



Kids Essentials Combo

US Product Claims Reference Guide



THE DO'S

- Use key words such as “support”, “help”, “healthy”, “maintain”, “wellness”, “well-being”, etc.
- Refer to general immune system and brain function. (e.g. “Supports immune health and brain function**”)



THE DON'TS

- Don't use “red flag” words (i.e. symptoms associated with COVID-19), or ANY OTHER HEALTH CONDITION, for example: ADD/ADHD, Airborne, Antimicrobial, Antiseptic, Anti-Viral, Asthma, Auto-immune, Chills, Cold (common), Congestion/Runny Nose, Coronavirus, COVID-19, Cough, Diarrhea, Digestive Disorders, Eczema, Endocrine Disorders, Epidemic, Fever, Flu, Genitourinary Disorders, Headache, Infection, Influenza, Inflammation, Nausea/ Vomiting, Mental & Behavioral Disorders, Muscle/Body Aches, Musculoskeletal Disorders, Nervous System Disorders, Pandemic, Parasites, Respiratory Disorders, Sickness, Shortness-of-breath, Skin Disorders, Sore Throat, Virus.
- Don't use words such as “disease”, “illness”, “cure”, “treat”, “repair”, “prevent”.
- Don't use testimonials about how the Kids Essentials Combo, helped someone treat, cure, or prevent any disease or health condition. 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.
- Don't claim that the Kids Essentials Combo can treat ANY disease or health condition 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 the combo 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.

Regulatory agencies and consumer advocacy groups are exceptionally sensitive to the truthfulness of dietary supplement advertisements targeting children or preying on parents' fears. Product efficacy statements for children's dietary supplements can be tricky because these products are truly only meant to support and complement good health. If stated improperly, however, these statements can easily imply disease prevention/treatment, or be considered deceptive. Plexus® has noted a significant, and appropriate increase in regulatory scrutiny around dietary supplements intended to support immune system function (given the COVID-19 pandemic), as well as products exclusively intended for use by children. This resource provides information on the various agencies at play and offers suggestions for Plexus Ambassadors to help mitigate risk when explaining the amazing health benefits of the Plexus Kids Essentials Combo.

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

Plexus is committed to the promotion and selling 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 Plexus Kids Essentials Combo in a compliant manner. Below are some examples of unacceptable implied disease statements, why they are problematic, and acceptable product efficacy statements you can make.

***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.**

Unacceptable Claim	Why is it an Implied Disease Claim?	Acceptable Claim
<p>Boost your child’s immune system during this challenging time.</p> <p>OR</p> <p>Have you strengthened your child’s immune system before they return to school?</p>	<p>Supporting the normal function of the immune system is acceptable. However, “boosting” your child’s immune system is not an acceptable claim for this combo. In addition, any reference to “this challenging time” (or similar language regarding a return to school) could be interpreted by a reasonable consumer as a reference to the current COVID-19 pandemic or the general cold & flu season.</p>	<p>Supports immune health / Support your child’s overall health and wellness / Helps ensure your kids receive beneficial nutrients to help them feel their best.*</p>
<p>Keep your kids virus free.</p>	<p>Any dietary supplement claiming to prevent their children from being infected by an unnamed virus would be automatically considered an implied COVID-19 disease claim by regulators.</p>	<p>Supports immune health / Support your child’s overall health and wellness / Helps ensure your kids receive beneficial nutrients to help them feel their best.*</p>
<p>Helps defend your kids against digestive disorders.</p>	<p>Any reference to “digestive disorders” suggests the products are intended to treat a disease.</p>	<p>Supports digestive regularity / Supports digestive health / Helps support intestinal yeast balance.*</p>
<p>Are you worried your child may have a mental or behavioral disorder (ADD/ADHD)?</p>	<p>Any reference to “mental or behavioral disorders” suggests the products are intended to treat a disease.</p>	<p>Supports healthy brain and cognitive development / Enriched with unique blend of brain-nurturing ingredients / Provides lutein, and important nutrient that helps support cognitive health in kids / Dietary DHA is associated with cognitive function in kids.*</p>
<p>With school back in session, don’t let nasty germs take them down.</p>	<p>Suggests products can “prevent” illness caused by germs, such as coronavirus.</p>	<p>Supports immune health / Support your child’s overall health and wellness / Helps ensure your kids receive beneficial nutrients to help them feel their best.*</p>
<p>Make sure your kids wash their hands, wear a mask, and add the Kids Essentials combo to their daily routine.</p>	<p>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.</p>	<p>Adding the Kids Essentials combo to your child’s daily routine is a great way to encourage proactive self-care.</p>
<p>Are you prepared for the second wave?</p>	<p>Suggests Combo can “prevent” infection from COVID-19 during a second increase in the number of positive cases.</p>	<p>Supports immune health / Support your child’s overall health and wellness / Helps ensure your kids receive beneficial nutrients to help them feel their best.*</p>
<p>Is your child immuno-compromised, have a weakened immune system, or are at risk (Asthma, Respiratory Illness, etc.)?</p>	<p>Plays on parent’s fear of their child contracting COVID-19, or other illnesses, and suggests the Kids Essentials combo can “treat, cure, or prevent” disease.</p>	<p>Supports immune health / Support your child’s overall health and wellness / Helps ensure your kids receive beneficial nutrients to help them feel their best.*</p>
<p>Why wait for a vaccine when you can boost your kid’s immune system now?</p>	<p>Suggests Kids Essentials Combo acts as a substitute treatment to prevent COVID-19 or other viruses typically prevented through vaccine inoculation.</p>	<p>Supports immune health / Support your child’s overall health and wellness / Helps ensure your kids receive beneficial nutrients to help them feel their best.*</p>

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. For example, our dietary supplement products must be promoted with properly worded structure-function claims, rather than unacceptable and misleading disease/drug claims. 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.

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

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