CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75-253

ADMINISTRATIVE

RECORD OF TELEPHONE CONVERSATION

DATE:

July 27, 1999

ANDA:

75-253

DRUG PRODUCT:

Ticlopidine HCl Tablets, 250 mg

FIRM:

PUREPAC

CONVERSATION WITH:

Joan Janulis

PHONE NUMBER:

908-659-2430

TOPIC:

Commitment to Provide Postmarketing Program to

OGD for Review at the Time of Marketing.

The firm was requested to submit a commitment, prior to approval of their application, to provide their postmarketing program to OGD for review at the time of marketing. The firm's representative acknowledged and stated that they will submit the commitment to their application shortly.

Koung Lee

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