DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 1995

Mr. Scott Koepsel
R&D Project Manager
John O. Butler Company
4635 West Foster Avenue
Chicago, Illinois 60630

Re: K952091
Trade Name: Butler G.U.M. With Flouride
Regulatory Class: I
Product Code: JES
Dated: April 26, 1995
Received: May 3, 1995

Dear Mr. Koepsel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised of our concerns regarding the proprietary name for your device which includes the word "fluoride". Although no specific claims with regard to fluoride content are made in the labeling, fluoride is a commonly recognized active ingredient in dental products associated with anticaries activity. Therefore, the name of the device, Butler G.U.M with Fluoride, implies that the fluoride ingredient will prevent caries. The Food and Drug Administration (FDA) is reevaluating the regulatory status of over-the-counter dental devices containing fluoride, including those for which no specific claims with regard to fluoride content are made in the labeling. You may receive further correspondence regarding this reevaluation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Timothy A. Ulatowski
Acting Director
Pilot Division
Office of Device Evaluation
Center for Devices and
Radiological Health

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708-888-1141

VI. Summary of Safety and Effectiveness

A. Name and Address

This summary of safety and effectiveness is being submitted by John O. Butler Company, 4635 West Foster Avenue, Chicago, IL 60630. The telephone number is: (312) 777-4000 and the contact person will be the Research and Development Manager. This summary was prepared March 28, 1995.

B. Name of the Device

The name of the device will be "Butler G.U.M with fluoride", and is to be sold with different variations of flavor / no flavor, and wax / no wax.

C. The Predicate Products

The predicate products used in this Premarket Notification are:

510 (k) Number	Product
925408	Oral B Mint Waxed Floss with Fluoride
925409	Oral B Mint Waxed Tape with Fluoride
935440	Johnson and Johnson REACH Dentotape with Fluoride
---------	John O. Butler, Butler Weave Product (exempt 21 CFR 872.6390)

D. Description of Device

The devices Butler intends to introduce are floss products impregnated with an average of 0.15 mg Sodium fluoride per 45 centimeters of floss. These product may be supplied with or without flavor and wax, using a nylon or teflon carrier.

E. Intended Use of the Device

These products are intended to be used for the removal of adherent plaque and debris from the teeth.

F. Comparison of Characteristics

The comparison of characteristics between the subject Butler products and the fluoridated predicate products are identical. All products are intended to remove plaque and debris from inter-dental spaces, and are manufactured to contain an average of 0.15 mg Sodium fluoride per 45 centimeters of floss. Similarly, the subject products are identical in every respect to the Butler predicate products except for the addition of fluoride.