LABELLING STANDARD

NICOTINE GUM

I) **Category**:

Smoking Cessation Aid

II) **Description**:

This labelling standard applies to Nicotine as a single medicinal ingredient in the form of a gum intended for use as an aid to help stop smoking when used as part of a smoking cessation program.

III) **Pharmaceutical Quality**:

a) All ingredients (medicinal and nonmedicinal) and finished product specifications should, as a minimum, meet Schedule B or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the products' identity, potency, purity and quality.

b) **Special Notes:**

i) Pharmacopoeial standards (Schedule B) for formulated preparations are shown in Appendix I. Note that this list is intended only as a guide and is not necessarily current or all inclusive.

ii) Finished product specifications should include tests for identification and an assay with suitable limits for the medicinal ingredient including its components. The specifications for all dosage forms should include a description of the dosage form including organoleptic properties as well as physico-chemical testing eg., pH, specific gravity, viscosity, appropriate to the dosage form. Where antimicrobial preservatives are added, an assay with suitable limits should be included. It is recommended that antimicrobial preservative effectiveness be determined in order to establish that the product is capable of resisting microbial contamination.

IV) **Ingredients**:

a) **Single Medicinal Ingredient:**

nicotine polacrilex 2 and 4 mg in a chewing gum base

b) **Nonmedicinal Ingredients:**

Nonmedicinal ingredients must be restricted to those substances, necessary for the formulation of the dosage form. Their concentration must not exceed the minimum required to provide their intended effect. They must be harmless in the amounts used, their presence must not affect the bioavailability, therapeutic efficacy or safety of the medicinal ingredients and they must not interfere with assays and tests for the medicinal ingredients and, if present, antimicrobial preservatives, prescribed in Schedule B publications.

Ingredients of botanical origin added as nonmedicinal ingredients must comply with the Drugs Directorate Policy, Herbs used as Nonmedicinal Ingredients in Nonprescription Drugs for Human Use.

V) Labelling:

a) This LS describes those requirements that are specific to this class of drugs. Other requirements described in the *Regulations to the Food and Drugs Act*, in the *Guide for the Labelling of Drugs for Human Use* must also be met.

b) **Directions for Use:**

i) **Indications**

As a temporary aid to those who want to stop smoking cigarettes or break the cigarette habit, when used as part of a smoking cessation program

Additional acceptable claims:

1) to provide partial substitution for the nicotine in cigarettes in order to lessen withdrawal symptoms of smoking cessation

2) anti-smoking aid

3) smoking cessation aid

The following comments should be in a prominent place on the front of the label:

1) The effectiveness of this product is directly related to your motivation to stop smoking. Consult your pharmacist or doctor regarding the availability of

smoking cessation programs in your area (as part of the indication).

2) Do not use if you are a non-smoker or occasional smoker.

ii) **Dosages:**

1) For adults only. Not to be used by persons under 18 years of age.

2) For a 4 mg product: Use (brand X) (4 mg) if you smoke more than X cigarettes a day.

3) For a 2 mg product: Use (brand X) (2 mg) if you smoke less than X cigarettes a day.

iii) **Directions**:

1) Once piece of nicotine gum to be chewed slowly and intermittently for 30 minutes. Use a chew and park sequence, retaining the gum in the mouth beside the cheek in between chews. After 30 minutes discard gum out of the reach of children.

2) Repeat dose with a new piece of gum when the urge is felt to smoke again.

3) Most people require 10 pieces per day at first. Do not exceed 20 pieces a day.

4) Detailed information to be included on how to gradually reduce the number of pieces of gum chewed each day until decreased to 1-2 pieces a day and then stopped. This may be accomplished in 2 or 3 months or may take up to 6 months.

5) Information (more detailed than on the label) on how to chew the gum properly including:

a) Do not chew more than one piece at a time.

b) Side effects which may be a sign of improper chewing such as light-headedness, nausea, hiccups.

c) Recommended number of chews per minutes and how to hold the gum in the mouth, e.g.:

i) Bite the gum slowly once or twice - not

like normal chewing gum - then "park" it between the cheek and gum.

ii) Chew the gum again when the taste has faded, then place it in your cheek again.

iii) Chew like this for about 30 minutes then discard the gum out of the reach of children.

6) Carry the gum with you at all times in the first few months in case you feel a sudden urge to smoke. One cigarette may be enough to start the smoking habit again.

7) Avoid drinking acidic beverages (coffee, tea, soft drinks, alcohol, citric juices) while chewing the gum as they may interfere with the effectiveness of the gum.

8) Nicotine gum is designed to release nicotine only when chewed. No harmful effects should occur if you accidently swallow a piece.

9) The Fagerstrom Test, and directions on how to use it, must be present at least on the package insert.

NOTE: Directions #5 to #9 may be given on a package insert. The consumer must be directed on the label to refer to the package insert.

iv) **Do not use if:**

1) You have temporomandibular joint disorder (TMJ disorder).

2) You are pregnant or nursing a child. Avoid becoming pregnant while using nicotine gum. If you think you are pregnant, stop using nicotine gum at once and see your doctor.

3) You are an occasional or non-smoker.

4) You are under 18 years of age

v) **Warnings:**

1) Do not smoke, use nicotine patches or any other form of nicotine while using nicotine gum.

2) Keep out of the reach of children and pets.

3) Consult your doctor before using this product if you have or have had heart, thyroid, circulation, stomach, or throat or mouth problems, high blood pressure, or if you are taking insulin or any prescription medicine.

4) Do not use for more than six months without consulting a doctor.

5) Consult your dentist or doctor if injury or irritation to the mouth, teeth or gum around dentures occurs.

6) Discontinue using nicotine gum and consult your doctor if irregular heart beat, chest pain or leg pain occurs or if severe persistent stomach upset (indigestion, heartburn) develops.

7) Consult your doctor if you have difficulty in reducing the quantity of gum.

8) In case of overdose or if a child chews or swallows one or more pieces of nicotine gum, contact your doctor or local poison control centre at once. Young children are especially sensitive to the effects of even small doses of nicotine.

9) Symptoms of an overdose include nausea, abdominal pain, vomiting, diarrhea, cold sweat, dizziness, disturbed hearing and vision, mental confusion, rapid heartbeat, difficulty breathing and marked weakness.

NOTE: If the package label does not have sufficient space, the above points #5 to #8 may be included on a package insert provided the label instructs the consumer to consult it.

NOTE: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

APPENDIX I

FORMULATED PREPARATIONS	**U.S.P.23 (1995)**	**B.P. (1993)**
Nicotine Polacrilex Gum	X	

REFERENCES:

1. USP DI, Advice for the Patient, 15th Edition, 1995.

2. USP DI, Drug Information for the Health Care Professional, 15th Edition, 1995.

3. United States Department of Health and Human Services, Food and Drug Administration, Federal Register, Smoking Deterrent Drug Products Tentative Final Monograph; Notice of Proposed Rule making, Vol. 50, No. 128, 1985, pp. 27552 - 27557.

4. The Pharmaceutical Journal, Clinical Pharmacy, May 4, 1991, p. 552.