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**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER  
21-343**

**Statistical Review(s)**

Memorandum of Statistical Review

Date: January 02, 2002

To: Mark Hirsch, MD, HFD-580

From: Mike Welch, PhD, HFD-715

Re: NDA 21-343

Sponsor: Atrix Laboratories, Inc.

Product: [redacted] 7.5 mg

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

A single, open-label, uncontrolled study (AGL9904) with 120 enrolled patients was conducted to demonstrate efficacy and safety of the study drug over six, monthly injections. The primary efficacy outcome was the proportion of patients whose serum testosterone concentration was suppressed to castrate levels (50 ng/dl or less) by study Day 28.

The sponsor reports that 112 of the 120 patients (93%) achieved testosterone suppression by Day 28; 117 (98%) by Day 35; and 119 (99%) by Day 42. Moreover, all responders are reported to have maintained castrate suppression levels throughout their participation in the study. These results are consistent with this reviewer's examination of the submitted data sets.

From a statistical perspective, this study should be considered as observational only. No *a priori* criteria were established for efficacy, and study results are purely descriptive. However, study protocol and data presentation appears to be consistent with prior guidance given by the Division.

cc: Jeanine Best, HFD-580  
Ed Nevius, HFD-715