

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

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No. 17-13884

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D.C. Docket No. 1:16-cv-01783-TCB

HI-TECH PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

versus

HBS INTERNATIONAL CORP.,

Defendant-Appellee.

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Appeal from the United States District Court  
for the Northern District of Georgia

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(December 4, 2018)

Before TJOFLAT and WILLIAM PRYOR, Circuit Judges, and MURPHY,\*  
District Judge.

WILLIAM PRYOR, Circuit Judge:

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\* Honorable Stephen Joseph Murphy III, United States District Judge for the Eastern District of Michigan, sitting by designation.

This appeal from the dismissal of a complaint raises questions about the relationship between the labeling requirements of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and state and federal laws against deceptive advertising. Hi-Tech Pharmaceuticals, Inc., filed a complaint that the label of a protein-powder supplement distributed by HBS International Corp. misleads customers about the quantity and quality of protein in each serving, violating both the Georgia Uniform Deceptive Trade Practices Act, O.C.G.A. § 10-1-372(a), and the federal Lanham Act, 15 U.S.C. § 1125(a). The district court dismissed the complaint on the grounds that the state-law claim is preempted by the Food, Drug, and Cosmetic Act and that the complaint fails to state a claim under the Lanham Act because it is not plausible that the label is misleading. We agree that the state-law claim is preempted, but we disagree that the label is not plausibly misleading. And we reject HBS's arguments that the Food, Drug, and Cosmetic Act bars the claim under the Lanham Act. We affirm in part, reverse in part, and remand.

## **I. BACKGROUND**

Hi-Tech Pharmaceuticals, Inc., is a Georgia-based firm that manufactures, markets, distributes, and sells dietary-supplement products. HBS International Corp. is a Canadian firm that distributes throughout the United States and Canada bodybuilding and sports-nutrition supplements supplied by its wholly owned subsidiary, Allmax Nutrition, Inc. One of the Allmax products HBS distributes, the

“Ultra-Premium 6-Protein Blend Hexa[P]ro,” is a protein-powder drink mix marketed as a bodybuilding and workout-recovery aid.

Because this appeal arises from the dismissal of a complaint, “we accept as true the facts alleged in the complaint, drawing all reasonable inferences in [the] plaintiff’s favor.” *Bailey v. Wheeler*, 843 F.3d 473, 480 (11th Cir. 2016). Under the doctrine of incorporation by reference, we may also consider documents attached to the motion to dismiss if they are referred to in the complaint, central to the plaintiff’s claim, and of undisputed authenticity. *See Horsley v. Feldt*, 304 F.3d 1125, 1134 (11th Cir. 2002); *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1369 (11th Cir. 1997). In particular, we consider the undisputed HexaPro marketing label attached to the motion to dismiss by HBS.

Hi-Tech filed a complaint against HBS and other defendants not involved in this appeal. As relevant here, the complaint alleges that the following HexaPro marketing label violates the Georgia Uniform Deceptive Trade Practices Act, O.C.G.A. § 10-1-372(a), and the Lanham Act, 15 U.S.C. § 1125(a):

**SCIENCE • INNOVATION • QUALITY • RESULTS**

**ALLMAX NUTRITION**

**HEXAPRO™**  
ULTRA-PREMIUM 6-PROTEIN BLEND™

**25G PROTEIN PER SERVING**

**4G FIBER PER SERVING**

**6 ULTRA-HIGH QUALITY PROTEINS**  
**5 AMINO ACID BLEND WITH BCAAs**  
**PREMIUM SATISFYING TASTE**

**Supplement Facts**

Amount Per Serving	% Daily Value*
Protein	17%
Calories from Fat	20%
Total Fat	4.1 g 8%
Saturated Fat	1.9 g 4%
Trans Fat	0 g 0%
Monounsaturated Fat	1.9 g 4%
Cholesterol	22 mg 4%
Sodium	122 mg 3%
Potassium	370 mg 11%
Total Carbohydrate	1.9 g 4%
Dietary Fiber	4.1 g 16%
Sugars	1.9 g 4%
Phenols	25.8 mg 60%
Vitamin A	12 IU 0%
Vitamin C	0.07 mg 0%
Calcium	113 mg 11%
Iron	0.1 mg 0%
Total	14.1 mg 26%

**Amino Acid Profile**

Amino Acid	Amount
Alanine	100 mg
Arginine	100 mg
Asparagine	100 mg
Aspartic Acid	100 mg
Cysteine	100 mg
Glutamic Acid	100 mg
Glutamine	100 mg
Glycine	100 mg
Histidine	100 mg
Isoleucine	100 mg
Leucine	100 mg
Lysine	100 mg
Methionine	100 mg
Phenylalanine	100 mg
Proline	100 mg
Serine	100 mg
Threonine	100 mg
Tyrosine	100 mg
Valine	100 mg

**HEXAPRO™ is an Ultra-Premium, Ultra-Satisfying Blend of 6 High-Quality Proteins**

HEXAPRO™ is a high-digestible protein mix that, medium and sustained release proteins that ensure high amino acid levels with both short and long term delivery. Each serving has been carefully selected to achieve maximum protein assimilation and absorption. HEXAPRO™ is also fortified with 5 amino acids to enhance absorption, including all 5 BCAAs essential for protein synthesis and providing a rapid energy source for muscles.

**WHEY PROTEIN CONCENTRATE (WPC)**  
Whey is considered to be one of the best, most high-digestible proteins. WPC rapidly rehydrates providing a surge of amino acids to the body to stimulate recovery and speed muscle repair.

**WHEY PROTEIN ISOLATE (WPI)**  
A more concentrated form of WPC, WPI provides a slower release of protein due to the unique properties of casein.

**WHEY PROTEIN HYDROLYZATE (WPH)**  
Considered by most to be the ultimate in protein digestibility due to its exceptionally rapid rate of absorption and activity.

**MEAT EXTRACT (ME)**  
The slowest rate of absorption, providing amino acid delivery for up to 72 hours. This ensures that you can store muscle breakdown due to lack of amino acids for a much longer duration.

**EGG PROTEIN**  
Egg protein is a high-quality protein that is easily absorbed and provides a steady release of amino acids.

**HYDROLYZED WHEY**  
Hydrolyzed whey has an extremely fast rate of assimilation, bypassing what you give through the process of being broken down into blocks. It acts as peptides and provides HEXAPRO™ with additional protein.

**THICK, SATISFYING PROTEIN.**  
HEXAPRO™ has a thick, rich, decadent chocolate milkshake taste that will make you think Protein, but that's not all. HEXAPRO™ contains no carbohydrates and no artificial sweeteners. All our agents, like yours, like this, you'll want to make HEXAPRO™ a part of your diet. You're getting more protein with less sugar. It'll help you achieve your goals.

**REACHING YOUR GOALS.**  
Every athlete, fitness competitor or bodybuilder will tell you that frequent feeding is essential. HEXAPRO™ makes getting frequent feeding a lot easier. It's a protein that, regardless of the delivery, HEXAPRO™ delivers truly satisfying protein with a taste that defines the term "Protein Shake".

NET WT: 3 LBS (48 OZ) 1.36 KG

31 SERVINGS

Decadent Chocolate Milkshake

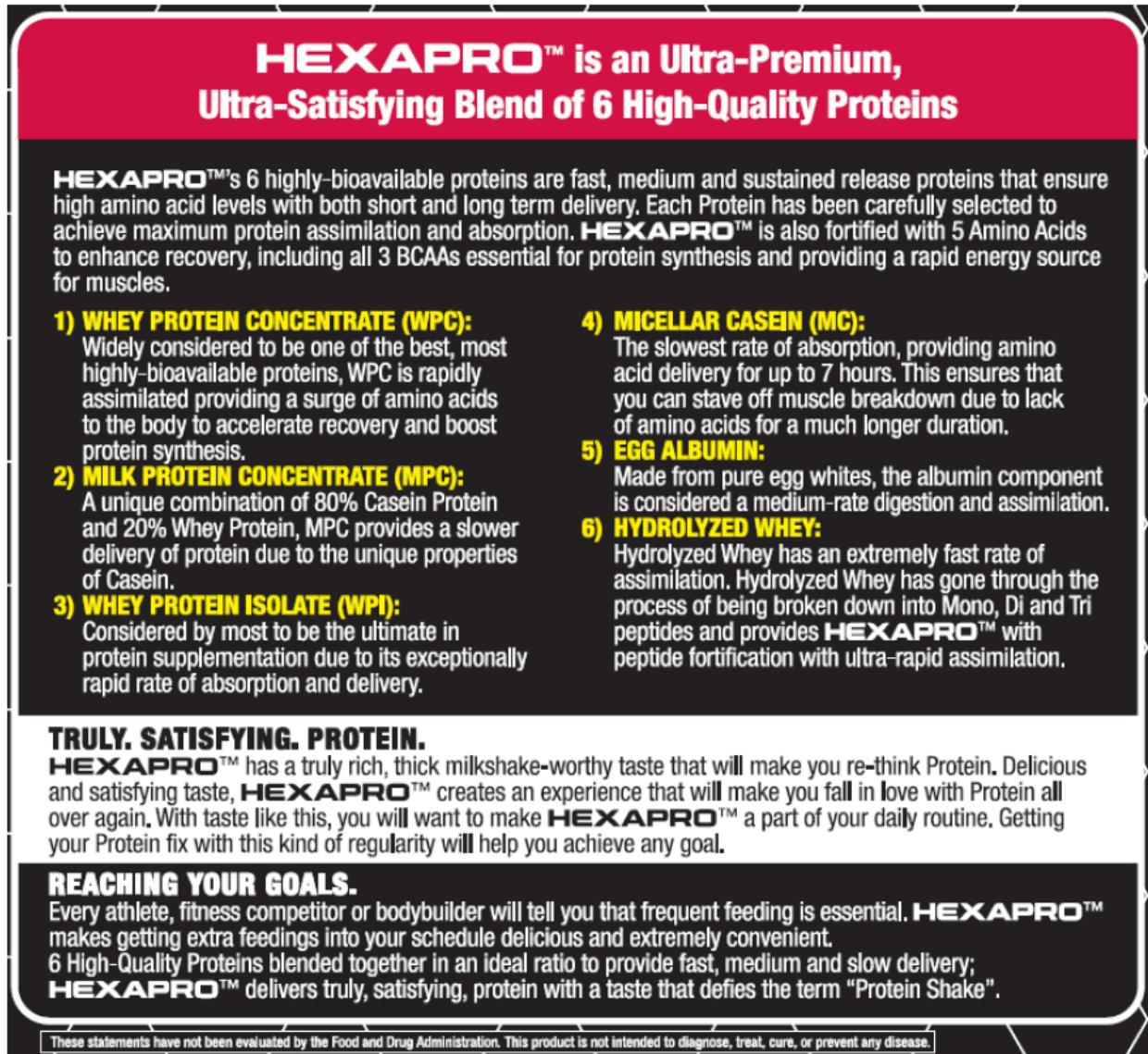
PROTEIN SUPPLEMENT

For ease of inspection, we provide close-up images of the three sections of the label. The front of the panel identifies the product as an “Ultra-Premium 6-Protein Blend” with “25 G[rams] Protein Per Serving,” and it touts the product’s “6 Ultra-High Quality Proteins” and “5 Amino Acid Blend with BCAAs [Branch-Chain Amino Acids]”:



The left side of the label again identifies HexaPro as “an Ultra-Premium, Ultra-Satisfying Blend of 6 High-Quality Proteins.” It elaborates on that claim by identifying the six whole-protein sources that HexaPro contains: whey protein concentrate, milk protein concentrate, whey protein isolate, micellar casein, egg

albumin, and hydrolyzed whey. And it states that the product “is also fortified with 5 Amino Acids to enhance recovery”:



**HEXAPRO™ is an Ultra-Premium, Ultra-Satisfying Blend of 6 High-Quality Proteins**

**HEXAPRO™**'s 6 highly-bioavailable proteins are fast, medium and sustained release proteins that ensure high amino acid levels with both short and long term delivery. Each Protein has been carefully selected to achieve maximum protein assimilation and absorption. **HEXAPRO™** is also fortified with 5 Amino Acids to enhance recovery, including all 3 BCAAs essential for protein synthesis and providing a rapid energy source for muscles.

- 1) WHEY PROTEIN CONCENTRATE (WPC):**  
Widely considered to be one of the best, most highly-bioavailable proteins, WPC is rapidly assimilated providing a surge of amino acids to the body to accelerate recovery and boost protein synthesis.
- 2) MILK PROTEIN CONCENTRATE (MPC):**  
A unique combination of 80% Casein Protein and 20% Whey Protein, MPC provides a slower delivery of protein due to the unique properties of Casein.
- 3) WHEY PROTEIN ISOLATE (WPI):**  
Considered by most to be the ultimate in protein supplementation due to its exceptionally rapid rate of absorption and delivery.
- 4) MICELLAR CASEIN (MC):**  
The slowest rate of absorption, providing amino acid delivery for up to 7 hours. This ensures that you can stave off muscle breakdown due to lack of amino acids for a much longer duration.
- 5) EGG ALBUMIN:**  
Made from pure egg whites, the albumin component is considered a medium-rate digestion and assimilation.
- 6) HYDROLYZED WHEY:**  
Hydrolyzed Whey has an extremely fast rate of assimilation. Hydrolyzed Whey has gone through the process of being broken down into Mono, Di and Tri peptides and provides **HEXAPRO™** with peptide fortification with ultra-rapid assimilation.

**TRULY. SATISFYING. PROTEIN.**  
**HEXAPRO™** has a truly rich, thick milkshake-worthy taste that will make you re-think Protein. Delicious and satisfying taste, **HEXAPRO™** creates an experience that will make you fall in love with Protein all over again. With taste like this, you will want to make **HEXAPRO™** a part of your daily routine. Getting your Protein fix with this kind of regularity will help you achieve any goal.

**REACHING YOUR GOALS.**  
Every athlete, fitness competitor or bodybuilder will tell you that frequent feeding is essential. **HEXAPRO™** makes getting extra feedings into your schedule delicious and extremely convenient. 6 High-Quality Proteins blended together in an ideal ratio to provide fast, medium and slow delivery; **HEXAPRO™** delivers truly, satisfying, protein with a taste that defies the term "Protein Shake".

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Finally, the right side of the label features the nutrition-facts table, which states that HexaPro contains 25 grams of protein per serving, and the list of ingredients. This side also provides a table labeled “Amino Acid Profile.”

Although the heading of the table indicates that HexaPro contains 44 grams of amino acids per serving, the table itemizes only 25,000 milligrams, or 25 grams:

**Supplement Facts**  
 Serving Size: 44 g  
 Servings Per Container: 31

Amount Per Serving		% Daily Value*
<b>Calories</b>	<b>176</b>	
Calories from Fat	36	
<b>Total Fat</b>	<b>4 g</b>	<b>6%</b>
Saturated Fat	1 g	5%
Trans Fat	0 g	†
Monounsaturated Fat	3 g	13%
<b>Cholesterol</b>	<b>24 mg</b>	<b>8%</b>
<b>Sodium</b>	<b>122 mg</b>	<b>5%</b>
<b>Potassium</b>	<b>370 mg</b>	<b>11%</b>
<b>Total Carbohydrate</b>	<b>10 g</b>	<b>3%</b>
Dietary Fiber	4 g	16%
Sugars	1 g	†
<b>Protein</b>	<b>25 g</b>	<b>50%</b>
Vitamin A	13 IU	0%
Vitamin C	0.01 mg	0%
Calcium	113 mg	11%
Iron	0.3 mg	2%

\* Percent Daily Values are based on a diet of 2,000 calories a day. Not a significant source of Vitamin A and Vitamin C. † Daily Value not established.

**Amino Acid Profile per serving 44g**

Essential Amino Acids (EAA)	
<b>Branched-Chain Amino Acids (BCAA)</b>	
L-Leucine	2859 mg
L-Valine	1131 mg
L-Isoleucine	1148 mg
L-Lysine	1588 mg
L-Methionine	599 mg
L-Phenylalanine	836 mg
L-Threonine	1126 mg
L-Tryptophan	489 mg
L-Alanine	913 mg
L-Arginine	661 mg
L-Aspartic Acid	1723 mg
L-Cysteine	548 mg
L-Glutamine	3085 mg
L-Glycine	2220 mg
L-Histidine	580 mg
L-Proline	1305 mg
L-Serine	980 mg
L-Taurine	2400 mg
L-Tyrosine	809 mg
<b>TOTAL</b>	<b>25,000 mg</b>

Protein value calculated on "as dry basis". Total protein yield, as performed by the analysis, includes amino acid content.

**Ingredients:** HEXAPRO™ 6-Protein Blend (Whey Protein Concentrate [WPC 80%, Cold-Temperature Processed, Cross-Flow Microfiltered], Milk Protein Isolate [80% Casein:20% Whey], Whey Protein Isolate [WPI 90%, Cold-Temperature Processed, Cross-Flow Microfiltered], Micellar Casein [MC 90%, Undenatured], Egg Albumin, Hydrolyzed Whey), HEXAPRO™ AminoPlex (L-Glycine, L-Taurine, L-Leucine, L-Isoleucine, L-Valine), HEXAPRO™ Suspension Matrix (Maltodextrin, Fibersol-2®, Inulin, Xanthan Gum, Cellulose Gum, Carrageenan), HEXAPRO™ Lipid Fuel (Sunflower Oil, Soy Oil, High-MCT Coconut Oil, CLA (Conjugated Linoleic Acid), High-Omega3 Flax Seed Oil).  
**Other Ingredients:** Cocoa Powder, Natural and Artificial Flavors, Caramel Color, Sodium Chloride, Acesulfame Potassium, Sucralose.

**ALLERGEN INFORMATION:** Contains Protein derived from Milk and Egg; contains Lecithin derived from Soy (less than 1%). Produced in a facility that also handles peanut, tree nut, fish, crustaceans/shellfish, and wheat products.

**SUGGESTED USE:** Blend, Mix or Shake 1 scoop (44 g) of HEXAPRO™ with 6 to 8 oz. of water or low-fat milk depending on desired taste and consistency anytime you want a premium satisfying high-protein beverage.

Distributed Exclusively by:  
 HBS INTERNATIONAL CORP.  
 711 S. Carson St., Suite 4 • Carson City, NV 89701

Formulated by and Manufactured for:  
 ALLMAX NUTRITION INC.  
 Toronto • Canada • www.ALLMAXNUTRITION.com

6 65553 20221 1 UST002

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In its complaint, Hi-Tech alleges that HexaPro’s label misleads consumers in three distinct but related ways. The first concerns the *quantity* of protein in a serving of HexaPro. Although HexaPro contains whole proteins, it also contains

free-form amino acids and other non-protein ingredients. Hi-Tech alleges that that an analysis that excludes these “spiking agents” and counts only “total bonded amino acids”—which alone are molecularly complete proteins—yields an “actual protein content” of “17.914 grams per serving,” not 25 grams per serving. But Hi-Tech does not allege that the HexaPro label is inconsistent with the applicable regulation of the Food and Drug Administration, which permits “[p]rotein content [to] be calculated on the basis of the factor 6.25 times the nitrogen content of the food,” 21 C.F.R. § 101.9(c)(7), even if not all of a product’s nitrogen content derives from whole-protein sources.

Second, Hi-Tech alleges that the label is misleading about the *source* of the protein content. In Hi-Tech’s view, the label suggests that the product’s entire stated protein content derives from the whole-protein sources identified on the left side of the panel. Observing that the front label identifies HexaPro as an “Ultra-Premium 6-Protein Blend,” Hi-Tech alleges that this “statement of identity is intended to lead consumers to believe that the Product contains protein derived exclusively from the ‘Ultra-Premium 6-Protein Blend.’”

Third, Hi-Tech alleges that the front of the label is misleading about both the quantity *and* the source of the product’s protein content. Hi-Tech alleges that the proximity of the phrase “Ultra-Premium 6-Protein Blend” to the phrase “25 G Protein Per Serving” on the front of the label misleads consumers into believing

that HexaPro “contains 25 grams of the ‘Ultra-Premium 6-Protein Blend’-type protein per serving,” that is, the six whole-protein sources. This representation is untrue because the product is “spike[d] . . . with free form amino acids and non-protein ingredients” and, in fact, “contains only 17.914 grams of the ‘Blend’-type protein per serving.”

HBS moved to dismiss the complaint for failure to state a claim, *see* Fed. R. Civ. P. 12(b)(6), and the district court granted the motion. The district court ruled that Hi-Tech’s claim under the Georgia Uniform Deceptive Trade Practices Act was preempted by the federal Food, Drug, and Cosmetic Act for two reasons: first, Hi-Tech’s claim fell within the ambit of the federal Act’s express preemption clause, which prohibits state-law “claim[s] seek[ing] to impose food labeling requirements that differ from the applicable federal regulation”; and second, Hi-Tech failed to allege that it had established the true protein content of HexaPro using a test that complies with the protein-testing requirements of the Food and Drug Administration, *see* 21 C.F.R. § 101.9(g). And the district court ruled that Hi-Tech failed to state a claim under the Lanham Act because HexaPro’s label “provides a detailed breakdown of all . . . ingredients, including the mix of amino acids.” The district court stated that “[t]hese statements indicate to consumers that the product is not made solely of the ultra-premium protein blend, but contains other ingredients as well.”



## II. STANDARD OF REVIEW

“We review *de novo* the district court’s grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim, accepting the complaint’s allegations as true and construing them in the light most favorable to the plaintiff.” *Chaparro v. Carnival Corp.*, 693 F.3d 1333, 1335 (11th Cir. 2012) (quoting *Cinotto v. Delta Air Lines Inc.*, 674 F.3d 1285, 1291 (11th Cir. 2012)).

## III. DISCUSSION

We divide our discussion in three parts. First, we reject HBS’s contention that Hi-Tech “waived” or forfeited dispositive arguments by failing to challenge them in the district court when HBS raised them in its motion to dismiss. Second, we explain that federal law preempts Hi-Tech’s state-law claim. Third, we explain that federal law does not bar Hi-Tech’s theory that the HexaPro label is false or misleading under the Lanham Act, and we conclude that Hi-Tech has stated a plausible claim for relief. We affirm in part and reverse in part.

### A. *Hi-Tech Has Not “Waived” or Forfeited Dispositive Arguments.*

HBS contends that we need not reach the merits of this appeal because Hi-Tech “waived”—HBS’s word, although “forfeited” would be more appropriate, *see United States v. Phillips*, 834 F.3d 1176, 1183 (11th Cir. 2016)—three dispositive arguments by failing to respond to them in the district court when HBS raised them in its motion to dismiss. First, HBS argued that Hi-Tech failed to plead a plausible

claim for relief because it did not attach test results to its complaint to support its allegation that the HexaPro label overstates its protein content. Second, HBS argued that Hi-Tech could not allege a plausible claim for relief because the HexaPro label “prominently disclosed the presence of amino acids on both the principal display and information panels of the label.” Third, HBS argued that Hi-Tech’s claim under the Lanham Act is precluded because there is a “genuinely irreconcilable conflict,” *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2237 (2014), between the Food and Drug Administration’s regulations and the labeling that Hi-Tech claims the Lanham Act requires.

HBS “misunderstand[s] the law. Parties can most assuredly waive [or forfeit] positions and issues on appeal, but not individual arguments . . . .” *Sec’y, U.S. Dep’t of Labor v. Preston*, 873 F.3d 877, 883 n.5 (11th Cir. 2017). Indeed, in *Preston*, we rejected the theory that a plaintiff “waived various arguments . . . by failing to make . . . them in response to the defendants’ motion to dismiss in the district court,” the very theory HBS raises in this appeal. *Id.* (alteration adopted) (internal quotation marks omitted). In the district court, Hi-Tech defended the sufficiency of its complaint and disputed HBS’s reading of *POM Wonderful*. Even if HBS were correct that Hi-Tech failed to respond in the district court to each individual argument that HBS made in its motion to dismiss, that failure would not amount to a waiver or forfeiture of Hi-Tech’s position that its complaint stated a

plausible claim under the Lanham Act. And, after the district court considered the merits of at least two of HBS's three arguments and relied on them in granting the motion to dismiss, Hi-Tech was entitled to challenge those arguments on appeal whether or not it had done so in the district court. *See United States v. Clariot*, 655 F.3d 550, 556 (6th Cir. 2011) (“[T]here can be no forfeiture ‘where the district court nevertheless addressed the merits of the issue.’ . . . When a district court resolves an issue, the losing party can challenge it.” (quoting *Blackmon-Malloy v. U.S. Capitol Police Bd.*, 575 F.3d 699, 707 (D.C. Cir. 2009))).

HBS compares this appeal to *Sapuppo v. Allstate Floridian Insurance Co.*, 739 F.3d 678 (11th Cir. 2014), but *Sapuppo* is inapposite. In *Sapuppo*, we explained that “[w]hen an appellant fails to challenge properly on appeal one of the grounds on which the district court based its judgment, he is deemed to have abandoned any challenge of that ground, and it follows that the judgment is due to be affirmed.” *Id.* at 680. And we explained that an appellant must directly challenge each of the district court's grounds in his initial brief; challenges that are merely hinted at or that first appear in a reply brief do not merit consideration. *See id.* at 681–83.

Hi-Tech has satisfied the standards for our appellate review. Its initial brief directly challenges each ground on which the district court dismissed the complaint. We turn to its arguments on the merits.

*B. Federal Law Preempts Hi-Tech's Claim Under the Georgia Uniform Deceptive Trade Practices Act.*

The district court ruled that federal law preempts Hi-Tech's claim under the Georgia Uniform Deceptive Trade Practices Act for two reasons. First, the district court concluded that the federal Food, Drug, and Cosmetic Act's express-preemption provision bars the claim because the claim would impose liability for conduct that does not violate the Act. Second, the district court determined that the claim is preempted because Hi-Tech did not allege that it had established the true protein content of HexaPro using a test that complies with certain regulatory protein-testing requirements, *see* 21 C.F.R. § 101.9(g). We agree that the Act's express-preemption provision bars the claim, so we need not and do not reach the district court's second ground.

The Act expressly preempts state laws that “directly or indirectly establish . . . any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except [for sales of food at some restaurants], or . . . any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title.” 21 U.S.C. § 343-1(a)(4)–(5). Section 343(q) regulates “nutrition information” that must be disclosed about certain nutrients in food products, including the “total protein contained in each serving size or other unit of measure.” *Id.* § 343(q)(1)(D). Section 343(r)

governs all other statements about nutrient content that “expressly or by implication” “characterize[] the level of any nutrient.” *Id.* § 343(r)(1)(A). A state-law requirement is “not identical to” federal requirements if “the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food that are not imposed by or contained in the applicable federal regulation or differ from those specifically imposed by or contained in the applicable federal regulation.” *Lilly v. ConAgra Foods, Inc.*, 743 F.3d 662, 665 (9th Cir. 2014) (alterations adopted) (quoting 21 C.F.R. § 100.1(c)(4)).

Hi-Tech’s state-law claim is preempted because it would impose liability for labeling that does not violate the Food, Drug, and Cosmetic Act or the regulations that carry it into effect. A federal regulation expressly allows “[p]rotein content [to] be calculated on the basis of the factor 6.25 times the nitrogen content of the food,” 21 C.F.R. § 101.9(c)(7), and Hi-Tech does not dispute that HexaPro’s labeling complies with this regulation. Instead, Hi-Tech alleges that HexaPro’s labeling misleads consumers about the nature, source, and quality of the whole proteins, free-form amino acids, and other ingredients that make up HexaPro’s advertised 25 grams of protein per serving. Assuming that Hi-Tech is right that the labeling is misleading, HBS could remedy the misrepresentation only by reducing the advertised amount of protein per serving or by redesigning its label to itemize

by amount each source of “protein” that contributes to the advertised 25 grams. But Hi-Tech has identified no provision of the Food, Drug, and Cosmetic Act or the relevant federal regulations that requires HBS to do either of those things.

Hi-Tech contends that its state-law claim “seeks to enforce the requirement that a food not be labeled in such a way as to lead consumers to believe that it is made solely of one ingredient when it is made of multiple ingredients,” but this argument is unpersuasive. True, a regulation provides that “[t]he labeling of a food which contains two or more ingredients may be misleading by reason . . . of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.” 21 C.F.R. § 101.18(b). But HexaPro’s name does not include the name of any of the product’s ingredients, so the object of Hi-Tech’s state-law claim cannot be to enforce this regulation. And, to the extent that Hi-Tech’s claim is that the labeling suggests that HexaPro’s only ingredient is the “Ultra-Premium 6-Protein Blend,” it is too implausible to survive a motion to dismiss for failure to state a claim. As the district court rightly stated, the label prominently discloses the presence of amino acids and other non-protein ingredients, and those disclosures would clearly “indicate to consumers that the product is not made solely of the ultra-premium protein blend, but contains other ingredients as well.”

Hi-Tech elsewhere retreats from the argument that its state-law claim would enforce federal law and contends instead that its state-law claim is “consistent” with the federal requirements. But to avoid preemption, Hi-Tech’s state-law claim must be *identical*, not merely consistent, with federal requirements. To the extent that the Georgia Uniform Deceptive Trade Practices Act would require changes to HexaPro’s labeling, it would “directly or indirectly establish” requirements that are “not identical to” federal requirements, 21 U.S.C. § 343-1(a)(4)–(5). The district court did not err when it ruled that Hi-Tech’s state-law claim is expressly preempted.

*C. The District Court Erred When It Dismissed Hi-Tech’s Claim Under the Lanham Act.*

Although we agree with the district court that Hi-Tech’s state-law claim is preempted, we agree with Hi-Tech that the district court erred in dismissing its claim under the Lanham Act. Hi-Tech has pleaded facts to support a plausible inference that a reasonable consumer would find HexaPro’s label misleading. And HBS is mistaken to argue that the Food, Drug, and Cosmetic Act bars Hi-Tech’s claim under the Lanham Act.

“To survive a motion to dismiss [for failure to state a claim], a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In other words, the

complaint must contain “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* A defendant is liable for false advertising under the Lanham Act if “(1) the defendant’s statements were false or misleading; (2) the statements deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on the consumers’ purchasing decision; (4) the misrepresented service affects interstate commerce; and (5) [the plaintiff] has been, or likely will be, injured as a result of the false or misleading statement.” *Sovereign Military Hospitaller Order v. Fla. Priory of Knights Hospitallers*, 702 F.3d 1279, 1294 (11th Cir. 2012).

To establish the “false or misleading statement” element of the claim, the plaintiff must prove that “the statements at issue were either ‘(1) commercial claims that are literally false as a factual matter,’ or ‘(2) claims that may be literally true or ambiguous but which implicitly convey a false impression, are misleading in context, or are likely to deceive consumers.’” *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1261 (11th Cir. 2004) (quoting *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998)). “When determining whether an advertisement is literally false or misleading, courts ‘must analyze the message conveyed in full context,’ and ‘must view the face of the statement in its entirety.’” *Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1308 (11th Cir. 2010) (alterations



adopted) (quoting *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1248 (11th Cir. 2002)).

The district court concluded that the complaint does not allow a plausible inference that HexaPro’s label is misleading, which is the only ground on which HBS challenged the facial sufficiency of the complaint. We disagree with that ruling and reverse the dismissal of Hi-Tech’s claim of false advertising under the Lanham Act. Because HBS has not argued that the complaint is insufficient based on any other element of the claim, we do not consider whether such arguments might have prevailed if HBS had raised them.

As an initial matter, we reject HBS’s contention that we may disregard the supposedly “conclusory” allegation of the true whole-protein content of HexaPro when assessing the sufficiency of the complaint. In *Twombly* and *Iqbal*, the Supreme Court made clear that “legal conclusions” are not entitled to be assumed true, and this tenet extends to “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.” *Iqbal*, 556 U.S. at 678; *accord Twombly*, 550 U.S. at 555. But Hi-Tech’s allegation that a serving of HexaPro contains “17.914 grams” of bonded amino acids—that is, molecularly complete proteins—is not in any sense a “legal conclusion[]”; instead, it is a specific assertion about physical and chemical fact that is either true or false, no matter what legal conclusions it may or may not support. The only sense in which it is

“conclusory”—and what HBS’s argument boils down to—is that the complaint does not itself prove HexaPro’s chemical composition. But no part of the *Twombly-Iqbal* pleading standard requires a plaintiff to provide *evidence* for the factual allegations in a complaint before they are “entitled to the assumption of truth” at the motion-to-dismiss stage, *Iqbal*, 556 U.S. at 679.

With that in mind, we conclude that the allegations in the complaint and the undisputed product label allow the plausible inference that HexaPro’s labeling is misleading. The front of the label identifies HexaPro as an “Ultra-Premium 6-Protein Blend” that contains “25 G Protein Per Serving,” and the left side of the label declares that HexaPro “is an Ultra-Premium, Ultra-Satisfying Blend of 6 High-Quality Proteins,” which are enumerated. The nutrition-facts panel on the right side of the label represents that each serving of HexaPro contains 25 grams of protein. Despite these representations, HexaPro—taking the facts alleged as true, as we must—“does not contain 25 grams of the ‘Ultra-Premium 6-Protein Blend’-type protein per serving,” that is, the six whole-protein sources listed on the left side of the panel. “Rather, because [HBS] spike[s] [HexaPro] with free form amino acids and non-protein ingredients, [HexaPro] contains only 17.914 grams of the ‘Blend’-type protein per serving.” Considering the label as a whole and taking its statements in context, we find it plausible that a reasonable consumer would be misled to believe that a serving of HexaPro contains 25 grams of protein derived

from the “6-Protein Blend” comprising the “6 High-Quality Proteins” listed on the label.

In ruling otherwise, the district court adopted the reasoning of *Gubala v. Allmax Nutrition, Inc.*, No. 14-cv-9299, 2015 WL 6460086 (N.D. Ill. Oct. 26, 2015), a case that dealt with nearly identical allegations about the HexaPro label. Following *Gubala*, the district court reasoned that HexaPro’s label is not misleading “because it clearly states that in addition to the ‘6 ultra-high quality proteins,’ it contains a ‘5 Amino Acid Blend with BCAAs’” and because this statement is “prominently located on the front of the label directly beneath the name of the product, ‘Hexa[P]ro.’” *Id.* at \*6. The district court also faulted Hi-Tech for “fail[ing] to explain how a label can be misleading when it provides a detailed breakdown of all [of] HexaPro’s ingredients, including the mix of amino acids.” And the district court reasoned that the ingredient breakdown on the label “indicate[s] to consumers that the product is not made solely of the ultra-premium protein blend, but contains other ingredients as well.”

This reasoning is unpersuasive. The district court—and the *Gubala* court—apparently assumed that Hi-Tech’s theory is that the HexaPro label would mislead consumers into believing that the only *ingredient* in the product is the “Ultra-Premium 6-Protein Blend.” But that is not Hi-Tech’s contention. Instead, Hi-Tech argues that the label would induce a reasonable consumer to believe that the

*protein* in HexaPro derives exclusively from the six-protein blend. And we agree that Hi-Tech's theory, stated this way, is at least plausible.

HexaPro's label provides no suggestion that the claimed 25 grams of protein per serving derives from any source other than the whole-protein ingredients that make up the "Ultra-Premium 6-Protein Blend." Not counting the 25-grams figure, the label never uses the word "protein" to refer to anything other than those six ingredients. The label never explains that the figure of 25 grams includes free-form amino acids or other non-protein ingredients. Indeed, the label appears consistently to treat "amino acids" as separate from and providing distinct nutritional benefits from "protein." For example, the front of the label lists the product's "6 Ultra-High Quality Proteins" and its "5 Amino Acid Blend with BCAAs" in separate bullet points. On the left side of the label, two sentences touting the product's "6 highly-bioavailable proteins" are followed by a third stating that HexaPro "is *also* fortified with 5 Amino Acids to enhance recovery" (emphasis added). And, although the "Amino Acid Profile" on the right side of the label lists 25 grams of amino acids, the label provides no explanation of how this figure relates either to the product's 25 grams of protein per serving or the 44 grams of amino acids per serving advertised at the top of the "Amino Acid Profile" table.

Based on the total impression given by the label, it is plausible that only sophisticated consumers schooled in federal regulations or nutrition science would

understand or even suspect that free-form amino acids or other non-protein ingredients form any part of HexaPro's stated 25 grams of protein per serving. Of course, the Food and Drug Administration permits protein calculations based on free-form amino acids and other nitrogen-containing non-protein ingredients. *See* 21 C.F.R. § 101.9(c)(7). But, as the Supreme Court made clear in *POM Wonderful*, the Food, Drug, and Cosmetic Act does not generally bar claims of false advertising of food under the Lanham Act. *See POM Wonderful*, 134 S. Ct. at 2237–41.

Despite this general rule, HBS argues that Hi-Tech's claim is barred for two specific reasons, but neither is persuasive. First, drawing on dicta in *POM Wonderful*, HBS argues that application of the Lanham Act would create “a genuinely irreconcilable conflict” with the federal regulation governing protein calculations. *See id.* at 2237 (declining to decide whether “the Court's task is to reconcile or harmonize [potentially divergent] statutes” or instead “to enforce both statutes in full unless there is a genuinely irreconcilable conflict”). HBS contends that “HexaPro cannot simultaneously comply with both the FDA's regulations and Plaintiff's demand. It cannot disclose both 25 grams to satisfy the requirements of the [Administration] and 17.914 grams to satisfy Plaintiff.” But HBS need not abandon the 25-grams-per-serving figure to cure the misrepresentation alleged by Hi-Tech. Among other possible solutions, it would suffice to clarify on the

HexaPro label how much protein in each serving derives from the six-protein blend and how much derives from free-form amino acids and other non-protein ingredients. No federal law prevents HBS from doing so.

Second, HBS argues that a claim under the Lanham Act is barred “if determining the truth or falsity of the [challenged] statement would require a court to interpret FDA regulations, which is generally left to the FDA itself.” To support this contention, HBS cites *Hi-Tech Pharmaceuticals, Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323 (N.D. Ga. 2016), for the proposition that the Food, Drug, and Cosmetic Act bars Lanham Act claims when they “would require a court to make determinations about the safety, legality, and classification of new drugs that are more properly within the exclusive purview of the FDA.” *Id.* at 1330. And HBS argues that Hi-Tech’s claim falls within the scope of this bar because “it asks this Court to substitute its own judgment regarding the most appropriate way to measure protein for the FDA’s judgment.”

Again, HBS is mistaken. The rule in *Hodges Consulting* applies only to claims that would “circumvent the FDA’s exclusive enforcement authority by seeking to prove that [d]efendants violated the FDCA, when the FDA did not reach that conclusion.” *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 928 (9th Cir. 2010); *see also Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) (holding that the Food, Drug, and Cosmetic Act precluded claims under the

Lanham Act related to labeling an ingredient “inactive” when the Food and Drug Administration had not yet determined whether the ingredient was active or inactive). In other words, the rule bars only “private actions under the Lanham Act premised on enforcement determinations that the FDA and other regulatory agencies did not themselves make,” *PhotoMedex*, 601 F.3d at 928, such as an action that would require an original determination “whether a drug is ‘new,’ and whether it can be lawfully marketed under the FDCA,” *Hodges Consulting*, 230 F. Supp. 3d at 1331 (quoting *JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1004 (C.D. Cal. 2014)).

Hi-Tech’s claim under the Lanham Act would not require a court to question the regulatory determination that “[p]rotein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food.” 21 C.F.R. § 101.9(c)(7). Instead, it would require a court to determine only whether the protein-content representations on the HexaPro label are misleading to consumers in the context of the label’s failure to specify the sources of the nitrogen measured by the federal test. Because this inquiry would not require a court “to interpret or apply the FDCA to determine whether or not the marketing of the supplement was deceptive,” resolving Hi-Tech’s claim under the Lanham Act would not “step on the FDCA’s toes,” *Hodges Consulting*, 230 F. Supp. 3d at 1331.

#### **IV. CONCLUSION**

We **AFFIRM** the dismissal of Hi-Tech's claim under the Georgia Uniform Deceptive Trade Practices Act but **REVERSE** the dismissal of its claim under the Lanham Act and **REMAND** for further proceedings consistent with this opinion.