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APPLICATION NUMBER:

75256_S2

CHEMISTRY REVIEW(S)

Addendum to Chemistry Review # 1 for:

ANDA 75-256/S-002

Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg

Duramed Pharmaceuticals

Purpose of supplement:

To add new regulatory analytical method for dissolution testing.

Date of amendment:

NC: 5-30-01

Telephone Amendment: 6-21-01

This addendum is written to update the CR # 1 completed by this reviewer on 5-9-01.

Review of unsolicited Amendment dated May 30, 2001:

Duramed has submitted samples to Wayne Smith of FDA Laboratory in Philadelphia. Duramed clarified that bioequivalence batch has expired and they have substituted a new batch. In this amendment, Duramed has submitted a copy of batch record (lot # 98277), in-process controls test results and its CoA for the batch of the tablets sent to the Philadelphia Lab for MV. The size of the batch is _____ tablets (_____ kg). This batch is manufactured via already approved manufacturing process. Test results of the batch meets already approved release specifications.

Review of NC: June 21, 2001

Update is:

In response to telecon dated June 21, 2001, Firm submitted a commitment as follows:

Duramed commits to work with FDA to resolve any issues discovered by the FDA Philadelphia District regarding methods validation.

Conclusion: The supplement is approved.

cc: ANDA 75-256 -
Division File
Field Copy

Endorsements:

HFD-625/M.Shaikh/6/26/01
HFD-625/M.Smela/6/26/01

/S/ /S/ 6/27/01 6/27/01

ANDA 75-256/S-002

NAME AND ADDRESS OF APPLICANT:

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

PURPOSE OF AMENDMENT/SUPPLEMENT

An improved analytical method for dissolution testing

DATE(S) OF SUBMISSION(S)

December 8, 2000

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

Chemistry Closed.

MVP is being sent.

RECALLS

N/A

Reviewer

Mujahid L. Shaikh

Date Completed

5-9-01

cc: ANDA # 75-256

Division File

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Endorsements: -

HFD-625/M.Shaikh/

HFD-625/M.Smela/

IS/

5/9/01

IS/

5/9/01