A-A-104 October 13, 1982

COMMERCIAL ITEM DESCRIPTION

TOOTHPASTE

The General Services Administration has authorized the use of this commercial item description in preference to Federal Specification FFF-D-191, Type I.

This description covers two classes of toothpaste: Class l - Regular, Class 2 - Fluoride, intended for use with a toothbrush to remove the usual daily accumulation of food, plaque and stain from the teeth.

Salient characteristics:

All material used in making the toothpaste shall be USP, NF, food or cosmetic grade and quality. The finished product shall conform in all respects to the provisions of the Federal Food, Drug and Cosmetic Act (21 CFR 1).

<u>Consistency</u>. The toothpaste shall be a homogeneous mixture and shall be free of lumps or particles which are palpable in the mouth as separate or discrete particles.

<u>pH</u>. The pH of the toothpaste shall be not less than 4.2 and not greater than 10.0 when tested as specified in ASTM E 70, using one part by weight of toothpaste dissolved in four parts by weight of distilled water as the test solution.

The issue of ASTM E 70 in effect on the date of the solicitation shall be used to determine compliance with these requirements.

Color. The toothpaste shall be white or made with FDA certified dyes.

Appearance. The toothpaste shall be opaque or translucent or a combination of both.

Flavor. The toothpaste shall have a distinct and pleasant flavor.

<u>Safety.</u> When used in the normal manner the toothpaste shall not cause injury or irritation to the teeth, gums or mucous membranes of the mouth.

Ease of extrusion. It shall be possible to extrude not less than 95 percent by weight of the toothpaste from the tube in a continuous mass at a temperature of 10°C without the application of excessive force which would damage the tube.

Stability. The toothpaste shall not segregate, ferment or deteriorate when cooled in a stoppered test tube to $\frac{-15^{\circ}C}{15^{\circ}C}$ for 72 hours or when heated in a stoppered test tube to 45 $^{\circ}C$ for 72 hours.

Class 2 toothpaste. Class 2 toothpaste shall contain a fluoride compound and shall have a formulation fulfilling the guidelines of the OTC Anticaries Drug Monograph, have an approved new Drug Application, or the Seal of Approval of the ADA council on Dental Therapeutics. The name of the fluoride compound shall be marked on the tube.

Preservation, packaging, packing, labeling, and marking. Preservation, packaging, packing, labeling and marking shall be as specified in the contract or order.

Note: The ASTM standards are available from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

MILITARY INTEREST:

no Military activity has an official interest in this document.

None: DoD has determined that

CIVIL AGENCY COORDINATING ACTIVITIES

GSA - OPP HHS - FDA, NIH VA - OSS

PREPARING ACTIVITY:

GSA - OPP