

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

BRIAN HULT, an individual, and FIONA
HULT,

Plaintiffs,

vs.

C.A. No. 1:18-cv-10453-MPK

DANIELE INTERNATIONAL, a Rhode
Island Corporation
Defendant.

**DEFENDANT DANIELE INTERNATIONAL, INC.’S
MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION
TO DISMISS PLAINTIFFS’ FIRST AMENDED COMPLAINT**

Defendant Daniele International, Inc. (“Daniele”) respectfully submits this memorandum of law in support of its Motion to Dismiss Plaintiffs’ First Amended Complaint (“Complaint” or “Compl.”) for failure to state a claim upon which relief may be granted.

INTRODUCTION

Plaintiffs’ state law claims, which attempt to hold Daniele liable for mislabeling its cured Italian meats, fail as a matter of law and must be dismissed because they are preempted by federal law. The Complaint alleges that Daniele’s meats contain a certain milk protein called sodium caseinate. Plaintiffs seek to impose liability against Daniele on the erroneous premise that the Food Allergen Labelling and Consumer Protection Act (“FALCPA”) requires ingredients derived from milk proteins to be described on meat product labels as “containing milk.” FALCPA, however, does not apply to meat and meat products.

The Federal Meat Inspection Act (“FMIA”) governs the production of meat in the United States, including the labelling and packaging of meat products. The Federal Meat Inspection Act does not require meat product labels to indicate whether the products contain milk. This Court

and numerous other courts have held that state law claims and statutes purporting to impose labelling obligations on meat producers that are “not identical” to the obligations set forth in the Federal Meat Inspection Act are preempted as a matter of law. Accordingly, Plaintiffs’ claims against Daniele are not viable and must be dismissed.

FACTUAL BACKGROUND

Plaintiff Brian Hult and his wife, Fiona Hult, bring this case to recover for an allergic reaction that Mr. Hult allegedly suffered as a result of consuming deli meat from Daniele’s Italian Brand Gourmet Pack (“Gourmet Pack”), which contains sopressata, capocollo, and mortadella. Compl. (Doc. 1-1) ¶¶ 4-6 & Ex. A. Mr. Hult allegedly is allergic to milk. Compl. ¶ 1. The Gourmet Pack’s label indicates that the mortadella contains the ingredient “sodium caseinate,” which Plaintiffs allege is a type of protein found in milk. Compl. ¶¶ 16-17 & Ex. A.

Plaintiffs claim that, pursuant to FALCPA, Daniele was required to state on the Gourmet Pack’s label that the product “contains milk.” Compl. ¶ 18. Plaintiffs bring this suit against Daniele for violation of numerous state law claims: breach of implied warranty, negligent misrepresentation, failure to warn, violation of Mass. Gen. Laws ch. 93A, loss of consortium, intentional or reckless infliction of emotional distress, and negligent infliction of emotional distress. Compl. ¶¶ 23-72. Plaintiffs predicate all of their claims on Daniele’s alleged wrongful failure to comply with FALCPA. Because FALCPA does not apply to meat products, and because both the Federal Meat Inspection Act and FALCPA preempt Plaintiffs’ state law claims, Daniele now moves to dismiss.

ARGUMENT

Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, this Court may dismiss a complaint that fails to state a claim upon which relief may be granted. Fed. R. Civ. P.

12(b)(6). To survive a Rule 12(b)(6) motion, the complaint ““must contain sufficient factual matter to state a claim to relief that is plausible on its face.”” *Rodriguez-Reyes v. Molina-Rodriguez*, 711 F.3d 49, 53 (1st Cir. 2013) (citations omitted). In considering whether a complaint states a plausible claim for relief, “the court must sift through the averments in the complaint, separating conclusory legal allegations (which may be disregarded) from allegations of fact (which must be credited).” *Id.* Federal “preemption issues . . . are [issues] of law, not of fact, and are amenable to resolution by a motion to dismiss the complaint.” *Fitzgerald v. Harris*, 549 F.3d 46, 52 (1st Cir. 2008).

This Court should dismiss Plaintiffs’ Complaint in its entirety because Plaintiffs’ claims are preempted by federal law.

I. FALCPA DOES NOT APPLY TO DANIELE’S GOURMET PACK.

Plaintiffs’ claims all fail as a matter of law because they are predicated on Daniele’s alleged violation of FALCPA, which does not apply to meat products. FALCPA, 21 U.S.C. § 343, is part of Federal Food, Drug, and Cosmetics Act (“FFDCA”), 21 U.S.C. § 301, *et seq.* The Food and Drug Administration (“FDA”) is charged with overseeing the FFDCA, including FALCPA. 21 U.S.C. § 393. With certain exceptions, FALCPA requires that if certain types of food products contain ingredients that are derived from a major food allergen, the label must indicate that the food “contains” the major food allergen. 21 U.S.C. § 343(w). FALCPA categorizes milk as a “major food allergen.” *See* 21 U.S.C. § 343 (note on congressional findings). Neither the FFDCA nor FALCPA applies to meat products, and the FDA does not regulate meat. 21 U.S.C. § 392 (“Meats and meat food products shall be exempt from the provisions of this chapter to the extent of the application or the extension thereto of the Meat Inspection Act.”); Laura E. Derr, *When Food Is Poison: The History, Consequences, and*

Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004, 61 Food & Drug L.J. 65, 159 (2006) (“Congress limited the FALCPA’s scope to food products regulated by FDA, thereby exempting . . . meat and poultry products from its labeling requirements.”). Rather, the Federal Meat Inspection Act, 21 U.S.C. § 601, *et seq.*, as implemented and enforced by the United States Department of Agriculture (“USDA”), Food Safety and Inspection Service (“FSIS”), controls the labeling and packaging of meat and meat food products.¹ 21 U.S.C. § 601, *et seq.*; *see also Animal Legal Def. Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 282 (D. Mass.), *aff’d*, 802 F.2d 440 (1st Cir. 1986) (“Meat and meat food products shipped in interstate commerce are regulated by the Federal Meat Inspection Act . . . The FMIA is administered by the United States Department of Agriculture.”).

Unlike FALCPA, the Federal Meat Inspection Act does not require that meat products containing ingredients derived from milk include a statement on the product label that it “contains milk.” *See* 9 C.F.R. § 317.2 (identifying the required features of a label on a meat product); *see also* 61 Food & Drug L.J. at 161 (“The FALCPA’s labeling requirements are restricted to foods under the jurisdiction of the FFDCA; therefore, they fall short of covering meat and poultry products, which are regulated by the U.S. Department of Agriculture (USDA).”). No meat producer can affix a label to a meat product without first obtaining approval from the FSIS. *See* 9 C.F.R. § 412.1(a) (“No final label may be used on any product unless the label has been submitted for approval to the FSIS Labeling and Program Delivery Staff . . . and approved by such staff, except for generically approved labels authorized for use in

¹ A “meat food product” is “any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats.” 21 U.S.C. § 601(j).

§ 412.2.”²). Because the FSIS must approve all labels affixed to meat products, meat producers’ “labels are presumptively lawful and not false or misleading.” *Kuenzig v. Kraft Foods, Inc.*, No. 8:11-CV-838-T-24 TGW, 2011 WL 4031141, at *7 (M.D. Fla. Sept. 12, 2011).

Consistent with the language of the FFDCFA, the FDA’s final guidance on FALCPA’s reach expressly indicates that FALCPA does not apply to meat products:

What types of foods are covered by the FALCPA labeling requirements?

FALCPA’s requirements apply to all packaged foods sold in the U.S. that are regulated under the Federal Food, Drug, & Cosmetic Act *FDA regulates all foods except meat products, poultry products, and egg products. . . .*

Does FALCPA affect the labeling of packaged meat, poultry, and egg products regulated by the U.S. Department of Agriculture (USDA)?

FALCPA’s requirements apply only to those foods regulated by the Food and Drug Administration under the [FFDCFA]. We recommend that producers of meat products, poultry products, and egg products regulated by USDA contact the appropriate USDA agency regarding the labeling of such products.

FDA, *Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance*, 2006 WL 8200203, at *2 (Oct. 1, 2006) (second emphasis added). Likewise, FSIS’s food labeling guidelines state that FALCPA does not apply to meat products. USDA, FSIS, *Allergies and Food Safety*, <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling> (click on “Allergies and Food Safety”) (“**Does the Food Allergens Labeling and Consumer Protection Act (FALCPA) apply to meat, poultry,**

² Generically approved labels, by definition, have been approved by FSIS. See 9 C.F.R. § 412.1(a) (indicating that generically approved labels have been “authorized for use”).

and egg products under FSIS jurisdiction? No. The FALCPA passed by Congress did not amend or implement regulations and policies for meat, poultry, and egg products in the acts related to them: the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).” (emphasis original)).

Plaintiffs allege in their Complaint that Daniele’s Gourmet Pack is subject to FALCPA. Compl. ¶¶ 21-22. Moreover, all of Plaintiffs’ causes of action are predicated on the belief that Daniele had a legal obligation to disclose that the Gourmet Pack contained dairy. Count I (breach of implied warranty) claims that the Gourmet Pack was defective because its label did not indicate that it contained milk. Compl. ¶¶ 23-32. Counts II, III, and VII (negligent misrepresentation, failure to warn, and negligent infliction of emotional distress) allege that Daniele had a duty under FALCPA or common law to disclose that the Gourmet Pack contained dairy. Compl. ¶¶ 33-46, 66-72. Count IV (violation of Chapter 93A) claims that Daniele’s failure to disclose that the Gourmet Pack contained milk was unfair and deceptive. Compl. ¶¶ 47-52. Count V (loss of consortium) alleges that Ms. Hult was deprived of Mr. Hult’s companionship as a result of Daniele’s actions in failing to label the Gourmet Pack as containing milk. Compl. ¶¶ 53-57. Finally, Count VI (intentional or reckless infliction of emotional distress) alleges that Daniele had no right to fail to disclose that its product contained dairy. Compl. ¶¶ 58-65. All of Plaintiffs’ claims incorporate by reference the factual allegations contained in the Complaint, which are replete with claims that Daniele was required and failed to comply with FALCPA. Compl. ¶¶ 18-23, 33, 40, 47, 53, 58, 66.

Plaintiffs’ allegations that FALCPA governs and applies to Daniele’s Gourmet Pack is false as a matter of law. As Plaintiffs concede, the Gourmet Pack is comprised of three deli meat products, sopressata, capocollo, and mortadella. Compl. ¶ 21 & Ex. A. While this Court must

take Plaintiffs' factual allegations as true at the Rule 12(b)(6) stage, it does not give any weight to Plaintiff's conclusions of law. *Rodriguez-Reyes*, 711 F.3d at 53. As indicated above, Plaintiffs' conclusion that FALCPA applies to the Gourmet Pack is categorically inaccurate, because the FFDCFA and FALCPA do not apply to meat products. To the contrary, pursuant to the Federal Meat Inspection Act, the USDA and FSIS regulate meat products like Daniele's Gourmet Pack. Thus, the underlying premise of the Complaint—that Daniele was required and failed to comply with FALCPA—is deficient as a matter of law.

II. THE FEDERAL MEAT INSPECTION ACT PREEMPTS ALL OF PLAINTIFFS' CLAIMS.

This Court must dismiss Plaintiffs' Complaint because the Federal Meat Inspection Act preempts all of Plaintiffs' claims. Under the Federal Meat Inspection Act, “[m]arking, labeling, packaging, or ingredient requirements” for meat products that are “in addition to, or different than, those [established by the Federal Meat Inspection Act] may not be imposed by any State.” 21 U.S.C. § 678. Stated otherwise, “meat ingredient standards, labeling and packaging have been pre-empted by the FMIA, . . . and states cannot impose different or additional affirmative requirements on meat and meat food products.” *Animal Legal Def. Fund Boston*, 626 F. Supp. at 286; *see also Kuenzig*, 2011 WL 4031141, at *6 (“[T]he USDA regulates the labeling of meat . . . products under . . . the FMIA.”) (holding that the Federal Meat Inspection Act preempts state labeling requirements that are “‘in addition to, or different than,’ the labeling requirements set forth in the FMIA.”).

“For the purposes of preemption, a requirement is a rule of law that must be obeyed, whether it arises from common law principles enforceable in damages actions or in a statute.” *Kuenzig*, 2011 WL 4031141, at *6 (quoting *Meaunrit v. ConAgra Foods, Inc.*, No C 09-02220 CRB, 2010 WL 2867393, at *5 (N.D. Cal. July 20, 2010)); *see also Riegel v. Medtronic, Inc.*,

552 U.S. 312, 324 (2008) (“Absent other indication, [a federal statute’s] reference to a State’s ‘requirements’ includes its common-law duties.”). The Federal Meat Inspection Act preempts inconsistent state statutory and common law, because “[s]tate statutory and common law can impose [labeling] requirements.” *Id.* (citations omitted).

This Court has recognized that the Federal Meat Inspection Act preempts causes of action based on Massachusetts law. *Animal Legal Def. Fund Boston*, 626 F. Supp. at 285-86. In *Animal Legal Defense Fund Boston*, the plaintiff brought suit against a veal producer under Chapter 93A, claiming that the defendant acted unfairly in not stating on its veal product labels that the veal comes from calves that are fed antibiotics subtherapeutically. 626 F. Supp. at 278-79. The Court dismissed the plaintiff’s case because the Federal Meat Inspection Act preempted Chapter 93A. *Id.* at 285-86. In so holding, the Court reasoned that Federal Meat Inspection Act “does not require meat and meat food product labels to carry a warning or an explanation about the subtherapeutic use of antibiotics,” and “states cannot impose different or additional affirmative requirements on meat and meat food products.” *Id.* at 286.

Similarly, in *Kuenzig*, the plaintiff brought negligent misrepresentation and breach of warranty claims against meat producers, alleging that the “percent fat free” claims on the meat product labels were misleading. 2011 WL 4031141, at *1-3. In holding that the Federal Meat Inspection Act preempted the plaintiffs’ claims, the Court noted that the meat producers:

had to submit their labels to the FSIS for approval prior to using the labels If the FSIS had determined that the labels were false or misleading, Defendants’ labels would not have been approved. . . . Therefore, because Defendants’ labels comply with the FSIS’s nutrition labeling regulations and have passed the FSIS preapproval process (as evidenced by Defendants’ use of their labels on the products at issue in this case), the labels are presumptively lawful and not false or misleading As such, any state law claim based on the contention that the labels are false or misleading is preempted, because such a claim would require Plaintiff to show

that the information stated on the labels should have been presented *differently* (thus imposing a *different and/or additional* labeling requirement than those found under the FMIA . . .).

Id. at *7 (emphasis original); *see also Phelps v. Hormel Foods Corp.*, 244 F. Supp. 3d 1312, 1316-17 (S.D. Fla. 2017) (“FSIS has preapproved all of the labels at issue, each of which contains the challenged ‘100% Natural’ and ‘No Preservatives’ claims. . . . By attempting to challenge the FSIS-approved claims as false, misleading, or deceptive, each of Plaintiff’s claims [for unfair trade practices, negligent misrepresentation, and breach of warranty] improperly seeks to impose additional or different requirements on Defendant’s labeling than those required by USDA. Such challenges are in direct conflict with the sweeping preemption clauses in . . . FMIA, and Plaintiff’s state-law claims therefore must be dismissed as expressly preempted by federal law.”); *Meaunrit*, 2010 WL 2867393, at *6-7 (finding that the Federal Meat Inspection Act preempted the plaintiffs’ state-law breach of warranty claims because the FSIS had approved the labels, such that they could not be misleading).

All of Plaintiffs’ state law claims seek to impose liability on Daniele for Daniele’s failure to state on the label that the Gourmet Pack “contains milk.” Compl. ¶ 24 (alleging that Daniele breached the implied warranty because “the goods were unfit for their intended and ordinary purpose because the meat did not warn consumers that it contained dairy”), ¶¶ 34-35 (claiming that Daniele “had a duty to disclose” that the Gourmet Pack “contained a dairy ingredient” pursuant to FALCPA), ¶¶ 43-44 (alleging failure to warn based on FALCPA’s “mandate[] that manufacturers use the word ‘milk’ to describe sodium caseinate.”), ¶ 50 (alleging a violation of Chapter 93A as a result of Daniele’s failure to label the product as containing milk), ¶ 54 (alleging loss of consortium as a result of Daniele’s “actions”), ¶ 60 (alleging intentional infliction of emotional distress as a result of Daniele’s failure “to disclose that its product

contained a major allergen”), ¶ 68 (alleging negligent infliction of emotional distress as a result of Daniele’s failure to disclose the presence of milk). As set forth above, however, the Federal Meat Inspection Act does not require that meat products containing sodium caseinate specify that they “contain milk.”

Moreover, since the FSIS approved the Gourmet Pack’s label, Plaintiffs’ attempt to challenge the label as insufficient “would require Plaintiff to show that the information stated on the labels should have been presented *differently* (thus imposing a *different and/or additional* labeling requirement than those found under the FMIA).” *Kuenzig*, 2011 WL 4031141, at *7 (emphasis original). Simply stated, in seeking to hold Daniele liable for failing to state that the Gourmet Pack contains milk, Plaintiffs attempt to impose a labeling requirement that is “not identical to” those mandated by the Federal Meat Inspection Act. Accordingly, as a matter of well-established federal law, the Federal Meat Inspection Act preempts all of Plaintiffs’ claims.

CONCLUSION

For the foregoing reasons, Daniele respectfully requests that this Court dismiss Plaintiffs’ Complaint in its entirety.

Dated: March 15, 2018

Defendant,
DANIELE INTERNATIONAL, INC.,
By its attorneys,

/s/ Geoffrey W. Millsom

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CERTIFICATE OF SERVICE

I hereby certify that I filed this Memorandum through the ECF system on the 15th day of March, 2018, and that notice will be sent electronically to all counsel who are registered participants identified on the Mailing Information for C.A. No. 1:18-cv-10453-MPK.

/s/ Geoffrey W. Millsom