DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

April 9, 2002

Hank Abbott
Pharmacist
Bird's Hill Pharmacy
401 Great Plain Ave.
P.O. Box 558
Needham, MA 02492

Rosalee Virusso
Pharmacist
Bird's Hill Pharmacy
401 Great Plain Avenue
P.O. Box 558
Needham, MA 02492

Dear Mr. Abbott and Ms. Virusso:

This letter concerns **Nicotine Lollipops,** which are currently marketed by your firm as shown on your Internet site www.birdshill.com. According to information on this site, your product consists of Nicotine Salicylate combined with a natural sweetener, and flavorings in a sugar-free base, and is available in 2 mg., or 4 mg. dosages. Based on this product's description on your Internet site, the **Nicotine Lollipops** are intended as an aid for smoking cessation or to reduce nicotine addiction.

The intended uses noted above are conveyed through claims on your Internet site. These include statements such as "...we recommend those who smoke in excess 1 ½ packs per day start with the 4 mg lollipop for approximately 2 to 3 weeks then move down to the 2 mg lollipops for another 2 to 3 weeks. For those that smoke less than 1 ½ packs per day, the recommended dose is 2 mg for approximately 4 to 5 weeks. Use: Place the lollipop in the mouth when you feel the urge to smoke. Leave it there until the urge is over. Once the urge passes, replace the lollipop in the bag provided and reuse the next time the urge strikes. One lollipop is usually last 4 to 5 cigarette breaks." "...The lollipops, ... are intended to help smokers quit their tobacco habit by suppressing symptoms of nicotine withdrawal. All of the replacement methods allow the individual to start with larger doses of nicotine and wean themselves over a period of time." "...Nicotine lollipops used by themselves...greatly assist those individuals who really want to quit smoking." "...Nicotine Lollipops allows the individual to control the amount of nicotine taken in based on the body's needs."

Based on the intended uses established by your Internet site, your **Nicotine Lollipops,** 2 mg. and 4 mg., are "drugs" as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The **Nicotine Lollipops** do not qualify for the exemptions from sections 505 and 502(f)(1) provided under section 503A of the Act since you offer to sell the products without a prescription. Among other requirements, to qualify for the statutory exemptions provided by Section 503A, drugs must be compounded based on the receipt of valid prescription orders from licensed practitioners. You must also use only those bulk substances that conform to Section 503A(b)(1)(A). Nicotine salicylate is not a component of an FDA approved drug, is not listed in a United States Pharmacopoeia (USP) or National Formulary (NF) monograph, and was not nominated for inclusion in a list of bulk drug substances for compounding. Although nicotine and nicotine polacrilex are components of FDA approved drugs and are listed in the USP/NF, nicotine salicylate is not. Therefore, nicotine salicylate is not permitted for use in compounding.

Your **Nicotine Lollipops**, 2 mg., and 4 mg., are also subject to Title 21 of the Code of Federal Regulations (CFR) section 310.544. Under that regulation, they are "new drugs" as defined by section 201(p) of the Act. Under section 505(a) of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA- approved new drug application (NDA) is in effect for such drug. We note that your **Nicotine Lollipops** drug products are not the subject of FDA-approved NDAs and, therefore, they may not be marketed in the United States. The continued distribution of these products without approved NDAs violates Section 505 of the Act.

In addition, your **Nicotine Lollipops,** 2 mg. and 4 mg., are misbranded within the meaning of section 502(o) of the Act in that they are manufactured in an establishment not duly registered under section 510 of the Act and they have not been listed as required by section 510(j) of the Act. They may also be misbranded under section 502(f)(1) of the Act on the grounds that their labeling fails to bear adequate directions for the uses for which they are being offered and they would not be exempt from this requirement under 21 CFR section 201.115 since they are unapproved new drugs. These products may also be misbranded under Section 502(f)(2) of the Act on the grounds that their labeling fails to bear such adequate warnings against use by children where their use may be dangerous to health.

This letter is not intended to be an all-inclusive review of your Internet site and the products marketed by your firm and is not intended to be an all-inclusive list of deficiencies of you and your firm. It is your responsibility to ensure that all drug

products manufactured and distributed by your firm are in compliance with Federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We request that you reply in writing within fifteen (15) days of your receipt of this letter stating the action your firm will take to discontinue marketing of these drug products. Your response should be directed to Melvin F. Szymanski, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Metropark North I, Room 200, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

David J. Horowitz, Esq.
Acting Director
Office of Compliance
Center for Drug Evaluation and Research