DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 12 1997

TRANSMITTED VIA FACSIMILE

Dr. Bennett Kaufman, Ph.D.
Director of Immunology and Regulatory Affairs
Novavax Inc.
8320 Guilford Road
Columbia, MD 21046

RE:

Estrasorb (estradiol micellar nanoparticles)
MACMIS 5635

Dear Dr. Kaufman:

Reference is made to Novavax's July 17, 1997, telefacsimile to the Division of Drug Marketing, Advertising and Communications (DDMAC) requesting comments on a press release for Estrasorb (estradiol micellar nanoparticles).

On July 24, 1997, before DDMAC completed its review of the press release, you telephoned DDMAC to say that the press release had been issued. Coincidentally, DDMAC has found similar press releases for Estrasorb on the Internet. These press releases were dated before July 17, 1997 (e.g., a press release dated June 26, 1997). Please note that DDMAC does not give advisory comments on materials that are already in use.

The press releases issued were false or misleading, in violation of the U.S. Food, Drug and Cosmetic Act for the following reasons:

1. The June 26, 1997, press release states that Estrasorb was "found to reduce hot flashes up to 98 percent during a two-week study of 10 post menopausal women." While the study protocol was accepted as a pharmacokinetics study for the Investigational New Drug Application, the study conducted by Novavax was of insufficient duration and was insufficiently powered to assess efficacy. Thus, any claims of efficacy for Estrasorb in the study of 10 post-menopausal women are considered to be false and misleading.

2. The claim that FDA "approved" the dose ranging/pharmacokinetics study is false and misleading because it implies that the results have

been vetted by the Agency. In fact, the Agency reviewed and approved the protocol. The study data have not yet been submitted to, or examined by, the FDA.

In order to address these objections, DDMAC suggests that Novavax take the following actions:

1. Immediately remove the violative press release(s) from the public domain.

2. Provide DDMAC, in writing, with a list of all the press releases that have been discontinued and with Novavax's intent to comply with number one above.

Novavax's response should be received no later than August 25, 1997. If you have any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5635 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications