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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

The undersigned organizations appreciate the opportunity to submit comments to the docket regarding the impact of dissolvable tobacco use on public health. Dissolvable tobacco products (DTPs) are the latest of several new smokeless tobacco products (STPs) on the market. While little is known about these products and their effect on the public health, they raise many concerns. Our comments focus on those concerns, and the need for more information on nearly every aspect of these products in order to determine the best course of action in regulating them. But even without any new information, prompt and effective FDA action to address the issues and concerns raised by these new dissolvable tobacco products is clearly still necessary.[±]

Dissolvable Tobacco Product Marketing

The introduction of novel smokeless, spit-less tobacco products such as R.J. Reynolds' Camel Orbs, Strips, and Sticks or Star Scientific's Ariva and Stonewall products is a major development in the marketing of tobacco products. Traditionally, STPs in the United States have typically taken the form of chewing tobacco or moist snuff, which is loose tobacco, placed between the lip and gum and requires frequent spitting. Today, STPs have expanded to other forms, including the new dissolvable tablets and strips of tobacco. These new DTPs do not require users to spit but instead dissolve in the mouth resulting in consistent exposure to nicotine and other ingredients in the products. Following the same kind of marketing strategies for their other STPs, tobacco companies appear to be marketing the new DTPs to appeal to youth and sustain cigarette smokers'

[±] We note that one of the organizations signing this letter, Legacy, has made a Freedom of Information Act (FOIA) request to obtain the information submitted by the dissolvable tobacco manufacturers to the FDA, and has also asked for an extension of time to submit comments to this docket based on the status of that FOIA request. At the date of this letter, Legacy has not received any information from the FDA in response to the FOIA request. By signing this submission, Legacy is not abandoning its FOIA request or its request for an extension to submit comments and reserves the right to supplement comments at a later date.

nicotine addictions.[1] If the strategies are successful, they would increase the overall harm of tobacco use and undermine the public health objectives of FSPTCA.

Star Scientific introduced Ariva in 2001 and Stonewall Hard Snuff in 2003 both are dissolvable tobacco tablets packaged in blister packs similar to mints or gum. The Camel products all have features that make them different from any tobacco products previously marketed. Camel Orbs are pellets of ground tobacco resembling the candy, “Tic Tac”, while Camel Strips are small, flat sheets containing ground tobacco that work like dissolvable breath strips or even dissolvable medication strips for children (i.e., Tylenol Meltaways or Triaminic Thin Strips). Camel Sticks are thin sticks of ground tobacco that resemble toothpicks. These Camel products were introduced in three test markets in 2009.

The Camel dissolvable tobacco products were all first commercially marketed after February 15, 2007 and, therefore, are “new tobacco products” within the meaning of section 910(a) of FSPTCA, the manufacturer is therefore obligated to obtain an order that these products may be introduced or delivered for introduction into interstate commerce in order to continue marketing such products after March 22, 2011. [Sec. 910(a), 910(c).] An application for an order permitting the marketing of such a new product must contain, inter alia, "full reports of all information concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products as well as a full statement of the components, ingredients, additives, and properties of such product as well as such other information relevant to the subject matter of the application as the Secretary may require." [Sec. 910(b)(1)(A)-(B), (G).] Unless the manufacturer can demonstrate that “permitting such tobacco product to be marketed would be appropriate for the protection of the public health” the statute requires the Secretary of Health and Human Services to deny the application [Sec. 910(c)(2).] The FDA should use this authority to require that the manufacturers of dissolvable tobacco products (and any other new tobacco products) demonstrate that these products meet this standard in accordance with all the requirements of section 910.

R.J. Reynolds may claim that some of its new dissolvable tobacco products are “substantially equivalent” to products commercially marketed on February 15, 2007 and therefore, are not subject to Section 910. In such a case, however, the manufacturer is still required to submit a report demonstrating that such products are substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007. [Sec. 905(j).] That submission under section 905(j) must include an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person. [Sec. 910(a)(4).] The FDA should use this authority under Section 910 to require that R.J. Reynolds and any other manufacturers of the new dissolvable tobacco products either submit all such information regarding "substantial equivalence" or submit an application for pre-market review as a new tobacco product. Furthermore, the FDA should examine carefully and critically whether any such tobacco products for which "substantial equivalence" is

claimed actually meet the standards for determining that a product is "substantially equivalent" to a predicate product within the meaning of section 910(a)(3).

Similarly, FDA should ensure that none of the dissolvable tobacco products are being marketed with any explicit or implicit claims that they reduce risk or are safer than any other tobacco products. Such claims would make them subject to the Section 911 requirement that no modified risk claims be made about any cigarettes or smokeless tobacco products absent prior FDA review of those claims to ensure that the tobacco products with any such claims will be packaged, labeled, marketed and sold in ways that will not increase overall harms from tobacco use.

There are three main reasons to be concerned about DTPs' effects on consumers. First, these products may appeal to children because they are flavored and packaged like candy and their use is easy to conceal (e.g. from parents or teachers) and may result in more children starting to use DTPs. Second, DTPs may discourage smokers from quitting by allowing them to sustain their nicotine addiction in places where they cannot smoke. These new products may result in more kids starting to use tobacco products, and becoming addicted to them, and fewer smokers quitting thereby increasing overall public health harms from tobacco use. Lastly, since DTPs have not been in the marketplace for an extensive period of time little is known about their exact negative health effects or any distinct effects from other types of STPs.

Potential for Youth Initiation

Tobacco companies know that most tobacco users start as adolescents and the companies have a long history of developing novel products with kid-friendly flavors and formulations that attract new users[2] by making the products easier for beginners to tolerate and use while their addiction develops.[3] Each year, there are more than one million new STP users. In 2008, of new smokeless tobacco users, nearly half were under 18 when they first used STPs.[4]

Over the past several years, several national surveys have documented an increase in the use of STPs among young males. For example, according to the National Survey on Drug Use and Health (NSDUH), while overall STPs usage levels were stable between 2002 and 2007, boys aged 12-17 experienced a significant increase in the use of STPs, moving from 3.4 percent in 2002 to 4.4 percent in 2007.[5] The 2009 Youth Risk Behavior Survey found 15 percent of U.S. high school boys currently using STPs – a 12 percent increase from 2007.[6] The Monitoring the Future survey found a 34 percent increase in STPs use among 12th grade males and a 35 percent increase among 10th grade males in just one year between 2008 and 2009.[7]

While little information exists about the effects of usage of DTPs, these products provide particular cause for concern in terms of enticing youth to use the products, and thereby becoming addicted to nicotine and tobacco use. First, the packaging of the products may be likely to appeal to youth. They are easily concealable, fitting readily into a pocket or purse. In addition, the packages are colorful and slick and look similar to mint, candy or

chewing gum containers. Thus, they are not immediately recognizable to either youth or to parents as a tobacco product.

Indeed, two state surveys show that youth mistake DTPs for candy because of their packaging. One in three youth (under age 18) surveyed in Virginia thought that both Camel Orbs and Stonewall dissolvable tobacco were candy, mint or gum.[8] A Utah survey found that almost half (46 %) of youth 18 and under surveyed believed that Camel Orbs packages contained mints.[9] Another disturbing finding from these surveys is that youth who were not current users of tobacco would consider using these products. In Virginia, one in four adolescents (27 percent) under age 18 who did not currently use tobacco said that they would try Camel Orbs Fresh based on packaging alone.[10] In Utah, 44 percent of youth 18 and under surveyed would consider using Camel Orbs based on the packaging, even though they otherwise would not have considered using tobacco products.[11] The findings from these two small surveys are preliminary but the data clearly suggest that these products appeal to youth and that these products put youth at risk for tobacco initiation. It is clear that more comprehensive and robust surveillance is needed to better assess how youth and adults perceive the packaging of DTPs and, more importantly, the products themselves.

The product design itself also may encourage youth and even adults to try the product. The fact that these products resemble non-tobacco products such as mints, gum, candy, breath strips, or toothpicks, may make them appealing in a way that cigarettes may not be. It is possible that youth who might not otherwise take up smoking because they don't like the smell or the smoke, may be tempted to try these products. They are a novel product without the tell-tale signs of cigarette packs, no butts to dispose of, no smell of cigarette smoke left on their hair or clothes, and no spitting. The fact that they are taken orally and do not require spitting may make it easier for youth to use them at any time, including during school or even at home.

Finally, these products are flavored, which may also appeal to youth. The Camel Orbs come in flavors named "Fresh" a minty flavor, and "Mellow" which is the original flavor. Camel Strips come in the Fresh flavor and the Camel Sticks come in the Mellow flavor. Ariva comes in Wintergreen and Java flavors and Stonewall comes in Natural, Java and Wintergreen flavors. As with cigarettes,[12] characterizing flavors in STPs mask the tobacco flavor, and can make the products appealing to youth.[13,14]

As one U.S. Smokeless Tobacco Company (UST) document states: "New users of smokeless tobacco -- attracted to the product for a variety of reasons -- are most likely to begin with products that are milder tasting, more flavored, and/or easier to control in the mouth. After a period of time, there is a natural progression of product switching to brands that are more full-bodied, less flavored, have more concentrated 'tobacco taste' than the entry brand."[15] Further, in a 1994 Wall Street Journal Article, one UST sales representative was quoted as saying, "Cherry Skoal is for somebody who likes the taste of candy, if you know what I'm saying."[16]

The limited information about DTPs and perceptions of them by youth and other potential users indicates a strong need for more information from the manufacturers as well as more research into these products. Camel-branded products are currently officially available in only three cities (Portland, OR; Columbus, OH; and Indianapolis, IN), and very little is known about who is using these products and why.

We encourage FDA to gather more information on these products in order to determine the best way forward in regulating these products and make that information available to the public.

Potential for Addiction – Particularly in Youth

Nicotine is highly addictive[17] and the amount of nicotine reportedly in these products raises concerns that users could become addicted to nicotine.

Star Scientific products (Ariva and Stonewall) reportedly contain 1.5 – 4.0 milligrams of nicotine per unit,[18,19] and the Camel-branded dissolvable products contain 0.6 – 3.1 milligrams of nicotine per piece,[20,21,22] while there is approximately 8.9 – 11.5 milligrams of nicotine yielded on average per cigarette.[23]

However, these products may contain greater amounts of un-ionized or "free" nicotine which is absorbed more rapidly in the mouth which may enhance toxicity.[24]

There is also concern that users of DTPs will "graduate" to use of other tobacco products. For example, some studies show that adolescents who use STPs are more likely to become cigarette smokers.[25,26] Indeed, a 2010 study found that while 17 percent of high school males that did not use STPs smoked, nearly 60 percent of male, high school, STP users had smoked in the past month. This same study found that while male daily dual users smoke fewer cigarettes per day than male daily smokers who do not use STPs, they have higher levels of serum cotinine, a marker of nicotine levels in the blood stream. It also found that 75 percent of daily smokers who also used STPs daily smoked within 30 minutes of waking – a strong indicator of nicotine dependence – compared with 64 percent of daily smokers who never used STPs. [27]

In considering the regulation of DTPs, we encourage FDA to keep in mind these products' strong addiction potential, as well as the possibility that these products may serve as gateways to other tobacco products, and the resulting effect on the public health this would have. There is a clear need for further study of these products to determine just what their addiction potential is, especially considering that some of these products have high levels of nicotine and free nicotine.

DTPs Are Advertised at the Point-of-Sale

Camel DTPs are heavily marketed at retail outlets in the three test market cities in which they are sold, a strategy similar to the marketing strategy used for other tobacco products. Point-of-sale marketing has constituted a steadily increasing portion of the advertising expenditures of the major tobacco companies. In 2006, (the latest year for which data are available), tobacco companies spent over $243 million on point-of-sale advertising, a

three percent increase from 2005.[28] Research has shown that heavy tobacco product advertising at retail outlets works directly to maintain tobacco use rates among adults and increases the likelihood of youth initiation. For example, a study published in the May 2007 *Archives of Pediatrics and Adolescent Medicine*, concluded that retail cigarette advertising increased the likelihood that youth would initiate smoking, and cigarette promotions increased the likelihood that youth would move from experimentation to regular smoking.[29,30,31,32,33]A 2009 study found that more frequent visits to stores selling tobacco and greater awareness of cigarettes sold in stores increased the likelihood of teenagers being susceptible to initiating, experimenting, or becoming current smokers.[34] More generally, point-of-purchase tobacco product advertising and displays have been found to increase average retail tobacco product sales by twelve to twenty-eight percent.[35]

Dual Use Marketing

Dual use is the use of two different types of tobacco products, for example smokeless tobacco and cigarette use. Currently, users of both cigarettes and STPs tend to be younger users.[36] Combined data from 2002-2007 showed that 39 percent of past month STP users had also used cigarettes in the past month. The rate among 12-17 year old past month STP users who were also current smokers was 53 percent, and among 18-25 year olds, the rate was 67 percent compared to 29 percent for those aged 26 or older.[37]

However, as smoke-free laws continue to be put into effect across the country, the shifting norms against smoking have not been lost on the tobacco industry. The industry appears to be attempting to create a new market for dual users, encouraging smokers to continue to use cigarettes where smoking is permitted and to use STPs or now DTPs where it is not, thus maintaining nicotine addiction.

While dual use currently appears most frequently in geographic areas in the U.S. where STP use has traditionally been highest, the test-market sites for new smokeless tobacco products, including DTPs, have included large urban areas and/or cities with large college student populations and, in the case of Columbus and Portland, comprehensive smoke-free laws.[38] This may indicate that the industry is working to open new markets for these new products, including DTPs. Further, the tobacco industry has increased advertising and promotional expenditures for STPs.[39] While the latest information pre-dates the release of the Camel-branded DTPs, this increased spending may be in part to encourage dual use of STPs in general, as a way for cigarette smokers to get a nicotine fix at times when smoking is not allowed. Regardless, the marketing campaigns for DTPs indicate that they are certainly part of this move to encourage dual use. Attachment A shows the Camel Dissolvables website touting, “Three new products from Camel give you a choice and the freedom to enjoy tobacco on your own terms.”[40] Attachment B shows the Ariva and Stonewall website claiming, “You can enjoy tobacco anywhere, smoke-free and discreet,” and “No Boundaries, Enjoy anywhere you want.”[41]

Health Concerns Associated with Dual Use of Dissolvable Tobacco Products and Cigarettes

From a public health standpoint, dual use is worrisome for several reasons. First, use of more than one tobacco product could expose users to an even greater level of dangerous constituents, and may increase their risk of diseases associated with both smoking and STP use. Secondly, dual use has the potential to delay tobacco cessation attempts and/or to perpetuate nicotine dependence. An NIH panel in 2006 concluded that tobacco products similar to DTPs may be perceived as having lower risk, but may actually provide a gateway to smoking among nonsmokers, especially youth, and may increase overall tobacco use by encouraging dual use of cigarettes.[42]

In addition to protecting everyone from secondhand smoke, smoke-free laws can lead to an increase in smoking cessation.[43] But initiating dual use with dissolvable tobacco products provides smokers with an easy alternative to quitting or cutting back when faced with new smoke-free laws or other smoking restrictions.

Dissolvable Tobacco Toxicity

Another health concern surrounding STPs, including DTPs, is tobacco toxicity. The toxicity of tobacco and nicotine is well known. Nicotine poisoning manifests itself through a number of different symptoms of varying severity. Milder symptoms of nicotine poisoning include vomiting, nausea, diarrhea, and headaches. In severe toxicity, one may experience muscle fasciculation's (involuntary twitching) and skeletal muscle paralysis, which can lead to difficulty breathing, sweating, palpitations, abdominal pain or cramps, seizures, or death.[44]

Ingestion of tobacco products remains a major cause of unintentional poisoning in the U.S. From 2006 to 2008, a total of 13,705 cases of tobacco product ingestion were reported for all types of tobacco products, more than 70 percent of which involved infants less than one year of age.[45] In the same study, STPs represented an increasing proportion of tobacco ingestions with each year of age from birth to five years.

Very small amounts of nicotine can be toxic to children. Ingestion of one cigarette, three to five cigarette butts, a pinch of chewing tobacco, or any amount of gum or transdermal nicotine may be toxic to a child.[46] The estimated minimal lethal pediatric dose is 1 milligram of nicotine per kilogram of body weight.[47]

Given the recognized toxicity of nicotine, there is reason for great concern about potential child poisonings from DTPs. The serious and potentially life-threatening health effects of nicotine ingestion, combined with the potentially easy access and attractive taste of DTPs, may result in an increase in nicotine poisoning among children.

As an example, one brand of DTPs (Camel Orbs) contains approximately 0.83 milligrams of nicotine per pellet.[48] Therefore, a one-year-old infant of average weight could suffer mild to moderate symptoms of nicotine poisoning by ingesting 8 to 14 dissolvable tobacco pellets. Ingesting 10 to 17 pellets could potentially result in severe toxicity or death. A four-year-old child of average weight would likely experience moderate symptoms by ingesting 13 to 21 pellets, and severe symptoms if 16 to 27 pellets were

consumed. A package of Camel Orbs contains 15 pellets, 5 more than necessary to cause fatal harm to a one-year-old infant.

Requiring DTPs to be sold in child-resistant packaging is insufficient to prevent infants and children from suffering nicotine poisoning as a result of ingesting these products. A study evaluating child poisoning incidents treated in U.S. hospital emergency departments demonstrated that approximately 55 percent of the more than 86,000 poisoning incidents in 2004 involved products that were stored in child-resistant packaging.[49] Studies have shown that infants as young as one year of age have developed a preference for sweet tastes.[50] Unlike the bitter, unattractive taste of cigarette tobacco, mint or cinnamon-flavored dissolvable tobacco will be much more palatable to children. Therefore, children could be more likely to ingest multiple pellets.

The practice and routine of adult consumption of DTPs will also impact the likelihood of nicotine poisoning among infants and children who may mistake DTPs for food products, especially due to their resemblance to products including breath mints and candy. Young children, in particular, do not possess the developmental and mental capacity to understand the difference between food products and DTPs, and in an attempt to imitate adult behavior, these children may ingest DTPs.

Parents also may not store these products safely as they would store prescription or over-the-counter drugs. It may be more likely that DTPs will be kept in purses or pockets, on tables, and otherwise within reach of children.

Finally, adolescents may consciously choose to use DTPs, but they may have little or no understanding of the proper dosage for such a product. Because some DTPs have significantly higher nicotine content than cigarettes or other tobacco products and a more palatable taste, adolescents may overestimate the proper amount of dissolvable tobacco to consume and may unknowingly overdose on nicotine. Therefore, DTPs might cause unintentional poisonings among adolescents as well as younger children.

In addition to the health concerns associated with the toxicity of and addiction to nicotine, there are several other health concerns associated with STPs.

STPs in general are also associated with periodontal disease; oral mucosal lesions; oral and pancreatic cancer; low birth weight; and cardiovascular disease.[51,52] These conclusions have been confirmed by important international bodies. While very little is known about the direct health concerns associated with DTPs, they raise the same concerns as any other STP about their effect on the public health.

Policy Recommendations

There is very little specific information on DTPs. More research is needed, both in terms of the health effects of these products, and from the industry itself in terms of their research in marketing and developing of these products. Because the most prominent DTPs are “new products” within the meaning of section 910, the burden is on the manufacturer to demonstrate that the marketing of such products is appropriate for the

protection of the public health. FDA must be able to consider the comprehensive information required for approval of new products in order to fulfill its statutory responsibilities. This information must be made available to the public so that public health and tobacco control officials are able to formulate the most effective policies to prevent use of these products by youth and new users, and to help in developing effective cessation programs.

We believe that FDA should take action that would not only address the problems with these new dissolvable smokeless tobacco products but would, at the same time, (1) prevent any other new tobacco products from being introduced and marketed in ways that attract youth, create new tobacco use fads, or otherwise increase overall tobacco product harms and also (2) prevent all other existing smokeless tobacco products from being marketed in ways that attract youth and increase tobacco use harms. At a minimum, that means:

- Prompt initiation of proceedings to consider preventing the use of candy flavors as a characterizing flavor in any smokeless tobacco product;

- Rigorous enforcement of the Section 910 prohibition against the introduction of any new types of cigarettes or smokeless tobacco products into the U.S. market unless they meet the standards for pre-market approval. Such approval should not be granted unless the manufacturer can demonstrate that such products will be packaged, labeled, marketed and sold in ways that will not increase overall tobacco use harms;

- Rigorous enforcement of the Section 911 prohibition against any cigarettes or smokeless tobacco products being marketed in the United States with any explicit or implicit claims that they reduce risk or are less harmful than other tobacco products unless the manufacturer has carried its burden of demonstrating such claims and products meet the public health standard of section 911.

If you wish to discuss these comments, or need further information, please contact any of the undersigned groups. We thank you for the opportunity to present this information and look forward to working with you on dissolvable tobacco products and their impact on public health in the future.

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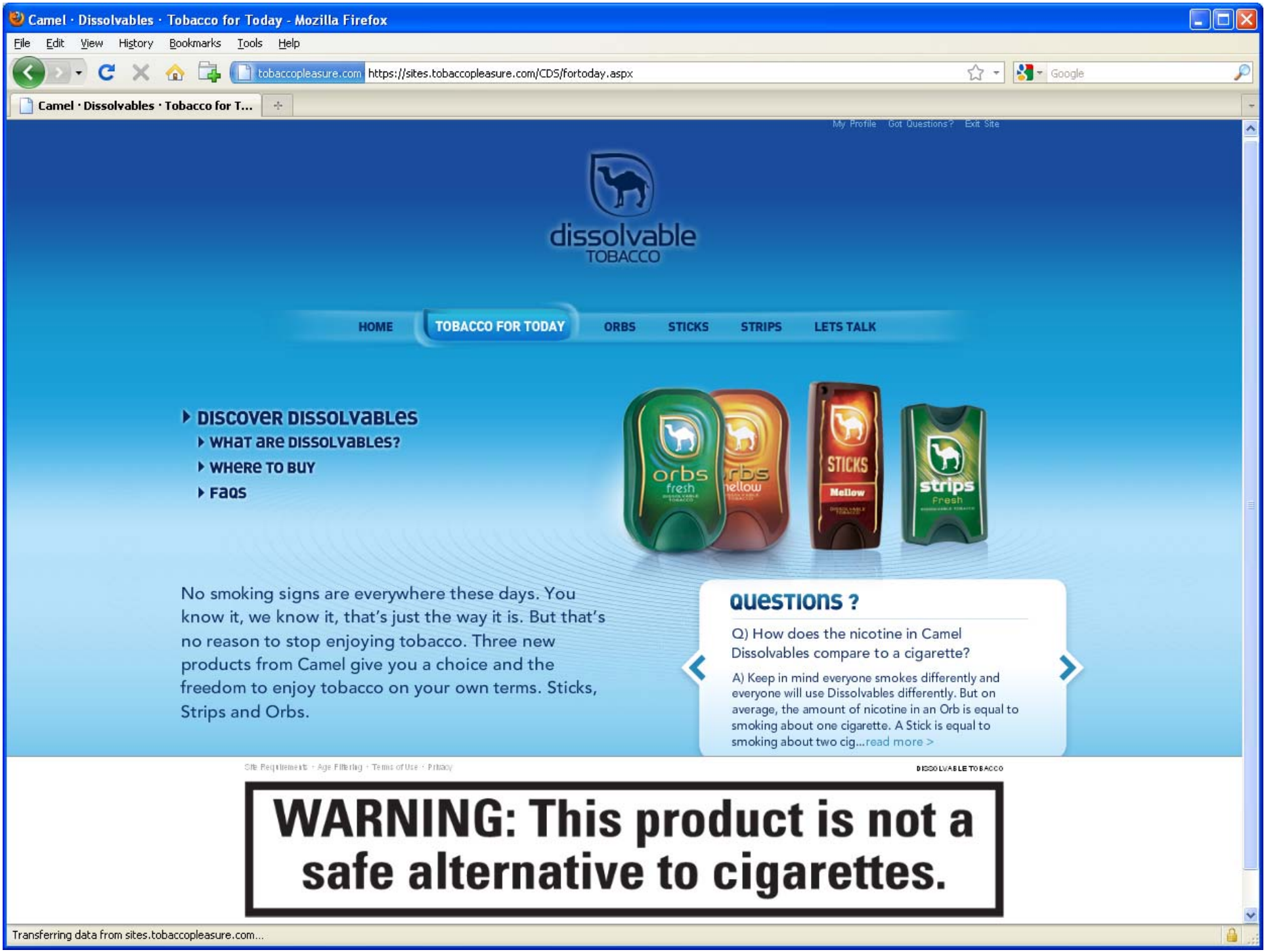
Attachment A



Attachment B