UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PLYMOUTH DIRECT, INC.
425 Stump Road, Box 427
Montgomery, PA 18936

and

NATURES PILLOWS, INC.,
2607 Interplex Drive
Trevose, PA 19053

Plaintiffs,

vs.

UNITED STATES FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, MD 20993

and

UNITED STATES OF AMERICA,
c/o Office of the United States Attorney for the District of Columbia,
555 4th Street, N.W.
Washington, D.C. 20530,

Defendants.

C.A. No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Plymouth Direct, Inc. and Natures Pillows, Inc. ("NPI") bring this action for judicial review of actions by the United States Food and Drug Administration ("FDA") that have restricted, and continue to restrict, importation of medical devices into

the United States. The Court should issue a declaratory judgment holding that FDA's actions restricting importation are unlawful and issue a permanent injunction setting those actions aside and otherwise prohibiting FDA from enforcing or effectuating them in the future.

Jurisdiction and Venue

1. This Court has jurisdiction over this action under 28 U.S.C. § 1331, to provide remedies set forth in 5 U.S.C. § 706 and 28 U.S.C. § 2201.

2. Venue is proper in this District under 28 U.S.C. § 1391(e).

Parties

3. Plaintiff Plymouth Direct, Inc. ("Plymouth") is incorporated under the laws of Pennsylvania, with its place of business at 425 Stump Road, Montgomeryville, PA. Plaintiff Natures Pillows, Inc. ("NPI") is incorporated under the laws of Pennsylvania, with its place of business at 2607 Interplex Drive, Trevose, Pennsylvania. Plaintiffs market and sell the BeActive® Brace. Plymouth markets and sells the Brace primarily through television advertising and commercials. NPI markets the Brace through retail and mail order channels.

4. Plaintiffs' supplier, Base4 Group Inc., is the Importer of Record for the Brace. Plaintiffs are the owners and consignees of the shipments that they order and receive, as imported by Base4. After ordering Braces from Base4, Plaintiffs are required to take possession and ownership of those products as they arrive in the United States. As soon as Braces arrive in the United States, to be offered for entry into domestic

commerce, Plaintiffs own those products, including the Braces detained by FDA as described below.

5. Defendant United States Food and Drug Administration ("FDA") has regulatory authority over the Braces at issue in this case and has imposed the import restrictions at issue. Defendant United States of America is named as a defendant pursuant to 5 U.S.C. §§ 702-703, because this is an action for judicial review of actions of an agency of the United States that have affected Plaintiffs adversely.

Statutory and Regulatory Background: Device Classification

6. In 1976, Congress amended the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, and granted FDA new authority to regulate medical devices intended for human use. FDA has authority to classify medical devices into one of three categories — Class I, Class II, or Class III — through notice and comment rulemaking.

7. FDA has classified hundreds of different device types within Class I, II or III. *See generally* 21 C.F.R. pts. 862-892. FDA's classification regulations group devices by generic type. "Generic type" means "a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness." 21 C.F.R. § 860.3(i). For example, the classification regulation at issue in this case applies to the generic device type "limb orthosis," which is defined as "a device intended for medical purposes that is

worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement." 21 C.F.R. § 890.3475.

8. This case focuses on the FDA premarket clearance processes that govern devices. FDA must authorize marketing in advance for any device first introduced into interstate commerce after the 1976 medical device amendments to the FFDCA were enacted (unless the agency exempts the pertinent category of devices from premarket clearance through notice and comment rulemaking). To obtain premarket clearance, the sponsor must submit an application to FDA containing specified information and data for the agency to review and determine whether marketing will be authorized. *See, e.g.*, 21 C.F.R. §§ 807.81-807.100, 814.20-814.47.

9. In general, Class III devices (which pose the highest potential risk) must go through the "premarket approval" process.

10. Class I and II devices pose fewer risks and are therefore able to enter the market more easily. Rather than requiring premarket approval for Class I and Class II devices, the FFDCA subjects them to a different premarket authorization process under section 510(k) of the statute. In order for FDA to authorize marketing of a Class I or II device through the so-called 510(k) process, the agency generally must determine that the device is "substantially equivalent" to a pre-existing, legally marketed Class I or II device. 21 U.S.C. § 360c(f)(1)(A)(ii). To be substantially equivalent, the new device must have "the same intended use as the predicate device," and either (i) have "the same technological characteristics as the predicate device" or (ii) be shown to be as safe and effective as the predicate device. *Id.* § 360c(i)(1)(A).

11. Class I devices are those that present the lowest risk. The FFDCA gives FDA authority to exempt a Class I device from the 510(k) premarket clearance process when adopting the regulation that classifies the device in Class I. 21 U.S.C. § 360c(d)(2)(A); 21 C.F.R. § 860.95. When such an exemption applies, a Class I device may be marketed without any prior FDA authorization. It is significant in this case that the classification regulation for "limb orthosis" devices expressly states that (with exceptions not applicable here) such devices are exempt from the 510(k) process. 21 C.F.R. § 890.3490(b).

12. Although FDA has promulgated classification regulations governing hundreds of different generic types of devices, there still are types that FDA has not classified. If a sponsor wishes to market such an "unclassified" device, and the device was not in commercial distribution before the 1976 medical device amendments to the FFDCA, the device must go through either the 510(k) clearance process or the premarket approval process. The sponsor of the device will receive 510(k) clearance if it can prove that its device is (1) "within a type of device" that was in commercial distribution before the 1976 amendments and (2) "substantially equivalent to another device within such type." 21 U.S.C. §§ 360c(f)(1)(A)(i)(I), (A)(ii). If the sponsor cannot prove both elements, the device is classified in Class III by operation of law (subject to premarket approval requirements). *Id.* § 360c(f)(1).

13. Because a device classification can affect such fundamental issues as those described above, the FFDCA requires FDA to inform interested persons of a device's classification upon request. Any person may submit a written request to FDA for

"information respecting the class in which a device has been classified or the requirements applicable to a device under [the FFDCA]." 21 U.S.C. § 360c(g). The statute requires FDA to respond within sixty days with "a written statement of the classification (if any) of such device and the requirements of [the FFDCA] applicable to the device." *Id*.

Statutory and Regulatory Background: Import Requirements

14. The FFDCA establishes a regime in which FDA and the U.S. Bureau of Customs and Border Protection work together to admit into domestic commerce (or refuse admission of) medical devices that are offered for import. In general, Customs has the formal responsibility to police the border (just as it does for all other products offered for import), and FDA provides the substantive expertise necessary to evaluate whether medical devices should be admitted into domestic commerce.

15. The FFDCA gives Customs authority to collect samples of medical devices offered for import and deliver them to FDA, at FDA's request. 21 U.S.C. § 381(a). In practice, Customs has delegated this authority to FDA, so that FDA is the agency that collects the samples.

16. The FFDCA also gives FDA authority to conduct an "examination" of a sample of medical devices. 21 U.S.C. § 381(a). The purpose of the examination is to determine whether the sample meets any of the statutory criteria for refusing its admission into domestic commerce — e.g., whether the medical device is "adulterated" or "misbranded" within the meaning of the FFDCA. *Id*. A medical device is both

"adulterated" and "misbranded" (among other things) if the FFDCA requires 510(k) premarket clearance and FDA has not granted it. *Id.* §§ 351(f)(1)(B), 352(o).

17. FDA's regulations expressly require that when an importing owner or consignee is notified that a sample has been taken, the owner or consignee must "hold" the medical device and not distribute it until further notice from the agency. 21 C.F.R. § 1.90. When FDA finishes its sample evaluation, it decides whether it "appears from the examination of such samples or otherwise" that any of the enumerated statutory criteria for refusal of admission have been met. 21 U.S.C. § 381(a). If there is no basis for refusal under these criteria, FDA issues a "notice of release." A "notice of release" is an agency action that lifts the existing "hold" and authorizes distribution of the medical device in domestic commerce. *See* 21 C.F.R. § 1.90.

18. If there is a case in which it "appears from the examination of such samples or otherwise" that any of the enumerated statutory criteria for refusal of admission have been met (21 U.S.C. § 381(a)), FDA gives the owner or consignee notice and an opportunity for an informal hearing. 21 C.F.R. § 1.94(a). Following the hearing, if FDA determines that it still appears that any of the statutory criteria have been met, the agency issues a "notice of refusal" that requires Customs to demand redelivery of the medical device, so that Customs can require its export or destruction. 19 C.F.R. § 141.113(c)(3); 21 U.S.C. § 381(a). Alternatively, if the owner or consignee prevails at the informal hearing, the agency issues a "notice of release." This notice authorizes distribution in domestic commerce under FDA's "hold" regulation. *See* 21 C.F.R. § 1.90.

19. FDA also has adopted rules for Detention Without Physical Examination, under which FDA "detains" medical devices offered for import, by requiring the importer to hold the devices at its own facility in the United States until FDA authorizes its release into domestic commerce. While the medical devices are being "detained," their owner or consignee must provide evidence to FDA that the devices do not meet the statutory criteria for refusal; FDA does not itself sample or test the devices. If the information that the owner or consignee submits satisfies FDA that the medical devices do not meet the refusal criteria, FDA releases the devices into domestic commerce.

20. These Detention Without Physical Examination rules — which shift the burden to the owner or consignee to prove that medical devices are not violative in order for the devices to be admitted into domestic commerce — do not appear anywhere in the FFDCA or in FDA's regulations published in the Code of Federal Regulations. Instead, the rules are stated in internal agency documents such as the FDA Regulatory Procedures Manual.

21. Under these rules, FDA ordinarily imposes Detention Without Physical Examination by issuing an Import Alert that publicly describes particular foreign shippers, manufacturers, products and/or countries of origin of imports that will be subject to detention and potential refusal. Often an Import Alert on a particular regulatory issue already exists and FDA imposes a new Detention Without Physical Examination by amending the existing Import Alert to add new companies or products. In some cases, as in this case, FDA imposes Detention Without Physical Examination before formally adding a company or product to an existing Import Alert.

22. In general, and as applied by FDA in this case, FDA imposes Detention Without Physical Examination on each and every import shipment of the allegedly violative product. Accordingly, FDA refuses admission into domestic commerce for each and every such import unless the owner or consignee submits the evidence described above and FDA decides to release the products into domestic commerce. In general, and as applied by FDA in this case, Detention Without Physical Examination will continue for all such imports until such time as FDA decides to remove the company from Detention Without Physical Examination.

The Parties' Dispute

23. The BeActive® Brace is a wrap-style brace for placement on a leg. The Brace creates pressure at a specific point on the calf muscle that causes the muscle to relax in a way that reduces tension on the sciatic nerve, thereby reducing lower back pain. Plaintiffs have invested millions of dollars to establish market demand for the Braces. Plymouth first began selling the Braces in May 2014, and NPI first began selling the product in August 2014. The product is extremely popular and has been purchased by thousands of United States consumers and other customers.

24. Plaintiffs have established a vast network of customers for BeActive® Braces. These customers range from individuals to several of the country's largest and most popular retailers. Plaintiffs continue to receive a steady stream of orders for hundreds of thousands of Braces, pouring in on a daily basis from television viewers, from the internet, from national and regional distributors, and from major retailers across the United States.

25. The BeActive® is, without question, each Plaintiff's most important and biggest selling product. Sales of the Braces constitute the majority of Plaintiffs' sales. In addition, Plaintiffs project that sales of this product will continue to grow dramatically, based on increasingly higher actual sales in recent weeks.

26. Although the Brace is not marketed as a medical product intended to cure any disease, it is nonetheless an FDA-regulated "device" within the meaning of the FFDCA because it is "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(h)(3). In April 2014, FDA evaluated and affirmatively confirmed in writing that this product can be lawfully imported into, and sold in, the United States without 510(k) premarket clearance. On April 11, 2014, Kim Yzaguirre (the Director of Operations for Plaintiffs' importer of record Base4 Group, Inc.) sent an email to Ms. Sylvia Gaytan at FDA, with pictures showing BeActive® Brace packaging and labeling, so that FDA could review and confirm the classification for that product. The purpose of this email was to confirm whether the Brace is exempt from any requirement to obtain 510(k) clearance before Base4 Group imported the devices for Plaintiffs' accounts. Ms. Yzaguirre wanted to be certain, as she found other braces that are 510(k)-exempt on FDA's website, "but I could not find a listing that specified a brace that fits around the knee for easing back discomfort."

27. FDA responded on April 24, 2014. In her response, Ms. Gaytan forwarded a determination from FDA headquarters (Center for Devices and Radiological Health ("CDRH")) that the Brace is 510(k)-exempt. Specifically, FDA headquarters confirmed that no 510(k) clearance is required for the Brace: "CDRH has determined that the brace

as described below would fall under 21 CFR 890.3475 as Class I, 510(k) exempt." To make this determination, FDA considered pictures of the product and product packaging and labeling for the Brace.

28. After FDA's classification determination, and in reliance upon it, Plaintiffs launched the Brace in the United States market. All of the suppliers who manufacture BeActive® Braces are located in China, and no company has manufactured the Braces in the United States, so Plaintiffs have to import those products. Plaintiffs have invested millions of dollars to advertise, purchase, promote, market, import, and sell Braces in the United States, following the FDA's express confirmation that no 510(k) clearance is necessary for this product.

29. For example, Plaintiff Plymouth Direct, Inc. sells the Brace through television advertising and internet websites. This required an enormous investment of funds, including to: (1) prepare and produce promotional programs; and (2) purchase air time for those programs. Plymouth has expended millions of dollars on television sales of the Braces and in launching the product.

30. Plaintiff NPI sells the Braces through mail order and retail channels. NPI has invested millions of dollars to launch this product. NPI invested in marketing and promotion of the Braces, secured multiple sales channels and customers for the Braces, and accepted purchase orders for millions of Braces from those customers.

31. In addition, Plaintiffs have placed substantial orders for the Braces from their own supplier, obligating themselves to pay for those products as they arrive in the United States. As each shipment arrives in the United States, Plaintiffs own those

products and are required to pay for them. To make those payments and earn revenue, however, Plaintiffs must be able to ship and sell those products to their customers.

32. As of October 2, 2014, more than 200,000 Braces were imported into the United States, without any problem. Plaintiffs sold those products to their customers in the United States. Plaintiffs have sold hundreds of thousands of Braces.

33. Plaintiffs continued to accept orders for more products, and, in turn, continued to increase their orders for more products to be manufactured in China. Plaintiffs also have obligated themselves to customers to deliver hundreds of thousands more units that are on order. Plaintiffs urgently need to deliver these products to their customers, particularly given the demand created by the holiday shopping season.

34. On September 27, 2014, an import shipment of Braces arrived at the Dallas-Fort Worth airport. Two weeks later, FDA detained that shipment, alleging for the first time that the Braces required (and lacked) section 510(k) premarket clearance. An FDA official in Dallas indicated that the Braces were being detained because of labeling claims concerning the relief of back pain caused by two particular conditions (pregnancy and pirifomis syndrome).

35. On October 8, counsel for Plaintiffs disputed FDA's suggestion that these labeling claims converted the device into one that required section 510(k) premarket clearance. Counsel also notified FDA that, as an accommodation, Plaintiffs would immediately remove the labeling claims that FDA expressed concerns about. The Dallas FDA official nonetheless indicated that the matter would be referred to FDA headquarters (the Centers for Devices and Radiological Health) for further review.

36. Between September 27, 2014 and October 20, 2014, six more import shipments of Braces arrived at the Dallas-Fort Worth airport. FDA also detained these shipments based on the same allegation regarding section 510(k) premarket clearance.

37. Following these detentions, FDA released all seven shipments; FDA released three of them "with comment." The three shipments that FDA released "with comment" represented, collectively, a total of 243,360 Braces. Release "with comment" is a procedure whereby FDA releases imported merchandise into domestic commerce, even though the agency believes it appears to violate regulatory requirements, because the regulatory violations at issue are considered to be minor. FDA's Regulatory Procedures Manual, which sets forth FDA's internal procedures governing imports, defines "release with comment" as a means of "handling minor violations." The Regulatory Procedures Manual further states that when FDA applies this procedure, "[t]he violation(s) must be minor, since a shipment with serious infraction(s) should be detained."

38. On October 26, 2014, two more import shipments of Braces arrived at Dallas-Fort Worth airport. On October 28, 2014, FDA detained both shipments without first conducting any physical examination. FDA issued a notice to the customs broker stating that FDA was detaining these shipments without physical examination because the devices were "in the process of being posted" to Import Alert 89-08.

39. Import Alert 89-08 is a public listing of the firms and products subject to Detention Without Physical Examination on the ground that a medical device is required to have, but does not have, section 510(k) premarket clearance. FDA's notice to the

customs broker attached information about how the specifics of the Import Alerts and Detention Without Physical Examination work. Among other things, the information stated that "if the appearance of the violation is not overcome, or the violation is not otherwise fixed, that the product is normally refused entry into US commerce by the FDA."

40. FDA has detained without physical examination every import shipment that has arrived in the United States since the two October 26 shipments described above. As of November 1, 2014, FDA has detained without examination a total of seven consecutive shipments collectively comprising more than 260,000 Braces. As a result of FDA's Detention, Plaintiffs are unable to ship hundreds of thousands of Braces ordered by customers.

41. The Detention Without Physical examination that FDA imposed beginning on October 28 is a uniform prohibition on all future imports of Braces that will continue until FDA lifts the Detention.

42. Plaintiffs have undertaken a number of efforts to accommodate FDA's stated concerns about the labeling for the Brace. As indicated above, Plaintiffs through counsel first attempted to accommodate FDA on October 8, immediately upon hearing the agency's concerns. More recently, beginning on October 24 and continuing through October 31, Plaintiffs have attempted to accommodate the agency in three different ways. *First*, Plaintiffs submitted proposed new boxes for devices sold through retail; the new boxes remove the verbiage that FDA found questionable. *Second*, Plaintiffs submitted to FDA "instructions for use" inserts, which is the only labeling that accompanies devices

sold through mail order. These instructions for use do not (and never have) made the claims that FDA has found objectionable, and they are the only labeling associated with mail order devices, which are shipped in unmarked plastic bags or boxes. *Finally*, Plaintiffs verified to FDA that they have discontinued making claims of concern to FDA in advertising (whether on the internet or otherwise).

43. Plaintiffs also informed FDA that they would be willing to file a 510(k) premarket clearance application even though Plaintiffs do not believe one is required. However, given the length of time that agency review of the application would take, Plaintiffs have requested FDA not to apply Detention Without Physical Examination to the Braces during the period that the application is completed and filed by Plaintiffs and reviewed by FDA.

44. FDA has not responded to any of these overtures as of the time this action is being filed.

Count I
(Agency Action in Excess of Statutory Jurisdiction, Authority, or Limitations, or Short of Statutory Right)

45. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 44 above.

46. The Detention Without Physical Examination is a final agency action reviewable in this Court.

47. FDA has no statutory authority to detain, or impose Detention Without Physical Examination on, any import entry of medical devices under the FFDCA if it

does not appear that the devices meet one of the statutory requirements set forth in 21 U.S.C. §§ 381(a)(1) through (4).

48. FDA has no statutory authority to detain, or impose Detention Without Physical Examination on, any import entry of medical devices under the FFDCA, on the ground that required 510(k) clearance has not been obtained, if does not appear that the devices are "adulterated" or "misbranded" within the meaning of 21 U.S.C. §§ 381(a)(3), 351(f)(1)(B) and 352(o).

49. Plaintiffs' BeActive® Braces do not, and do not appear to, require 510(k) premarket clearance because they fall within the classification regulation for limb orthoses (21 C.F.R. § 890.3475) and that regulation exempts such devices from 510(k) clearance requirements under the facts of this case. Accordingly, the Braces are not, and do not appear to be, "adulterated" or "misbranded" medical devices within the meaning of 21 U.S.C. §§ 381(a)(3), 351(f)(1)(B) and 352(o).

50. Under 5 U.S.C. § 706(2)(C), this Court should hold unlawful and set aside (1) any FDA detentions currently being imposed on individual entries of BeActive® Braces; and (2) FDA's Detention Without Physical Examination regarding the Braces.

51. Under 5 U.S.C. § 706(2)(C), this Court should enjoin FDA from imposing future detentions regarding the Braces.

52. Under 28 U.S.C § 2201, this Court should declare unlawful (1) any FDA detentions currently being imposed on individual entries of BeActive® Braces; and (2) FDA's Detention Without Physical Examination regarding the Braces.

Count II
(Arbitrary and Capricious Agency Action)

53. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 44 above.

54. The Detention Without Physical Examination is a final agency action reviewable in this Court.

55. To the extent that FDA has concluded that its April 2014 classification determination regarding BeActive® Braces was incorrect, and thereby changed its April 2014 interpretation of 21 C.F.R. § 890.3475, FDA has not articulated any rationale supporting that conclusion.

56. To the extent that FDA's basis for imposing Detention Without Physical Examination is a change in the April 2014 interpretation of 21 C.F.R. § 890.3475, the Detention is an arbitrary and capricious final agency action within the meaning of 5 U.S.C. § 706(2)(A) because the action has no articulated rationale.

57. Under 5 U.S.C. § 706(2)(A), this Court should hold unlawful and set aside (1) any FDA detentions currently being imposed on individual entries of BeActive® Braces; and (2) FDA's Detention Without Physical Examination regarding the Braces.

58. Under 5 U.S.C. § 706(2)(A), this Court should enjoin FDA from imposing future detentions regarding the Braces.

59. Under 28 U.S.C § 2201, this Court should declare unlawful (1) any FDA detentions currently being imposed on individual entries of BeActive® Braces; and (2) FDA's Detention Without Physical Examination regarding the Braces.

Count III
(Agency Action Without
Observance of Procedure Required by Law)

60. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 44 above.

61. FDA's imposition of Detention Without Physical Examination regarding the BeActive® Braces is a legislative rule and a final agency action. It is a legislative rule, among other things, because it imposes uniform prospective legal limitations on the importation of the Braces that did not exist before the agency action was taken.

62. Under 5 U.S.C. § 553, FDA was required either to follow notice and comment procedures, or to publish written findings establishing good cause that notice and comment procedures were impracticable, unnecessary, or contrary to the public interest, before imposing the Detention Without Physical Examination. However, FDA did neither and thereby violated 5 U.S.C. § 553. Because of this violation of 5 U.S.C. § 553, FDA's imposition of Detention Without Physical Examination constitutes final agency action "without observance of procedure required by law" within the meaning of 5 U.S.C. § 706(2)(D).

63. Under 5 U.S.C. § 706(2)(D), this Court should hold unlawful and set aside (1) any FDA detentions currently being imposed on individual entries of BeActive® Braces; and (2) FDA's Detention Without Physical Examination imposed regarding the Braces.

64. Under 5 U.S.C. § 706(2)(D), this Court should enjoin FDA from imposing future detentions regarding the Braces.

65. Under 28 U.S.C § 2201, this Court should declare unlawful (1) any FDA detentions currently being imposed on individual entries of BeActive® Braces; and (2) FDA's Detention Without Physical Examination regarding the Braces.

Prayer for Relief

Plaintiff respectfully requests the Court to grant the following relief:

I. Issue an injunction setting aside FDA's actions, and prohibiting its future actions, as described above in paragraphs 50-51, 57-58 and 63-64;

II. Issue a declaratory judgment declaring that FDA has acted unlawfully as described above in paragraphs 52, 59 and 65; and

III. Award such other relief as this Court deems just and proper.

Respectfully submitted,

/s/ Daniel G. Jarcho

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