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RESEARCH**

APPLICATION NUMBER:

75256_S4

CHEMISTRY REVIEW(S)

ANDA 75-256/S-004

NAME AND ADDRESS OF APPLICANT:

Duramed Pharmaceuticals, Inc.
5040 Lester Road
Cincinnati, OH 45213

PURPOSE OF AMENDMENT/SUPPLEMENT

New Regulatory Test Method for Placebo Identification

DATE(S) OF SUBMISSION(S)

February 23, 2001

PHARMACOLOGICAL CATEGORY

Oral Contraceptive

TRADE NAME

None used

NONPROPRIETARY NAME

Desogesterel and Ethinyl Estradiol

DOSAGE FORM

Tablets

POTENCY

0.15 mg/0.03 mg

RX OR OTC

Rx

REMARKS AND CONCLUSION

Approved.

RECALLS

N/A

Reviewer

Mujahid L. Shaikh

Date Completed

7-10-01

cc: ANDA # 75-256
Division File
Field Copy

Endorsements:

HFD-625/M. Shaikh/7/10/01
HFD-625/M. Smela/7/10/01

Handwritten initials and dates: /S/ /S/ 7/11/01