DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

HFI-35
purged 1/19/2000 PAO
M3330n

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

January 7, 2000

**NWE-17-00W**

**FEDERAL EXPRESS MAIL**
**RETURN RECEIPT REQUESTED**

C. Boyd Bush, President
Tender Corporation, Inc.
106 Burndy Road
Littleton, New Hampshire 03561

Dear Mr. Boyd:

During an inspection on November 11 through 17, and 19, 1999, of your over-the-counter (OTC) drug manufacturing facility located in Littleton, New Hampshire our Investigator documented serious violations from the current Good Manufacturing Practice (cGMPs) Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211). These deviations cause your After Bite$^R$ to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) as follows:

1. Failure to perform stability testing on your After Bite$^R$ according to 21 CFR § 211.166 to assure your drug products meets the applicable standards of identity, strength, quality, and purity at the time of use. Further a [redacted] post production ammonia assay done on [redacted] of After Bite$^R$ failed to meet your minimum specification for ammonia content.

2. Failure to follow SOP #33, Processing Product Complaints (21 CFR § 211.198), e.g., none of the complaints received since August 1998 have been processed according to SOP #33.

This letter is not intended to be an all inclusive review of all products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and it implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. Your should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, New England District Office, Attention: Bruce R. Ota, Compliance Officer.

Sincerely,

Michael R. Kovochich for.

John R. Marzilli,
District Director
New England District Office