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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-488

Statistical Review(s)

Memorandum of Filing

Date: May 30, 2002

Re: NDA 21-488 (Received April 16, 2002)

Sponsor: Atrix Laboratories, Inc.

Product: Eligard (Leuprolide Acetate) 30 mg

Indication: For use in the palliative treatment of advanced prostate cancer

A single, open-label, uncontrolled study (AGL0001) with 90 enrolled patients was conducted to demonstrate efficacy and safety of the study drug over eight months, with a dosing frequency (30 mg inj) of four months. The primary efficacy outcome is based on serum testosterone concentrations measured at various sampling time-points

The sponsor reports that 85 of the 90 patients (94%) achieved testosterone suppression by Day 28 and 89 (99%) by Day 42. Median time to suppression was 21 days. Three participants failed to maintain suppression throughout the course of the study

From a statistical perspective, this study is observational as the data are presented and analyzed with descriptive statistics only, that is, no confirmatory hypotheses are tested. This is consistent with other studies approved and under review for this indication.

This NDA can be filed. No further statistical review is warranted at this time.

/S/

**Mike Welch, PhD
Team Leader, HFD-715**

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/s/

Mike Welch
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