

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75256_S2

ADMINISTRATIVE DOCUMENTS

RECORD OF TELEPHONE CONVERSATION

I called Ms. Arlinghaus of Duramed Pharmaceuticals regarding ANDA 75-256/S-002. I left a voice mail message stating the reviewing chemist had completed the review of the supplemental application and methods validation was pending. I requested she submit a methods validation commitment to the Agency stating that they will work with the Agency to resolve any methods validation issues discovered after approval.

DATE

June 21, 2001

APPLICATION NUMBERS

75-256/S-002

IND NUMBER

TELECON

INITIATED BY

 APPLICANT / SPONSOR

FDA

PRODUCT NAME

Desogestrel/Ethinyl Estradiol
Tablets 0.15 mg/0.03 mg

FIRM NAME

Duramed Pharmaceuticals, Inc.

**NAME AND TITLE OF
PERSON WITH WHOM
CONVERSATION WAS HELD**

Annette Arlinghaus

TELEPHONE NUMBER

513-731-9900

SIGNATURE

(/ST)

Michelle Dillahunt

cc:

ANDA: 75-256/S-002
DUP/DIVISION FILE