this yield by the manner in which the cigarette is smoked, e.g., by puffing more or less frequently, by inhaling more or less deeply, or by covering, with the fingers holding the cigarette or the lips, the vent holes that may be part of the filter.

As discussed in "Nicotine In **Cigarettes And Smokeless Tobacco** Products Is A Drug And These Products Are Nicotine-Delivery Devices Under The Federal Food, Drug, And Cosmetic Act," there is significant evidence now before the agency that the manufacturers of cigarettes intend, as a primary purpose of these products, to deliver the drug nicotine to consumers. That evidence supports a finding at this time that part of a cigarette, the nicotine, is a drug under the act. However, as described above, cigarettes are not simply packaged nicotine. Rather, they are carefully engineered, complex products that are designed to deliver a controlled amount of nicotine to the consumer using such device components as the tobacco, the paper, and the filter.

Nicotine-containing loose cigarette tobacco is used by smokers who roll their own cigarettes usually with paper made for that purpose. The evidence before the agency supports a finding at this time that the processed loose cigarette tobacco product is a device for the same reasons that the tobacco in factory-made cigarettes to be a device: it contains within it the drug intended to be consumed and is not dependent upon being metabolized for the achievement of its principal intended purpose, i.e., the delivery of nicotine, and must be lit and burned in order for the nicotine to be released in a form in which it can be absorbed by the body.

b. Smokeless Tobacco Products. Four principal kinds of smokeless tobacco are manufactured in the United States: loose leaf, plug, twist or roll, and oral snuff. Loose leaf chewing tobacco consists of tobacco leaves that have been heavily treated with licorice and sugars. Plug tobacco is made from tobacco that is immersed in a mixture of licorice and sugar and then pressed into a plug. Twist tobacco is produced from leaves that are flavored and twisted to resemble a rope. Oral snuff is available in both dry and moist varieties. Dry snuff consists of powdered tobacco that contains flavor and aroma additives. Moist snuff is fine particles of tobacco that hold considerable moisture; many types are made with a variety of flavorings such as wintergreen or mint.³ Chewing tobacco and snuff are treated by the manufacturer to achieve an alkaline pH that facilitates absorption of nicotine.4

Smokeless tobacco products function like temporary implants or infusion devices that deliver a controlled amount of nicotine to the cheek and gum tissue for absorption into the bloodstream. The device element of smokeless tobacco products is the tobacco, which contains the drug nicotine and delivers the nicotine to the cheek and gum tissue for absorption into the body, but is not intended to be consumed. Instead, in normal use, most of the tobacco is extruded from the mouth after absorption of the nicotine. This extrudable portion of the product does not achieve its primary intended purpose through chemical action in the mouth, but allows nicotine to be extracted from the tobacco by the user's saliva and: (a) mechanically holds the nicotine in a form that is palatable, thereby allowing sufficient time for absorption of nicotine through the cheek and gum tissue; and (b) delivers chemical agents, primarily alkalines, to increase the pH within the oral cavity, to affect the rate of absorption of nicotine through the cheek and gum tissue.

3. FDA May Exercise Its Discretion to Regulate Cigarettes and Smokeless Tobacco Products Under the Device Provisions of the Act

As explained above, the agency's factual and legal inquiry supports a finding at this time that nicotinecontaining cigarettes and smokeless tobacco products are drug/device combination products, namely, drug delivery devices. Under the combination product authority of section 503 of the act, FDA must designate a component of FDA to regulate combination products based on a determination of the product's 'primary mode of action." In the case of cigarettes and smokeless tobacco, the primary mode of action is that of a drug, due to the nicotine, and, therefore, primary jurisdiction over these products belongs in CDER. CDER's primary jurisdiction over cigarettes and smokeless tobacco is not determinative, however, of which provisions of the act apply. Rather, the agency has the discretion to regulate these drug delivery systems using drug authorities, device authorities, or a combination of both authorities. (See 21 CFR 3.2(e)(1994); 56 FR 58754 at 58754 and 58755 (November 21, 1991); Intercenter Agreement, Section VII.A.1.(b).) It is within FDA's discretionary power to determine which, if any, of the available regulatory authorities it will employ in the regulation of a product. See Heckler v. Chaney, 470 U.S. 821 (1985).

In determining which statutory authority to apply to these products, FDA has carefully considered the regulatory schemes for human drug products and devices, as well as the differing effects of these regulatory schemes on the millions of Americans who use these products. If FDA were to regulate cigarettes, cigarette tobacco, and smokeless tobacco under the drug authorities of the act, the new drug provisions would be applied, and each nicotine-containing cigarette, cigarette tobacco, and smokeless tobacco product would either have to: (a) be shown to be not a "new drug" because it is generally recognized as safe and effective (21 U.S. \tilde{C} . 321(p)); or (b) be the subject of an approved new drug application containing, among other things, adequate tests of the safety and substantial evidence of the effectiveness of the product. (See 21 U.S.C. 355.) In light of the accumulated data on the adverse health effects of tobacco, neither of these outcomes can be viewed as a realistic possibility in currently marketed products. The products would be unapproved new drugs, and as such, FDA could require their removal from the market. (See 21 U.S.C. 331(d), 355(a).)

The agency does not believe that their sudden and total withdrawal from the market would provide the best means of protecting the public health. The nicotine in tobacco products is highly addictive and is the principal reason adults continue to use tobacco products in the face of clear evidence of harm. Major recent studies reveal that the vast majority of the Nation's more than 50 million cigarette and smokeless tobacco users are addicted to the nicotine in these products. Surveys also show that while as many as 70 percent of current smokers would like to quit, only a tiny percentage are able to quit permanently. Studies on smokeless tobacco users show a similar pattern of persistent attempts to quit with extremely low success rates.5

Because of the high addiction rates and the difficulties smokers experience when they attempt to quit, there may be adverse health consequences for many individuals if the products were to be withdrawn suddenly from the marketplace. Our current health care system and available pharmaceuticals may not be able to provide adequate or sufficiently safe treatment for such a precipitous withdrawal. Moreover, banning all tobacco products may not achieve the primary health objective addressed in this regulation, i.e. reducing the number of children and adolescents who become addicted to these products. Given the long,