

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-778

MEDICAL REVIEW

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

DATE: February 1, 2005

FROM: David G. Orloff, M.D.
Director, Division of Metabolic and Endocrine Drug Products

TO: NDA 21-778
Megace ES (megestrol acetate) oral suspension 125 mg/mL
Treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with AIDS

SUBJECT: NDA review issues and recommended action

Summary of issues

This product is being approved based on full CMC and bioequivalence investigations compared to Megace 40 mg/mL oral suspension. The studies, as reviewed by OCPB, demonstrate that, of the strengths of Megace tested, the two higher strengths (625 mg/5 mL and 675 mg/5 mL) are bioequivalent to Megace 800 mg/20 mL. The former is the one being approved. Pediatric studies are waived. Financial disclosure information is in order. All disciplines recommend approval. The product will have a 24-month expiry. Labeling is complete.

Recommendation

The application may be approved.

NDA # 21-778
Megace ES oral suspension 125 mg/mL
Treatment of cachexia in AIDS

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/s/

David Orloff
7/5/05 02:07:17 PM
MEDICAL OFFICER