



April 24, 2019

The Honorable Ned Sharpless  
Acting Commissioner  
*and*  
Steven Tave, Director  
Office of Dietary Supplement Programs  
*and*  
Janet Woodcock, Director  
Center for Drug Evaluation and Research

Food and Drug Administration  
10001 New Hampshire Ave  
Hillandale Bldg., 4th Floor  
Silver Spring, MD 20993  
*and*  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless and Directors Tave and Woodcock:

This letter is intended to provide the Food and Drug Administration (FDA) with disturbing findings regarding 15 products currently sold as dietary supplements that explicitly or implicitly claim to help smokers quit smoking and that should therefore be classified as unapproved new drugs. Attached below is a chart detailing the products we investigated. As you will see, all of them failed to provide us, upon request, with scientific substantiation regarding their claimed efficacy for treating nicotine addiction.

The indication for the two FDA-approved prescription smoking cessation products, varenicline (Chantix) and bupropion (Zyban), is for use “as an aid to smoking cessation treatment.” The over-the-counter (OTC) products Nicoderm, Nicorette, and Habitrol state that each “reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.” The label for another OTC product, Nicotrol, says it is to be used as “an aid to smoking cessation for the relief of nicotine withdrawal symptoms.”<sup>1</sup> (The OTC products are all various formulations of nicotine replacement therapy.) The unapproved products described in this letter bear claims that are remarkably similar to those on the FDA-approved products (see attached chart) and risk diverting consumers from these proven-effective products.

We contacted 15 companies selling smoking-cessation supplements on amazon.com or advertising smoking-cessation supplements on the Internet and asked for evidence that their products increased the likelihood of quitting smoking. Ten companies responded, while five did not, despite repeated inquiries. Of those responding:

- 4 claimed they knew of studies, but didn't specify any (even when asked);
- 2 claimed their evidence was positive customer reviews;
- 2 conceded they had no studies;
- 1 claimed traditional use in China; and
- 1 offered no studies or evidence.

We hope that the FDA will cite these products as unapproved and/or misbranded drugs under the Food, Drug, and Cosmetic Act by issuing warning letters to the offending companies and prohibiting their sale.

These products warrant FDA enforcement action under the agency's own principles for enforcement priorities for unapproved drugs.<sup>2</sup> FDA has established six enforcement priorities and at least three apply here: 1. Drugs that lack evidence of effectiveness; 2. Health fraud drugs; and 3. Drugs that present direct challenges to the new drug approval and OTC drug monograph systems inasmuch as they are "unapproved drugs that directly compete with an approved drug."

As you know, smoking is a leading cause of preventable deaths in the United States.<sup>3</sup> Thirty-four million Americans smoke tobacco and, according to the Centers for Disease Control and Prevention (CDC), smoking is responsible for nearly one in five deaths in the United States, or 480,000 deaths per year.<sup>4</sup> While two-thirds of smokers express an interest in quitting, and about half tried quitting in the previous year, less than 10% succeed annually.

Difficulty in overcoming nicotine addiction creates a demand for smoking-cessation aids. As noted, FDA has approved two prescription drugs and several over-the-counter nicotine replacement therapies consisting of patches, gums, and lozenges. Competing with these FDA-approved products are at least 15 dietary supplements that we identified that purport to help consumers overcome nicotine addiction but that have not undergone the safety and efficacy review required of their FDA-approved counterparts. The products bear tempting names like EZ Quit, Kick It, Nicoban, Nicotine Quit, Smoke Away, and Vice Breaker.

As detailed in the attached chart, the products also make extravagant explicit and implied claims that using the products would help smokers to quit and even make it easy to quit, including statements such as those below:

- “Stop Smoking Forever” (Nicoban)
- “Guaranteed to Work or Your Money-Back” (Nicoban)
- “We Guarantee You Will Stop Smoking in Just 7 Days” (Nicoban)
- “Aids in overcoming Smoking Addiction” (Kick It)
- “This natural supplement will help you to get rid of smoking without the need to deal with any kind of addictions” (Eliminiotion)
- “will help you to become smoke free immediately” (EZ Quit)

“Fast acting formula makes it easy to quit for good” (NicRx)  
“take the struggle & stress out of quitting” (Quit WTR)  
“Quit smoking for the last time with minimal effort” (Vice Breaker)  
“users may stop smoking after several days, possibly without realizing they've lost the desire” (Clear Airways)  
“Quit Smoking for the Last Time” (Resist)  
“You are one click away from being SMOKE FREE!” (Nicotine Quit)

Certain products go so far as to claim to be as effective—or even more effective—than are FDA-approved smoking-cessation products:

“Excellent alternative to patches, gums, lozenges” (Clear Airways)  
“you can expect to recover faster from the effects of smoking withdrawal than when using a nicotine quit aid” (NicRx)  
“No need for patches, gum, lozenges” (EZ Quit)  
“does the same as other pharmaceutical drugs on the market” (EZ Quit)  
“Chantix vs. ElimiNiction...ElimiNiction is a better option...Nicorette Gum vs. ElimiNiction...ElimiNiction will a better solution as compared to the gum” (Elimination)  
“There’s never been a better, safer and healthier way to quit smoking!” (Quit WTR)

Yet when we contacted the sellers or manufacturers of these products and requested evidence that the use of their products increased the likelihood of quitting smoking, not one identified a clinical study demonstrating that result. Instead, replies included:

- (1) Vague references to research, with no response to follow-up questions asking for specifics;
- (2) Statements to the effect that their evidence for efficacy is customer reviews;
- (3) Admissions that they had no evidence from studies;
- (4) Claims of traditional use of lobelia (a botanical substance that FDA previously found ineffective for this purpose<sup>5</sup>); and
- (5) No studies or evidence, just an incoherent quasi-scientific statement (“it will help leveled (sic) Nicotine in your body”).

(Full responses from each of the 10 producer/manufacturers who responded are included in the Attachment. Five others did not respond to repeated inquiries.)

When we asked the manufacturers of NicRx whether there are any studies showing that their product helps people quit smoking, the company’s representative replied to us as follows:

A great number of our customers, who have used NicRx, provided positive feedback based on their results, however, as with any product, results will vary with each individual and we cannot predict what your personal experience will be . . . NicRx is a natural, herbal formula with Lobelia to help quit smoking, and reduce nicotine withdrawal and addiction. Unfortunately, we are not qualified to advise customers about medical studies and conditions.”<sup>6</sup>

Twenty-six years ago, FDA banned Lobelia-containing smoking-cessation products from the OTC marketplace because there was no credible evidence that Lobelia helped people quit smoking. The FDA has long recognized that Lobelia “lacks . . . adequate data to establish general recognition of the safety and effectiveness of [Lobelia] for OTC use as a smoking deterrent.”<sup>7</sup>

The respondent for another manufacturer, Greenbush Natural Products—which makes Red Clover Flowering Tops—did not know the formulation or dosage of red clover used in studies, writing us:

I haven't been able to find the details of any of the studies, only references to the studies. So I don't know exactly what they were using, or at what dosage . . . If you are trying to quit smoking, [taking red clover] certainly can't hurt. Since it is nearly impossible to take too much red clover, the general rule for dosing would be to make sure you are getting enough of it. If you are using the red clover capsules an average dose would be 2 capsules three times per day.<sup>8</sup>

Nicotine dependence is a disease. Products that claim to help people quit smoking are drugs under the Food, Drug, and Cosmetic Act because they are intended to cure, treat, or mitigate a disease by affecting the structure or function of the body.<sup>9</sup> Further, these products are unapproved OTC drugs because, under 21 CFR § 310.554, “[a]ny OTC drug product that is labeled, represented, or promoted as a smoking deterrent is regarded as a new drug within the meaning of section 201(p)” of the Food, Drug and Cosmetic Act.<sup>10</sup> For OTC drugs to be lawfully marketed, they require “an approved application or abbreviated application under section 505 of the [FDCA] and part 314 of this chapter. . . .”<sup>11</sup> None of these products have such an approved application

These products are also misbranded because they do not have an approved new drug application or an abbreviated new drug application, which would be required of prescription drugs.<sup>12</sup> Additionally, a product may be deemed misbranded if it is “misleading in any particular.”<sup>13</sup> These products are misleadingly labeled because they use exaggerated and unsubstantiated claims about effectiveness to divert consumers from FDA-approved products and treatment.

The above claims also constitute “health fraud,” as defined by the FDA to mean “[t]he deceptive promotion, advertisement, distribution or sale of articles . . . that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or to provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes.”<sup>14</sup>

We believe that these products should qualify as an enforcement priority under for the FDA’s Health Fraud Compliance Policy Guide § 120.500.<sup>15</sup> Under that Compliance Guide, which makes clear the agency’s views on enforcement priorities, they would be considered “indirect health hazards” that: (1) claim to treat a condition that is significant, as roughly 480,000 deaths per year result from smoking; (2) the scientific data relied upon to support the efficacy of these products is weak (and, in the case of Lobelia-containing products, refuted by evidence according to the FDA); (3) those seeking treatment are both numerous and vulnerable, as more

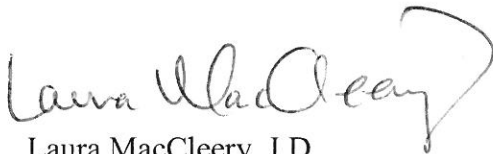
than half of smokers are interested in quitting and “people living below the poverty level and people having lower levels of educational attainment have higher rates of cigarette smoking than the general population;”<sup>16</sup> and (4) these products directly compete with FDA-approved treatments. Accordingly, action to address these misleading products as health fraud should be a high priority for the FDA.

We respectfully urge the FDA to issue warning letters and bring other enforcement actions that require cessation of sales of these and other such products and allow inspectors to seize products. We appreciate the strong action FDA took in January 2018 in response to our prior letter identifying unapproved drugs marketed for the treatment of opioid addiction<sup>17</sup> and FDA’s recent action with respect to products claiming to prevent, treat or cure Alzheimer’s disease and a number of other serious neurological diseases and health conditions.<sup>18</sup> We would welcome the opportunity to speak with you at your convenience regarding our urgent and mutual interest in promoting the integrity, safety, and efficacy of the supplement marketplace.

Sincerely,



Peter Lurie, M.D.  
President



Laura MacCleery, J.D.  
Policy Director

Cc: Andrew Smith, Director, Bureau of Consumer Protection, Federal Trade Commission  
Mitch Zeller, Director, Center for Tobacco Products, Food and Drug Administration  
David Goldman, Chief Medical Officer, Office of Foods and Veterinary Medicine,  
Food and Drug Administration

## Notes

---

<sup>1</sup> All labels available at *Drugs@FDA: FDA Approved Drug Products*, FDA.GOV, <https://www.accessdata.fda.gov/scripts/cder/daf/> (last accessed April 8, 2019).

<sup>2</sup> U.S. FOOD & DRUG ADMIN., MARKETED UNAPPROVED DRUGS – COMPLIANCE POLICY GUIDE. SEC. 440.100: GUIDANCE FOR FDA STAFF AND INDUSTRY (2011).

<sup>3</sup> *Id.*

<sup>4</sup> CENTERS FOR DISEASE CONTROL AND PREVENTION, *Health Effects of Cigarette Smoking*, CDC.GOV, [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/health\\_effects/effects\\_cig\\_smoking/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm) (last visited Feb. 1, 2019).

<sup>5</sup> 21 C.F.R. § 310.544 (2018).

<sup>6</sup> E-mail response from NicRx to Center for Science in the Public Interest (see Addendum).

<sup>7</sup> 21 C.F.R. § 310.544 (2018).

<sup>8</sup> E-mail response from Greenbush Natural Products to Center for Science in the Public Interest (see Addendum).

<sup>9</sup> *Id.*

<sup>10</sup> 21 C.F.R. § 310.544.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> Under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)], a drug is misbranded if its labeling “is false or misleading in any particular.” Section 201(n) of the FD&C Act [21 U.S.C. § 321(n)], provides that, in determining whether an article’s labeling or advertising “is misleading, there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which labeling or advertising fails to reveal facts material in light of such representations . . . .”

<sup>14</sup> U.S. FOOD & DRUG ADMIN., MARKETED UNAPPROVED DRUGS – COMPLIANCE POLICY GUIDE. SEC. 440.100: GUIDANCE FOR FDA STAFF AND INDUSTRY (2011).

<sup>15</sup> U.S. FOOD & DRUG ADMIN., COMPLIANCE POLICY GUIDE SEC. 120.500: HEALTH FRAUD - FACTORS IN CONSIDERING REGULATORY ACTION (2015).

<sup>16</sup> CENTERS FOR DISEASE CONTROL AND PREVENTION, *Cigarette Smoking and Tobacco Use Among People of Low Socioeconomic Status*, CDC.GOV, <https://www.cdc.gov/tobacco/disparities/low-ses/index.htm> (last visited Mar. 7, 2019).

<sup>17</sup> Letter from Laura MacCleery, Director, Legislative Affairs, Center for Science in the Public Interest, to Scott Gottlieb, M.D., Commissioner, Food and Drug Administration, and Steven Tave, Director, Office of Dietary Supplement Programs (Dec. 8, 2017), <https://cspinet.org/sites/default/files/attachment/fda-opioids-letter.pdf>.

<sup>18</sup> *FDA Takes Action Against 17 Companies for Illegally Selling Products Claiming to Treat Alzheimer’s Disease*, FDA.GOV (Feb. 11, 2019), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631064.htm>.

## “Smoking-cessation” dietary supplements

Supplement and company	Claims	Responses to questions from CSPI
<p><b>1 Clear Airways</b>  <a href="https://vitinity.com">https://vitinity.com</a>                      Edgewater, NJ</p>	<p>“help kick the habit” (label and website)                      "Helps you Break Free from your habit the Natural Way" (website and amazon.com)                      "May help reduce the urge" (website)                      "Vitinity users may stop smoking after several days, possibly without realizing they've lost the desire" (website)                      "EXCELLENT ALTERNATIVE TO PATCHES, GUMS, LOZENGES. Clear Airways users may get off sooner, may stop after several days, possibly without realizing they've lost the desire" (website)</p>	<p>Q: Are there are scientific studies showing that smokers who take Clear Airways are more likely to succeed in quitting smoking? The label says "help kick the habit."</p> <p>A: Yes we do have studies on the supplement done by a Doctor however one needs to also be willing &amp; take an initiative to cut back on smoking, exercise regularly, eat healthy &amp; drink a lot of water with lemons which help you through the process in reaching the goal. Results do vary from customer to customer depending on the smoking habits &amp; amount of time one has been smoking.</p> <p>Q: Did these studies compare similar people, some of whom took Clear Airways and some who took a placebo? Are these studies written up or published somewhere?</p> <p>A: No response</p> <p>Q: Did these studies of Clear Airways by a doctor compare similar people, some of whom took Clear Airways and some who took a placebo? Are these studies written up or published somewhere?</p> <p>A: These are white paper studies done on the ingredients of the product.</p> <p>Q: Do these white papers cite studies showing that smokers who take the ingredients in Clear Airways are more likely to succeed in quitting smoking? Are the papers publicly available?</p> <p>A: No response</p>

<p><b>2 Elimination</b></p> <p>Always Be Healthy, LLC, Granbury, Texas  <a href="https://elimination.com">https://elimination.com</a></p> <p><i>[Note: also sells "Opioid Addiction Relief" supplement  <a href="http://elimination.com/opiate-addiction-relief/">http://elimination.com/opiate-addiction-relief/</a>]</i></p>	<p>"provides a means to lessen nicotine cravings without having to quit 'cold turkey'." (website)  "will allow for a smooth and less painful withdrawal" (website)  "provides an excellent smoking cessation method that allows you to stop smoking at your own pace without having to quit cold turkey" (website)  "ElimiNiction is a better option [than Chantix]" (website)  "ElimiNiction will a better solution as compared to the [nicotine] gum" (website)  "ElimiNiction is available in the spray form as well. Spray it when you feel the desire to smoke and you can get rid of smoking in a limited time" (website)  "ElimiNiction is a better option [than nicotine patches] to help you get rid of smoking" (website)  "We feel the best smoking cessation method is Elimination" (website)  "This natural supplement will help you to get rid of smoking without the need to deal with any kind of addictions" (website)</p> <p>"QUIT SMOKING SAFELY AND NATURALLY" (amazon.com)  "NO NEED FOR NICOTINE GUM" (amazon.com)  "Elimination helps you fight addiction by easing your withdrawal symptoms" (amazon.com)  "Elimination effectively and safely helps customers stop smoking" (amazon.com)</p>	<p>Q: Are there scientific studies showing that smokers who take Elimination are more likely to succeed in quitting smoking?</p> <p>A: No response</p> <p>Q: Are there scientific studies showing that smokers who take Elimination are more likely to succeed in quitting smoking? Second request.</p> <p>A: Elimination has helped many, many people give up smoking for good, but there are no scientific studies that show the likeliness of success.</p>
--	---	---



<p><b>3 EZ Quit</b></p> <p>Manufactured by UltraHealth Christchurch, New Zealand  <a href="https://ultrahealth.net.nz/">https://ultrahealth.net.nz/</a></p> <p>Sold in U.S. by HerboPharma on amazon.com  <a href="http://www.herbopharma.net/">http://www.herbopharma.net/</a>  No address on website</p>	<p>"Herbal is a great way in assist you in kicking the addiction for good. No need for patches, gum, lozenges" (UltraHealth website)  "keeping you calm, relaxed and in control to kick the addiction for good" (UltraHealth website)  "This natural herbal blended formula does the same as other pharmaceutical drugs on the market with out the negative and sometime harmful side effects" (UltraHealth website)  "Now with EZQuit, it has never been easier to start your new SMOKE FREE healthy lifestyle. The EZQuit program will allow you to become smoke free from day 1" (UltraHealth website)  "You will quit smoking from day 1" (UltraHealth website)</p> <p>"If you really want to quit and follow the full course, you will have a 100% success rate" (UltraHealth website)</p> <p><i>[Note: Success rates in clinical trials for FDA-approved smoking-cessation products are about 15-20%.]</i></p>	<p>Q: Are there studies showing EZ Quit can really help people quit smoking? Where can I find them?</p> <p>A: "Unfortunately we haven't got any reply yet [from NZ manufacturer]. What we could do is to recommend you to do a research on the ingredients of the product on the Internet."</p> <p>Q: Is there evidence that smokers who take EZ Quit are more likely to quit smoking? (Emailed to NZ mfger)</p> <p>A: It has a herb in it called lobelia which is the active ingredient. If you do some research on lobelia you should find some information relating to giving up smoking</p> <p>Q: Thank you for your response about lobelia in EZ Quit. I have looked for some research on it, but don't find credible evidence that people who take lobelia are more likely to quit smoking. In fact, I find more evidence that lobelia is ineffective. Can you point me to studies showing its effectiveness?</p> <p>A: No response</p> <p><i>[Note: FDA in 1993 banned new shipments of OTC smoking-cessation aids containing Lobelia because Lobelia lacked evidence of efficacy.]</i></p>
--	--	--

<p><b>4 Kick It</b></p> <p>Grandma's Herbs, St. George, Utah  <a href="https://www.grandmasherbs.com">https://www.grandmasherbs.com</a></p>	<p>"Kick the Habit" (label)</p> <p>"Herbal Remedy for Quitting Smoking" (website)</p> <p>"Aids in overcoming Smoking Addiction" (Amazon)</p> <p>"Aids in overcoming drug addiction" (Amazon)</p>	<p>Q: Are there any scientific studies showing that smokers who use Kick It are more likely to succeed in quitting smoking?</p> <p>A: No response from manufacturer on Amazon. Email to manufacturer's website bounced back.</p> <p>Q: Are there any scientific studies showing that smokers who use Kick It are more likely to succeed in quitting smoking? Second Request.</p> <p>A: No response</p>
---	--	--

<p><b>6 Nicoban</b></p> <p>Supplement Spot, Benbrook, Texas  <a href="https://www.supplementspot.com">https://www.supplementspot.com</a></p>	<p>"Nicoban Will Help You Break Free from Nicotine Addiction the Natural Way" (website)  "Stop Smoking In As Little As Just 7 Days" (website)  "Kick the Tobacco Habit In as little as 7 Days!" (website)  "No matter how many smoking cessation products you've tried before, NICOBAN'S natural herbal system attacks and removes every roadblock to your success" (website)  "Our All-Natural Formula will Eliminate Your Cravings and All of the Withdrawal Symptoms that will Temp (sic) You to Cheat" (website)  "Our System Incorporates 4 Unique Herbal Formulas To Overcome Every Obstacle You May Face. Over 93,000 Individuals Just Like You Have Quit Smoking for Life Using This Amazing, All-Natural, Proven System" (website)  "Over 94% of Our Users Succeed!" (website)  "Stop Smoking In As Little As Just 7 Days or we will Refund the Purchase Price. No Questions Asked" (website)</p>	<p>Q: Are there any scientific studies showing that smokers who use Nicoban are more likely to succeed in quitting smoking?</p> <p>A: "No. We estimate that Nicoban works about 75% of the time. If it does not work for you, we will refund you."</p>
--	--	--

<p><b>5 Nicotine Quit</b></p> <p>MD.LIFE, West Palm Beach, Florida 33404. No street address on label. No website.</p> <p>Sold by Shop Smart Live Smart, an Amazon store</p>	<p>"Herbal Blend Designed to Help You Stop Smoking Permanently" (Amazon)</p> <p>"Promotes a Safe and Natural Withdrawal Process" (Amazon)</p> <p>"BECOME THE EX-SMOKER YOU ALWAYS WANTED TO BE!" (Amazon)</p> <p>"We also know that using chemical-based drugs or products to stop smoking may not be effective, and can even put your health at further risk. With MD LIFE™ Nicotine Quit, you finally have a real, safe and healthy chance to quit smoking FOREVER!" (Amazon)</p> <p>"CLEANSE YOUR BODY OF SMOKING TOXINS THAT KEEP YOU ADDICTED" (Amazon)</p> <p>"You are one click away from being SMOKE FREE!" (Amazon)</p>	<p>Q: Are there studies showing Nicotine Quit can really help people quit smoking? Where can I find them?</p> <p>A: Amazon seller: "They responded (sic) it will help leveled (sic) Nicotine in your body."</p>
---	--	---

<p><b>7 NicRx</b></p> <p>Health Formula Inc, Dania, Florida  <a href="http://www.nicrx.com">www.nicrx.com</a>  <a href="https://www.healthformula.com/">https://www.healthformula.com/</a></p>	<p>"NicRx Helps You Quit" (website)  "providing the body with everything it needs to ease the pain of addiction to nicotine and tobacco, while also helping the body recover from the detrimental effects of smoking. The result is a powerful tool that can help you FREE YOURSELF FROM NICOTINE FOREVER" (website)  "providing you with the best-known herbs for helping to quit smoking" (website)  "Quit Smoking the All Natural Way" (website)  "We are so sure that this will be the last time you quit that we've guaranteed NicRX for thirty days. Just think: thirty days from now, you may be smoke free!" (website)  "Learn how Nic RX's herbal ingredients can help you quit forever" (website)  "There are a lot of ways to quit smoking - the patch, the gum, the pill, hypnosis - the list can go on and on. We think the NicRX way is the best because it relies on the power of nature - not drugs" (website)  "NicRX provides you with total relief for quitting" (website)  "When using NicRX, you can expect to recover faster from the effects of smoking withdrawal than when using a nicotine quit aid or going 'cold turkey'." (website)    "the ingredients in NicRX ease all of the effects of withdrawal" (website)  "Natural Anti Smoking Pills with Lobelia to Help Quit Smoking &amp; Curb Nicotine Addiction" (Amazon)  "THE SAFE &amp; EASY WAY TO END SMOKING" (Amazon)  "QUIT FOR THE LAST TIME" (Amazon)  "NicRX helps reduce your desire for tobacco products so you can stop smoking forever" (Amazon)  "NicRX helps you quit so you can protect yourself and your family from the dangers of smoking" (Amazon)  "STOP SMOKING &amp; START LIVING" (Amazon)  "NicRX uses ancient herbs to help you quit for good, so you can achieve all your smoke free dreams" (Amazon)  "NicRX helps you quit smoking on your terms. Imagine the power to decide which cigarette is your last" (Amazon)  "Now is the best time to break the chains of nicotine addiction! Try NicRX and quit today!" (Amazon)  "You can break free of cigarettes with NICRX" (Amazon)  "Say goodbye to cigarettes for good!" (Amazon)  "Try NicRx today and free yourself from addiction" (Amazon)  "Free yourself from nicotine forever" (Amazon)  "Fast acting formula makes it easy to quit for good" (Amazon)  "You can finally break free from your need for cigarettes" (Amazon)  "Quitting doesn't have to hurt. Try NicRx today" (Amazon)  "Quit smoking for the last time" (Amazon)  "Nix RX works hard to break your addiction" (Amazon)  "Quit forever" (Amazon)</p>	<p>Q: Are there studies showing NicRx can really reduce nicotine cravings and help people quit smoking? Where can I find them?</p> <p>A: "A great number of our customers, who have used NicRx, provided positive feedback based on their results, however, as with any product, results will vary with each individual and we cannot predict what your personal experience will be...NicRx is a natural, herbal formula with Lobelia to help quit smoking, and reduce nicotine withdrawal and addiction. Unfortunately, we are not qualified to advise customers about medical studies and conditions."</p> <p>[<i>Note: FDA in 1993 banned OTC smoking-cessation aids containing Lobelia from the marketplace because Lobelia lacked evidence of efficacy.</i>]</p>
--	---	---

<p><b>8 Quit Nutrition/Quit Support</b></p> <p>The Quit Company, LLC  <a href="https://quitmarket.com">https://quitmarket.com</a></p>	<p>"specifically designed to provide the nutrients that smokers typically lack, making it easier to adhere to a smoking cessation plan" (label and website)</p> <p>"Smoking cigarettes depletes the body of key nutrients. Supplementing those vitamins and minerals is an important part of supporting health and quitting smoking" (website)</p> <p>"will help temporarily support willpower for a new healthy, smoke-free life" (website)</p> <p>"Smoking depletes the body of key nutrients which need to be supplemented to help improve health and make quitting easier" (Amazon)</p> <p>"B-Vitamins and herbs help improve your energy and stamina as you quit smoking, to make it easier to feel better and stick to your smoking cessation plan" (Amazon)</p> <p>"support the specific nutritional needs of smokers with vitamins, minerals, amino acids, and herbs, that can be helpful for quitting smoking" (Amazon)</p>	<p>Q: Are there studies showing Quit Nutrition makes it easier to adhere to a smoking cessation plan and helps people quit smoking? Where can I find them?</p> <p>A: "Many of the individual ingredients have been studied for smoking cessation. And we have conducted surveys on thousands of smokers using our products, and found a higher rate of success when Quit Nutrition was used in addition to other products. These were unscientific, but observed in large numbers in surveys. The results were up on our old website, but will be soon up on our new site QuitMarket.com where we will link to all relevant studies."</p> <p><i>[Note: QuitMarket.com currently lists one study, a 2011 Dutch pilot study of 22 heavy smokers who were asked to quit smoking for 4 days. Twelve were assigned a placebo and 10 were assigned 3,600 mg a day of N-acetylcysteine, which is at least six times NAC than is found in Quit Nutrition. There was no significant effect of NAC on craving or withdrawal symptoms and success in quitting smoking was not reported. <a href="https://www.ncbi.nlm.nih.gov/pubmed/21606648">https://www.ncbi.nlm.nih.gov/pubmed/21606648</a></i></p> <p><i>No longer on the website are details of a company survey of product users. 17 of 53 reported being able to refrain from smoking while using the product. Also no longer on the website is a reference to a clinicaltrials.gov registration of a SAME trial by the Mayo Clinic. The website did not mention that the results of this trial were published in 2012, showing that SAME at 8 times the dosage found in Quit Nutrition had no effect on smoking cessation or withdrawal symptoms. <a href="https://www.ncbi.nlm.nih.gov/pubmed/22901308">https://www.ncbi.nlm.nih.gov/pubmed/22901308</a> ]</i></p>
---	--	---

<p><b>9 Quit Smoking Bundle</b></p> <p>Sigmaceutical, Delray Beach, Florida  <a href="http://sigmaceutical.com/">http://sigmaceutical.com/</a></p> <p>Operated by Spin Web Holdings LLC (no website)</p> <p>Sold on Amazon, but supplement does not appear on company website.  <a href="https://www.amazon.com/Quit-Smoking-Bundle-Cleanse-Detox/dp/B07JVXB2GY/ref=sr_1_4_s_it?">https://www.amazon.com/Quit-Smoking-Bundle-Cleanse-Detox/dp/B07JVXB2GY/ref=sr_1_4_s_it?</a></p>	<p>"Quit smoking now" (Amazon)  "Quitting Smoking Now Greatly Reduces Serious Risks to Your Health" (Amazon)  "Quitting at any age and at any time is beneficial. It's never too late to quit, but the sooner the better" (Amazon)  "You've tried every stop smoking aid, every smoking cessation product; acupuncture needles, acupuncture earrings, nicotine lozenge, nicotine liquid, nicotine spray, ear magnets to quit smoking, even ear seeds. But have you tried a lung support supplement" (Amazon)</p>	<p>Q: Are there any scientific studies showing that smokers who use the Quit Smoking Bundle are more likely to succeed in quitting smoking?</p> <p>A: No response</p> <p>Q: Is there evidence showing that smokers who use the Quit Smoking Bundle are more likely to succeed in quitting smoking?</p> <p>A: No response</p>
---	--	--

<p><b>10 Quit WTR</b></p> <p>Harmless Brands (no address on website)  <a href="https://www.harmlessbrands.com/">https://www.harmlessbrands.com/</a></p>	<p>"Fast Acting" "Craving Relief" "No withdrawal" (label)</p> <p>"Smoking Cessation to help people quit nicotine" (website)</p> <p>"Leading the way in providing safer, better and healthier Quit Smoking alternatives" (website)</p> <p>"Harmless Products Co is the nation's fastest-growing producer of natural and drug-free OTC smoking cessation products. We work with the entire healthcare ecosystem to help patients defeat their smoking addiction naturally" (website)</p> <p>"We offer a variety of smoking cessation aid products that help smokers quit smoking without the harmful effects, backed by exceptional results and customer satisfaction" (website)</p> <p>"A better way to quit smoking" (website)</p> <p>"Use Quit WTR to help overcome the urge to smoke, conquer nicotine withdrawal, reduce stress, and suppress cravings naturally" (website)</p> <p>"There's never been a better, safer and healthier way to quit smoking!" (in comparison with nicotine patches, gum, or lozenges) (website)</p> <p>"Quit WTR® Drinkable Smoking Cessation Supplement to Help Curb Craving, Stop Smoking, Support Withdrawal Symptoms, Reduce Stress and Anxiety" (Amazon)</p> <p>"Make this the time you finally quit for good" (Amazon)</p> <p>"Quit WTR is a smoking cessation shot that can help you curb cravings and stop smoking" (Amazon)</p> <p>"Easy to use, works fast, takes away the urge to smoke" (Amazon)</p> <p>"Whether you want to quit one day at a time or one cigarette at a time Quit WTR can help" (Amazon)</p> <p>"Quit WTR is a drinkable smoking cessation supplement made with a blend of herbs and spices that are formulated to help you quit smoking" (Amazon)</p> <p>"Drink a shot of Quit WTR to overcome the urge to smoke and successfully quit smoking" (Google ad)</p>	<p>Q: Are there any scientific studies showing that smokers who use Quit WTR are more likely to succeed in quitting smoking?</p> <p>A: "A study is currently being conducted and (sic) John Hopkins University and will have updates shortly. However, as of 2018 we have heard from users and 8 out of 10 people that use Quit WTR say it worked for them and helped them Stop Smoking"</p> <p>Q: Is this a clinical trial with a placebo?</p> <p>A: No response</p> <p>Q: Is the study of Quit WTR at Johns Hopkins a clinical trial comparing Quit WTR with a placebo? Are the results available yet?</p> <p>A: No response</p>
---	--	--



<p><b>11 Red clover flowering tops</b></p> <p>Greenbush Natural Products, Fountain Hills, Arizona  <a href="https://www.greenbush.net">https://www.greenbush.net</a></p>	<p>"Red clover contains compounds that are being studied as cell antioxidant agents and it has been found to be helpful in quitting smoking" (website)</p> <p>"TOP USES - Women's reproductive health, PMS, cramps, hot flashes, cholesterol and quitting smoking"(Amazon)</p> <p>"it has been found to be helpful in quitting smoking" (Amazon)</p>	<p>Q: Are there any scientific studies showing that smokers who use red clover are more likely to succeed in quitting smoking?</p> <p>A: "I know there have been some small scale studies, plus at least one larger scale study in Japan. Wild Oats extract is also mentioned as helpful. This link will take you to some articles and information on the subject [links to a google search for red clover and quitting smoking]"</p> <p>Q: I looked through the first 10 results of the google search you sent me, but there was no mention in any of them about evidence for red clover helping people stop smoking. There are no studies in PubMed or on clinicaltrials.gov, including the larger-scale Japanese study you mentioned. How do you know that the dose of Greenbush red clover is the same dose used in these studies?</p> <p>A: "I haven't been able to find the details of any of the studies, only references to the studies. So I don't know exactly what they were using, or at what dosage. I have found references to using red clover along with licorice root in chewing tobacco-like form as an aid to quitting smoking. Other references use it along with yellow dock and licorice root in tea form to help with quitting. Dr. James Duke, former herbal researcher for the USDA and author of the book The Green Pharmacy, recommends red clover as an aid to quit. I have been reading herbal research for nearly 20 years and I have a recollection of reading this study. But, so far, no luck in finding it. If you are trying to quit smoking, it certainly can't hurt. Since it is nearly impossible to take too much red clover, the general rule for dosing would be to make sure you are getting enough of it. If you are using the red clover capsules an average dose would be 2 capsules three times per day."</p>
--	--	---

<p><b>12 Resist</b></p> <p>Libertas (no address on website) <a href="https://smokefreehealth.com/">https://smokefreehealth.com/</a></p>	<p>"Quit Smoking for the Last Time" (website) "We've created a combination of health supplements that help you to quit smoking, decrease withdrawal symptoms and add back nutrients lost from smoking. Our products help you stay smoke-free and reduce the urge to smoke." (website) "We can help you conquer the physical craving to smoke" (website) "Resist the Urge to Smoke. Whether you want to quit altogether or simply reduce the number of cigarettes you smoke throughout the day, Resist can help you conquer the physical craving to smoke" (website)  "Resist The Urge to Smoke   Scientifically Proven Blend" (Amazon) "Help to Quit Smoking" (Amazon) "RESIST THE URGE OF SMOKE - Libertas Resist Vitamins for Smokers supplements will directly assist you with smoking cessation" (Amazon) "It is scientifically proven that these vitamins help you to resist the urge to smoke" (Amazon) "Scientifically proven blend to help reduce the urge to smoke" (Amazon) "Helps to quit smoking" (Amazon)</p>	<p>Q: Are there any scientific studies showing that smokers who take your product Resist are more likely to succeed in quitting smoking? I see that your website mentions a meta-analysis of studies looking at N-acetylcysteine and cravings. But those studies used far greater doses of NAC than what's in Resist. Plus, the studies didn't look at whether the effect on cravings was enough to help people stop smoking.</p> <p>A: No response</p> <p>Q: Are there any scientific studies showing that smokers who take your product Resist are more likely to succeed in quitting smoking? I see that your website mentions a meta-analysis of studies looking at N-acetylcysteine and cravings. But those studies used far greater doses of NAC than what's in Resist. Plus, the studies didn't look at whether the effect on cravings was enough to help people stop smoking. Second request.</p> <p>A: No response</p>
---	--	---

<p><b>13 Smoke Away</b></p> <p>Smoke Away, Naples, Florida  <a href="https://www.smokeaway.com/">https://www.smokeaway.com/</a></p>	<p>"We have put together a group of all natural easy-to-use components that provide an extra line of defense to assist as you become a non-smoker" (website)</p> <p>"Fight withdrawal symptoms naturally" (website)</p> <p>"To quit smoking is hard and we realize that and in our quest to keep you smoke free, we have provided you with resources and other support groups to help you ensure that when you quit smoking you stay that way" (website)</p> <p>Testimonials on website</p> <p>"I couldn't believe how easy it was. After a few days I didn't even feel like a cigarette!"</p> <p>"I Followed the Directions and Have Been Smoke Free Every Since. I Feel Amazing."</p> <p>"I'm Still Not Smoking. I am so Impressed With it I Tell All My Friends"</p> <p>"The Next Morning I Didn't Feel Like Smoking"</p> <p>"Within a couple days I could tell it was different... I Didn't Have the Cravings I Had When I Tried to Quit Before."</p> <p>"Nothing worked until I found Smoke Away"</p> <p>"designed to help reduce cravings and keep you calm as you go through the process of quitting smoking" (Amazon)</p> <p><i>[NOTE: Smoke Away paid \$1.3 million in 2005 to settle Federal Trade Commission charges that it deceptively marketed dietary supplements by claiming the supplements would allow smokers to quit smoking quickly, easily, permanently, and without cravings or other side effects. The company was prohibited from making any claims about the benefits, performance, efficacy, safety, or side effects of Smoke Away or any other smoking cessation product or program unless those claims are true, non-misleading, and substantiated.</i></p> <p><a href="https://www.ftc.gov/news-events/press-releases/2005/08/marketers-smoke-away-pay-13-million-settle-ftc-charges">https://www.ftc.gov/news-events/press-releases/2005/08/marketers-smoke-away-pay-13-million-settle-ftc-charges</a></p>	<p>Q: Are there any scientific studies showing that smokers who use Smoke Away are more likely to succeed in quitting smoking?</p> <p>A: No response</p> <p>Q: Are there any scientific studies showing that smokers who use Smoke Away are more likely to succeed in quitting smoking? Second request.</p> <p>A: No response</p>
---	---	---

<p><b>14 Stop Smoking Detox Formula</b></p> <p>Jen-On Herbal Science International, City of Industry, California  <a href="http://www.hsusa.net">www.hsusa.net</a></p>	<p>"Stop Smoking Detox Formula" (Amazon)  "May also be used for: Addiction-Tobacco, Drugs" (Amazon)  "This formula can assist persons who want to quit smoking or free themselves from addiction" (Amazon)  "assist in eliminating addiction to tobacco and drugs" (Amazon)  "When combined together, the herbs in this formula can assist in the elimination of addiction to tobacco and drugs" (Amazon)</p> <p>No claims for supplement on website  <a href="http://www.hsusa.net/product_info.php?&amp;products_id=221">http://www.hsusa.net/product_info.php?&amp;products_id=221</a></p>	<p>Q: Are there studies showing the Jie Yan Jie Du Fang supplement helps people quit smoking? Where can I find them?</p> <p>A: No response</p> <p>Q: Is there evidence showing that people who take the Jie Yan Jie Du Fang supplement are more likely to quit smoking? Where can I find the evidence?</p> <p>A: No response</p>
--	---	--

<p><b>15 Vice Breaker</b></p> <p>Nutraceutical Life Sciences, Scarborough, Ontario, Canada <a href="https://nutratecls.com/">https://nutratecls.com/</a></p> <p><i>[Note: Vice Breaker is available from website and Amazon, but not in Canada]</i></p>	<p>"Helps you quit smoking" (label) "Herbal Quit Smoking Aid" (label)</p> <p>"a traditional herbal medicine to help cleanse lungs, help you quit smoking and reduce nicotine dependence" (website) "Helps you to quit smoking" (website) "Helps to reduce nicotine dependence" (website)</p> <p>Quit smoking for the last time" (Amazon) "Effects in three months" (Amazon) "Quit smoking for the last time with minimal effort" (Amazon) "Quit without even knowing it" (Amazon) "Vice Breaker acts as a barrier to block nicotine receptors in your brain, making it easier for you to avoid and eventually wean yourself off tobacco" (Amazon) "HOW LONG WILL IT TAKE? A maximum of one to two months (though some people find they no longer crave nicotine in as early as two weeks). Some customers get an extra bottle and quit together with a friend" (Amazon) "Vice Breaker can also help the body remove nicotine toxins faster, speeding the withdrawal process and alleviating symptoms" (Amazon) "Decide to quit, and take advantage of Vice Breaker's natural formula to help you quit for the last time" (Amazon) "An excellent alternative or complement to nicotine gums, patches and lozenges - Vice Breaker users quit sooner, experiencing a loss of desire to smoke and even stop smoking after several days, often without realizing they've lost the desire to smoke" (Amazon) "has been very successful in treating those trying to quit smoking" (Amazon)</p>	<p>Q: Are there studies showing that Vice Breaker really helps people quit smoking? Where can I find them?</p> <p>A: "The main ingredient is Lobelia that has been used for hundreds of years in China...We have been selling Vice Breaker over 10 years. Nutraceutical has always had positive reviews from our customers."</p> <p><i>[Note: FDA in 1993 banned OTC smoking-cessation aids containing Lobelia from the marketplace because Lobelia lacked evidence of efficacy.]</i></p>
---	---	---