

plexus

Immune Plus™

US Product Claims Reference Guide



Immune support claims can be very tricky for dietary supplement companies because these products are truly meant to augment the body's ability to stay well. If stated improperly, however, these immune-related claims could imply disease prevention in the eyes of regulatory agencies. Plexus® has noted a significant increase in regulatory scrutiny around dietary supplements intended to support immune system function, given the COVID-19 pandemic. This resource provides information on the various agencies at play, and offers suggestions for Plexus Ambassadors and Employees to help mitigate risk when explaining the amazing health benefits of Plexus Immune Plus.

Understandably, the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) consider the sale and promotion of fraudulent or misleading COVID-19 dietary supplements as a threat to public health. Therefore, these agencies have ramped up surveillance and enforcement activities against companies selling dietary supplements that directly state or imply an effect in treating, curing, or preventing COVID-19.

Plexus is committed to the promotion and sale of our products in accordance with applicable laws and regulations in all markets wherein we do business. To that end, the Regulatory Affairs Department has created this resource to help you understand how to confidently promote the Immune Plus dietary supplement in a compliant manner. Below are some examples of unacceptable implied disease claims, why they are problematic, and acceptable claims you can make for Immune Plus.



THE DO'S

- Use key words such as “support”, “help”, “healthy”, “maintain”, “wellness”, “well-being”, etc.
- Refer to general immune system function. (e.g. “helps maintain healthy immune system function*” or “daily immune support**”)
- Share this product using only approved product claims, like: Daily immune support and wellness formula, Promotes immune health, Supports healthy immune system function, Cellular immune support, and Helps maintain a strong immune system.*



THE DON'TS

- Don't claim that Plexus products can treat COVID-19 in either a direct or implied manner, even if you don't actually name the disease, but use everyday terms (instead of medical terminology). U.S. regulators look at the intent of advertising statements when determining if a disease claim is being implied. For example, if you are discussing the importance of the immune system in minimizing the effects of COVID-19 or ANY other illness, and then refer to Immune Plus with what would otherwise be a compliant “general immune support*” claim, the two will be read together and considered an implied (and illegal) claim for the mitigation or prevention of a disease.
- Don't use the following “red flag” words or symptoms associated with COVID-19 and/or other illnesses: Airborne, Antimicrobial, Antiseptic, Anti-Viral, Asthma, Auto-immune, Chills, Cold (common), Congestion/Runny Nose, Coronavirus, COVID-19, Cough, Diarrhea, Epidemic, Fever, Flu, Headache, Infection, Influenza, Inflammation, Nausea/Vomiting, Muscle/Body Aches, Pandemic, Sickness, Shortness-of-breath, Sore Throat, Virus.
- Don't use words such as “disease”, “illness”, “cure”, “treat”, “repair”, “prevent”.
- Don't use testimonials about how Plexus products, including Immune Plus, helped someone treat, cure, or prevent COVID-19. Personal experiences can be incredibly compelling, but they are regulated speech when used by the company. No matter how remarkable someone's personal experience may be, it could be a violation of U.S. regulations.

This reference guide applies to the United States and may not be applicable to other markets.

*These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

Acceptable Claim	Unacceptable Claim	Why is it an Implied Disease Claim?
Daily immune support and wellness formula*	Strengthen your immune system during this challenging time.	Any reference to “this challenging time” (or similar language) could be interpreted by a reasonable consumer as a reference to the current COVID-19 pandemic or the general cold & flu season.
Immune Plus provides 100% of the Reference Daily Intake (RDI) for Vitamin C. Vitamin C helps maintain our immune defense by supporting cellular functions related to the innate and adaptive immune system.*	Helps your body defend against airborne invaders (pathogens).	Any reference to “airborne invaders” suggests the product can “prevent” airborne pathogens.
Supports a healthy innate immune response.*	The key ingredients in Immune Plus have been studied for their potent anti-viral properties.	Any reference to “anti-viral” properties of the product or its ingredients suggests an intended use to “treat, cure, or prevent” an active viral infection.
Cellular immune support.*	Boosts white blood cell activity to kill viruses, bacteria, and other pathogens	Suggests the product may treat or prevent viral, bacterial, or other pathogenic infections.
Immune Plus helps maintain a strong/robust immune system.*	Are you sick of being sick? (or) Worried about getting sick?	Suggests Immune Plus can “prevent” illness caused by germs, such as Coronavirus.
Helps maintain the body’s immune response at the cellular level.*	With school back in session, don’t let nasty germs get you down.	Suggests Immune Plus can “prevent” illness caused by germs, such as Coronavirus.
Add Immune Plus to your daily proactive self-care routine.	Wash your hands, wear your mask, and add Immune Plus to your daily routine.	Given frequent hand washing and face masks are public health measures to specifically limit the spread of COVID-19, any reference to a dietary supplement complementing these measures would be interpreted as an implied disease claim by FDA.
Stimulates the body’s natural immune-defense system.*	Are you prepared for the second wave?	Suggests Immune Plus can “prevent” infection from COVID-19 during a second increase in the number of positive cases.
Supports healthy immune system function.*	Are you immuno-compromised, have a weakened immune system, or are at risk?	Plays on consumer’s fear of contracting COVID-19, or other illnesses, and suggests Immune Plus can “treat, cure, or prevent” disease.
Did you know the key ingredients in Immune Plus stimulate the body’s innate (natural) immune-defense system?*	Why wait for a vaccine when you can boost your immune system now?	Suggests Immune Plus acts as a substitute treatment to prevent COVID-19 or other viruses typically prevented through vaccine inoculation.

Plexus® products are founded on science. This science can be explained, and the amazingly effective products can (and must be) promoted in a compliant manner. By following the guidance in this resource, you are doing your part to help Plexus keep its commitment to the principles of trustworthiness and honesty. If you ever need additional guidance on how to stay compliant with applicable laws and regulations, please do not hesitate to contact the regulatory affairs department at rplexus@plexusworldwide.com.

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