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RESEARCH**

APPLICATION NUMBER:

75256_S3

CHEMISTRY REVIEW(S)

ANDA 75-256/S-003

NAME AND ADDRESS OF APPLICANT:

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

PURPOSE OF AMENDMENT/SUPPLEMENT

Provide for reduction of in-process blend uniformity testing.

DATE(S) OF SUBMISSION(S)

Original Submission: 1-19-01
* Minor Amendment: 10-23-01

PHARMACOLOGICAL CATEGORY

Oral Contraceptive

TRADE NAME

None used

NONPROPRIETARY NAME

Desogestrel 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

11-6-01

cc: ANDA # 75-256
Division File
Field Copy

Endorsements:-

HFD-625/M.Shaikh/11/6/01
HFD-625/B.Cai for/M.Smela/11/8/01

/S/

11/13/01

/S/

11/13/01

ANDA 75-256/S-003

NAME AND ADDRESS OF APPLICANT:

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

PURPOSE OF AMENDMENT/SUPPLEMENT

To delete in-process blend uniformity testing.

DATE(S) OF SUBMISSION(S)

January 19, 2001

PHARMACOLOGICAL CATEGORY

Oral Contraceptive

TRADE NAME

None used

NONPROPRIETARY NAME

Desogestrel and Ethinyl Estradiol

DOSAGE FORM

Tablets

POTENCY

0.15 mg/0.03 mg

RX OR OTC

Rx

REMARKS AND CONCLUSION

Not approved. A NA letter w/minor amendment is being issued.

RECALLS

N/A

Reviewer

Mujahid L. Shaikh

Date Completed

6-13-01

cc: ANDA # 75-256
Division File
Field Copy

Endorsements:

HFD-625/M.Shaikh/6/13/01

HFD-625/M.Smela/

/S/

6/14/01

/S/
6/14/01