# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER:

## MEDICAL REVIEW(S)

**MEDICAL OFFICER REVIEW**
May 18, 1998

**ANDA 74-707**

**Product:** Nicotine Polacrilex Gum, 4 mg/ piece

**Sponsor:** Circa Pharmaceuticals

**Reference Listed Drug:** Nicorette, Marion Merrell Dow

## SMOKER'S ATTITUDES TOWARD AND PREFERENCES IN NICOTINE GUMS
### Findings From a Series of Personal Interviews

This survey was conducted by
----- on behalf of Circa
Pharmaceuticals in July 1996.

**Background:**

Circa's Nicotine Polacrilex Gum 4 mg/piece was originally formulated with a change in flavoring compared to that of the innovator. The Division of Anesthesia, Critical Care and Analgesic Drug Products was consulted about this. The taste of the innovator product Nicorette had been limited in its appeal by the Division to discourage chronic use of the gum as a cigarette substitute. The Division expressed concern that the change in flavoring of the generic might enhance the appeal of the generic product compared to the innovator product and encourage use of the generic gum as a substitute for cigarette smoking. The Division emphasized the need to match flavoring components in the generic product and/or conduct a "taste survey" as a possible way to discern whether this hypothesis was true. The following study was completed in July 1996.

**Objectives:**

The primary objectives of the study were:

1. To obtain reactions to the taste and flavor of the and Nicorette gums.
2. To determine participant preferences between the two products.
3. To learn if either product was one they would choose to smoke for "recreational" purposes.

The survey was conducted as structured in-person interviews of a sample of 52 smokers who were 18 years or older in Fort Lee, New Jersey. Subjects had no prior experience of nicotine gum and were randomized into two groups, light smokers (<20 cigarettes a day) or heavy smokers (>/=30 cigarettes a day). The sample was divided to receive either the Watson or the Nicorette product first. The alternate product was tested after "washing out" the taste of the first by chewing a saltine cracker.

The replies were examined according to the order of administration of each gum, and whether the participant was a light or a heavy smoker. Four areas, including product taste, product flavor, product taste compared to the gum currently chewed and likelihood of chewing this product as a "gum", were explored during the structured interview.

A review of this study has been completed by Dr. Moo Park who concluded that "The study demonstrated that the taste and flavor of Circa's Nicotine Polacrilex Gum 4 mg/piece, is equivalent to those of Marion Merrell Dow's Nicorette[R] DS, 4 mg/piece." Having reviewed the study, I concur with that opinion.

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