application (NDA) dated June 29, 2001, received June 29, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Estrasorb (estradiol topical emulsion).

We acknowledge receipt of your submission dated April 26, 2002 requesting withdrawal of this application. We also acknowledge your resubmission of the application dated September 12, 2002, and your submissions dated November 20 and 27, December 5 and 17, 2002, January 13, 16 and 28, February 15, April 1 and 30, May 5, 12, 19, 22 and 27, June 5, 6 and 16, July 11, 29 and 31, August 4, September 5, 17 and 30, October 7 (2) and October 9 (2), 2003. The May 19, 2003 submission constituted a major amendment to this application.

This new drug application provides for the use of Estrasorb (estradiol topical emulsion) for the treatment of moderate to severe vasomotor symptoms associated with menopause.

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert and patient package insert) and the immediate container and carton labels submitted August 4, 2003. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and 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 21-371.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated October 9, 2003. This commitments is listed below:

1. To conduct a study to determine the lowest effective dose of Estrasorb

Protocol Submission:	Within 6 months of the date of this letter
Study Start:	Within 6 months of reaching protocol agreement with DRUDP
Final Report Submission:	Within 6 months of the study completion

Submit the clinical protocol to your IND for this product. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this 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 the number of patients entered into the study. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

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

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
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 George Lyght, R.Ph., Regulatory Project Manager at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

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

Enclosures: Physician Insert and Patient Package Insert

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

/s/

Daniel A. Shames
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APPEARS THIS WAY
ON ORIGINAL