

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75256_S1

ADMINISTRATIVE DOCUMENTS

RECORD OF TELEPHONE CONVERSATION

On September 23, 1999, I telephoned Mr. William Stoltman of Duramed Pharmaceuticals, Inc. regarding their "Prior Approval Labeling Supplement" submission dated August 31, 1999. In this submission, Duramed added the proprietary name "Apri" in their product labeling, and also requested an expedited review of the supplement. I informed Mr. Stoltman that their request for an expedited review had been denied, and that the supplement would receive a standard review. I also told Mr. Stoltman that our Division determined that their proprietary name "Apri" was acceptable, and therefore we would not need to forward a consult to the Labeling and Nomenclature Committee.	DATE Sept. 23, 1999
	APPLICATION NUMBERS 75-256/SL-001
	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 William Stoltman
	TELEPHONE NUMBER 513-731-9900 ext. 7316
	SIGNATURE  Debra M. Catterson

cc:

ANDA: 75-256/SL-001
DUP/DIVISION FILE