UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Church & Dwight Co. Inc.,

Plaintiff,

-v-

SPD Swiss Precision Diagnostics, GmbH, *et al.*,

Defendants.

14 Civ. 00585 (AJN)

OPINION AND ORDER

ALISON J. NATHAN, District Judge:

Plaintiff Church & Dwight ("C&D") has filed a Complaint against Defendant SPD Swiss Precision Diagnostics ("SPD") bringing claims for false advertising under the Lanham Act and New York General Business Law § 349.[1] In connection with this Complaint, C&D also filed a motion for a preliminary injunction. In response, SPD has opposed the preliminary injunction and has moved to dismiss the Complaint, arguing primarily that C&D cannot bring its claims because these are matters more properly resolved by the FDA. For the reasons explained below, the Court denies SPD's motion to dismiss and does not at this juncture reach the arguments raised by the preliminary injunction papers.

I. Legal Standard

When deciding a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), a court must accept as true all well-pleaded facts and draw all reasonable inferences in the light most favorable to the non-moving party. *See Kassner v. 2nd Ave. Delicatessen, Inc.*, 496 F.3d 229, 237 (2d Cir. 2007). Although factual allegations are therefore afforded a presumption of truth, a court is "not bound to accept as true a legal

[1] C&D also brings a claim for breach of contract, the merits of which are not currently at issue.

conclusion couched as a factual allegation." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). "To survive a motion to dismiss, the plaintiff's pleading must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570).

In addition to the allegations in the complaint, a court may consider documents attached as exhibits, incorporated by reference, or relied upon by the plaintiff in bringing suit, as well as any judicially noticeable matters. *See Halebian v. Berv*, 644 F.3d 122, 131 n.7 (2d Cir. 2011); *In re Harbinger Capital Partners Funds Investor Litig.*, No. 12 Civ. 1244 (AJN), 2013 WL 5441754, at *15 n.6 (S.D.N.Y. Sept. 30, 2013). "If a document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, control, and the court need not accept the allegations in the complaint as true." *TufAmerica, Inc. v. Diamond*, 968 F. Supp. 2d 588, 592 (S.D.N.Y. 2013) (quoting *Poindexter v. EMI Record Grp. Inc.*, No. 11 Civ. 559 (LTS), 2012 U.S. Dist. LEXIS 42174, at *6 (S.D.N.Y. Mar. 27, 2012)) (internal quotation marks omitted).

II. Background

A. C&D's Alleged False Advertising

1. C&D, SPD, and the Weeks Estimator Product

C&D and SPD are competitors in the market for home pregnancy test kits. Compl. ¶¶ 2, 15. Sometime around August 2013, SPD began marketing a new home pregnancy test kit, the "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator" (the "Weeks Estimator"). Compl. ¶¶ 2, 17. Like other home pregnancy test kits, the Weeks Estimator was designed to tell a woman whether or not she is pregnant but also was designed to estimate the number of weeks

that had passed since the woman last ovulated. Compl. ¶ 17.

The crux of C&D's claims is that the Weeks Estimator cannot be used to provide an estimate of how long a woman has been pregnant. In particular, according to C&D, the medical profession does not measure pregnancy with reference to the time of ovulation—the time that an egg is released from the ovary—but rather measures it based on the "universally accepted convention" that pregnancy begins at the time of the woman's last menstrual period. Compl. ¶ 18. The last menstrual period occurs, on average, approximately two weeks before ovulation and, as a result, C&D alleges that doctors would determine the length of a woman's pregnancy differently using this standard than they would based on the date of ovulation. Compl. ¶ 18.

2. Allegedly False Advertising

C&D alleges that SPD has made false statements about the Weeks Estimator in a variety of different media.

a. The Weeks Estimator Box

First, C&D objects to the box containing the Weeks Estimator. In particular, C&D points to the product name—"Advanced Pregnancy Test With Weeks Estimator"—which is prominently displayed on the box, as well as rectangular graphics (representing the product's display window) on the box in which the words "Pregnant 1-2 Weeks," "Pregnant 2-3 Weeks," and "Pregnant 3+ Weeks" appear. Compl. ¶ 27. C&D also alleges that "[i]n violation of the FDA's directives, the indications for use statement does not appear in close proximity to the trade name or in similar font size or in bold font." Compl. ¶ 27. According to C&D "[t]he literal communication (or, at the very least, the necessary implication) of the Product packaging is that the Weeks Estimator can tell a woman how many weeks she has been pregnant -- specifically that she is 1-2 weeks pregnant, 2-3 weeks pregnant, or 3+ weeks pregnant." Compl. ¶ 29.

b. The Television Commercial

C&D also objects to a television commercial promoting the Weeks Estimator as promoting the same message: "that the Product can tell a woman how long she has been pregnant." Compl. ¶ 30. A woman tells a friend that she is pregnant, to which her friend exclaims "Really?!" Compl. ¶ 31. The woman holds up two fingers and says "two weeks." Compl. ¶ 31. After her friend asks whether she has already seen a doctor, the woman responds "Not yet," holds up the pregnancy test stick, and says "but I just took this new Clearblue test." Compl. ¶ 31. The scene moves to a close up of the test stick, with the Clearblue logo, and a display window with the word "Pregnant" and "1-2 Weeks" immediately below that word. Compl. ¶ 31. The pregnant woman then is heard to say "It's like two tests in one!" Compl. ¶ 31. The scene then changes to a graphic reflecting the three display windows noted above, while an announcer states "the new Clearblue pregnancy test also estimates how many weeks." Compl. ¶33. At the end of the commercial, the announcer concludes "Weeks Estimator. Only from Clearblue." Compl. ¶ 33.

c. SPD's Website

SPD also maintains a webpage promoting the Weeks Estimator product. Compl. ¶ 35. According to C&D, until its recent alteration that page referred to the Weeks Estimator as "the ONLY Pregnancy test that Estimates Weeks" next to a graphic of a test stick with "Pregnant 1-2 weeks" in the display window, with similar statements repeated farther down on the page. Compl. ¶ 36. The page also suggests that the Weeks Estimator "estimates the number of weeks," is "Like 2 Tests in 1," and notes that 78% of women surveyed believe it is important to know "how far along they are." Compl. ¶ 36.

Farther down, the page notes that the Weeks Estimator "estimate[s] how many weeks based on time since ovulation"—a phrase C&D claims is deceptive because time since ovulation is not the standard used to measure pregnancy. Compl. ¶ 37. At the bottom of the page, SPD includes the FDA's indications for use statement, including the required language quoted above. Compl. ¶ 38 & Ex. D.

d. Point of Purchase and Retail Advertising

C&D makes similar allegations that the point-of-purchase displays in which the Weeks Estimator is sold by retailers also are deceptive, in that each tray bears either the claim "First pregnancy test to estimate weeks" or "How far along are you?" Compl. ¶ 39. The trays do not contain the FDA's indications for use statement or disclose that the product measures time since ovulation. Compl. ¶ 40. C&D also challenges a web advertisement for the Weeks Estimator which states "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator. Is there a baby on board? How far along? Find out!" and other similar advertisements. Compl. ¶ 41.

e. The Press Release

Finally, C&D also raises a different challenge to the Weeks Estimator based on a press release announcing the launch of the product. Specifically, that press release claimed that the product was "approximately 93 percent accurate in estimating the number of weeks based on time since ovulation." Compl. ¶ 44. According to C&D, this statement is false because SPD's own package insert states that "Agreement of Weeks Estimator results with clinical findings ranged widely from 45%-99%." Compl. ¶ 45.

B. The FDA Process

In response to the preliminary injunction motion, SPD submits significant documentary evidence of its discussions of the Weeks Estimator product with the FDA, and urges the Court to

take judicial notice of its communications with the FDA in resolving the motion to dismiss. C&D does not contest this evidence as to the preliminary injunction but contends the Court may not consider it for purposes of the motion to dismiss. To provide context for this evidence, the Court will first briefly turn to the scheme under which the FDA regulates medical devices such as pregnancy test kits before discussing the evidence and whether it is properly considered in resolving the motion to dismiss.

1. The 510(k) Process

The FDA has authority to regulate medical devices under the Medical Devices Amendments Act. *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006). Under that statute, "each medical device is classified according to the stringency of regulatory control necessary to ensure safety and effectiveness." *Id.* at 74 (citing 21 U.S.C. § 360c(a) (defining the three classes of device)). Class I devices include, for example, elastic bandages and are subject to the least stringent regulation; "such devices can be marketed without prior approval and are subject only to 'general controls' that cover all medical devices." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 108-109 (2d Cir. 2006) (citing § 360c(a)(1)(A)). Devices such as powered wheelchairs and infusion pumps—and, as important here, SPD's Weeks Estimator product—are Class II devices which can be marketed without advance approval but, in addition to the general controls applied to all medical devices, may be also subject to "special controls." *Id.* at 109 (noting that special controls include postmarket surveillance, patient registries, or other measures) (citing § 360c(a)(1)(B)); *see also* 21 C.F.R. § 862.1155 (2014) (providing that devices testing for human chorionic gonadotropin are Class II devices when intended for use in detecting pregnancy but are Class III devices when used for any other purpose). Class III devices are generally subject to the most stringent regulation, including in particular a requirement of "premarket approval" by the

FDA before they may be commercially distributed. *Yale-New Haven Hosp.*, 470 F.3d at 74.

Class II devices are subject to the requirements of 21 U.S.C. § 360(k), also known as the "§ 510(k) process." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-479 (1996); *see also* 21 C.F.R. § 807.81 (2014) (describing the circumstances requiring a premarket notification submission). Under the § 510(k) process, a party seeking to market a medical device is required to submit a "premarket notification" to the FDA. *Id.* This notification includes a description of the devices and a statement of the intended use of the device, the proposed labeling to be included on the device, and the information necessary for the FDA to determine if the device is "substantially equivalent" to a pre-existing device. *See* 21 C.F.R. § 807.92 (2014); *Rita Med. Sys. v. Resect Med., Inc.*, No. C 05-03291 WHA, 2006 U.S. Dist. LEXIS 52366, at *7-9 (N.D. Cal. July 17, 2006); *see also* 21 U.S.C. § 360c(i) (defining "substantial equivalence"). If the FDA determines that the device is "substantially equivalent" to a pre-existing device, the device may be marketed without further regulatory analysis unless and until the FDA initiates proceedings with respect to the pre-existing device. *See Lohr*, 518 U.S. at 478-479; *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 (9th Cir. 2010). Unlike the more rigorous premarket approval process "510(k) clearance 'does not in any way denote official approval of the device.'" *PhotoMedex*, 601 F.3d at 925 n.3 (quoting 21 C.F.R. § 807.97).

2. The Clearance Letter

In approving the Weeks Estimator for marketing, the FDA issued a Clearance Letter. Specifically, the Clearance Letter stated that the FDA had "determined that there is a reasonable likelihood that [the Product] will be used for an intended use not identified in the proposed labeling and that such use could cause harm." Compl. ¶ 22 & Ex. A at 1; Feldman Decl. ¶ 7 & Ex. A. Although not specifically identifying off-label use as the FDA's concern, the letter

required that, in the package insert, the "Weeks Estimator results should not be expressed as 'weeks pregnant' and should only be explained as the number of weeks that may have passed since ovulation." Compl. Ex. A at 2. It likewise required a chart in the package insert from which women could interpret the results of the Weeks Estimator in terms of how a doctor might date the pregnancy. *Id.* This chart explained that the Weeks Estimator result was measured by time of ovulation and that a doctor would date the pregnancy roughly two weeks longer than the Weeks Estimator, and also explained that doctors dated pregnancy based on last menstrual period. *Id.*

The Clearance Letter also required that the Weeks Estimator's "indications for use" statement be "prominently displayed in all labeling, including pouch box and carton labels and instructions for use, in close proximity to the trade name, of a similar point size and in bold and shall be conveyed accurately—including any limitations—in all promotional materials." Compl. Ex. A at 3. The required statement included the following:

> This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor's determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.

Id. The Clearance Letter concluded by stating, among other things, that "FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." *Id.*

3. C&D's Post-Clearance FDA Communications

On March 21, 2014, the Court ordered that C&D produce documents to SPD comprising its communications with the FDA regarding SPD's Weeks Estimator. In connection with its reply to the motion to dismiss, SPD has submitted four such documents produced to it by C&D. (Supp. Request for Judicial Notice ("SRJN") Exs. A-D). Based on these documents, it appears that starting in October 2013, counsel for C&D communicated with the FDA raising before that body many of the same concerns it now brings in this litigation, particularly as to the Weeks Estimator labeling, the television advertisement, and the point-of-purchase advertising. SRJN Exs. A-D.

4. Request for Judicial Notice

The facts discussed above are derived from the allegations in the Complaint, the Clearance Letter attached as an exhibit to the Complaint, and C&D's communications with the FDA which C&D has conceded are properly before the Court on the motion to dismiss. MTD Hr'g Tr. 18:8-13, May 22, 2014.

In addition, in connection with the motion to dismiss, SPD urges that the Court take judicial notice that the FDA took certain actions and held certain positions with respect to the Weeks Estimator. In support, SPD submits copies of the FDA's Hold Letter as to the Weeks Estimator (Request for Judicial Notice ("RJN") Ex. B); certain correspondence between SPD and the FDA discussing issues raised in the Hold Letter (RJN Exs. D-H); SPD's minutes of a 2013 teleconference with the FDA and proposed mitigation plan submitted to the FDA (RJN Ex. I); and two FDA guidance documents (RJN Exs. A, C), as evidence of those actions and positions.

Courts may consider materials properly subject to judicial notice in deciding a motion to dismiss. *Kalyanaram v. Am. Ass'n of Univ. Professors at the N.Y. Inst. of Tech.*, 742 F.3d 42, 44

n.1 (2d Cir. 2014); *cf. Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (noting a case in which the court had stated in dicta that courts may consider facts subject to judicial notice in considering motions to dismiss, but stating that "a plaintiff's reliance on the terms and effect of a document in drafting the complaint is a necessary prerequisite to the court's consideration of the document on a dismissal motion; mere notice or possession is not enough") (citing *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47-48 (2d Cir. 1991)).[2] Federal Rule of Evidence 201 provides that a court "may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." SPD apparently requests judicial notice under Rule 201(2), citing a handful of cases in which courts have taken notice of facts contained in agency communications. *See Massachusetts v. Westcott*, 431 U.S. 322, 323 n.2 (1977) ("The fact that respondent holds such a license has been ascertained from the records of the Merchant Vessel Documentation Division of the Coast Guard."); *Hein v. Capitan Grande Band of Diegueno Mission Indians*, 201 F.3d 1256, 1259 n.4 (9th Cir. 2000) ("Upon the Splinter Group's motion, we take judicial notice of the letter from the Gaming Commission to counsel for the Splinter Group which states that the Commission cannot act without a definitive determination by the Secretary."); *Jones v. Conagra Foods, Inc.*, 912 F. Supp. 2d 889, 900-01 & n.6 (N.D. Cal. 2012) (taking judicial notice of an FDA letter stating the agency's position that a product containing "naturally-derived citric acid" may be labeled "natural").

[2] There is some conflict between the quotation from *Chambers* in the above parenthetical and other opinions taking judicial notice of matters that do not appear to have been relied on in the drafting of a complaint. *See, e.g., N.J. Carpenters Health Fund v. Royal Bank of Scot. Group, PLC*, 709 F.3d 109, 126-27 & n.11 (2d Cir. 2013) (judicial notice of newspaper articles). Nevertheless, even if the Court does not adopt the broad view of *Chambers* advocated by Plaintiff that judicial notice is only proper where the plaintiff relied on the documents at issue when drafting the complaint, *Chambers* still supports the proposition that judicial notice is not proper if plaintiff could not even have known of or possessed the documents containing the facts to be noticed.

However, SPD's communications with the FDA are not public records of agency actions. Rather, the documents SPD submits in support of its request for judicial notice are internal documents that SPD held in confidence and, in fact, that SPD urged must remain confidential even during the course of this litigation. The Court has found no case in which judicial notice of facts contained in such documents has been held proper. *See United States v. Speakman*, 594 F.3d 1165, 1172 n.4 (10th Cir. 2010) (refusing to take judicial notice of an arbitration award because the arbitration organization was not a public agency); *FDIC v. Loudermilk*, No. 1:12-CV-4156-TWT, 2013 U.S. Dist. LEXIS 166924, at *5-7 (N.D. Ga. Nov. 22, 2013) (refusing to take judicial notice of favorable FDIC reports that were not public documents); *cf. Chambers*, 282 F.3d at 153. Moreover, the authenticity of these documents is not beyond dispute. Nor is their accuracy beyond reasonable question, a concern that is particularly acute as to the 2013 teleconference meeting minutes, a document prepared by SPD purporting to memorialize a telephone call. Even the documents embodying communications between SPD and the FDA are subject to interpretation such that discovery may illuminate their meaning. Resolving a pre-discovery dispositive motion by taking notice of potentially disputed facts contained in such documents would not be proper. For purposes of this motion to dismiss, then, the Court will not consider them.

III. Lanham Act Claims and FDCA Preclusion

SPD argues that the FDA, rather than this Court, is the proper body to resolve C&D's Lanham Act claims, citing a doctrine that courts commonly describe as "preclusion" of Lanham Act claims by the Food, Drug, and Cosmetic Act ("FDCA"). As one court has noted, this doctrine is not subject to a "bright-line" rule of decision. *Healthpoint, Ltd. v. Stratus Pharms.*, 273 F. Supp. 2d 769, 786-87 (W.D. Tex. 2001). The Court first briefly addresses the general

doctrine and origins of FDCA preclusion. The Court then turns to applying the doctrine to this case.

A. FDCA Preclusion Generally

The law surrounding the possible preclusion of a cause of action by the FDCA—in this case C&D's claim for a Lanham Act violation—arises out of a tension between attempting to respect the boundaries Congress has imposed on enforcement of the FDCA while still giving effect to other federal statutes.

On the one hand, the FDCA "imposes a comprehensive set of requirements upon medical devices." *PhotoMedex*, 601 F.3d at 924. And, importantly, although citizens may in some circumstances petition the FDA to take administrative action, it is the FDA that is charged with investigating potential violations of the FDCA and there is no private right of action to enforce the FDCA. *See id.* (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001)); *see also POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1175-76 (9th Cir. 2012), *cert. granted* 134 S. Ct. 895 (2014). As a result, courts have held that the FDCA may "preclude" claims that stray into the FDA's enforcement domain. *See, e.g.*, *POM Wonderful*, 679 F.3d at 1175-76; *PhotoMedex*, 601 F.3d at 924; *Stratus*, 273 F. Supp. 2d at 780-81.

On the other hand, concerns about giving full effect to federal statutes—statutes such as the Lanham Act—that provide for a private right of action have made courts wary of applying this approach too broadly. *See Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 934 (C.D. Cal. 2006) ("Courts have instead struck a balance between the two, allowing breathing space for the Lanham Act, but at the same time not letting it be misused as a naked attempt to enforce the FDCA and its implementing regulations."). It is well recognized that, when faced with two conflicting federal statutes, courts endeavor, as much as possible, to give maximum

effect to both of them. *See J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l*, 534 U.S. 124, 143-44 (2001); *POM Wonderful*, 679 F.3d at 1175. Likewise, courts have suggested that the differing aims of the FDCA and the Lanham Act may counsel against preclusion. *See, e.g.*, *Ivax*, 459 F. Supp. 2d at 933-34. The Lanham Act is directed toward protecting commercial interests and preventing unfair competition that arises due to false advertising. *See id.* at 933. In contrast, the FDCA is generally not focused on the truth or falsity of advertising claims but is instead directed to ensuring that drugs and medical devices are safe, effective, and not misbranded. *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008); *Ivax*, 459 F. Supp. 2d at 933-34.

The Court turns briefly to C&D's reference at oral argument to the Supreme Court's recent decision in *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1386 (2014), which, in the course of discussing the parties' arguments that the case presented an issue of "prudential standing," explained that courts have a virtually unflagging obligation to hear and decide cases within their jurisdiction. As the foregoing cases make clear, the doctrine of FDCA preclusion is grounded in a view that the lack of a private action to enforce the FDCA necessarily brings that statute into tension with the Lanham Act. As a result, courts have essentially limited the substantive scope of Lanham Act claims to alleviate this concern. Thus, FDCA preclusion is not concerned with the Court's "jurisdiction" or a prudential doctrine regarding when a court should decide a claim authorized by law, but is rather focused on an implied statutory limitation to the Lanham Act itself by virtue of its potential conflict, in some situations, with the FDCA. As a result, the Court does not find *Lexmark* particularly informative as applied to this case.

B. Principles of FDCA Preclusion and Application to C&D's Claims

Based on the Court's survey of precedent, the basic application of the doctrine of FDCA preclusion is that courts refuse to usurp the FDA's role in the enforcement of the FDCA and the FDA's authority under that statute. *See POM Wonderful*, 679 F.3d at 1176 ("*PhotoMedex* teaches that the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority."); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) ("Sandoz's position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations."). Courts have explained that preclusion is required not only when a plaintiff "seeks to enforce directly the FDCA through the Lanham Act" but also when a plaintiff attempts to "maintain a Lanham Act claim [that] requires direct application or interpretation of the FDCA or FDA regulations." *Stratus*, 273 F. Supp. 2d at 786; *see also Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL, 1997 U.S. Dist. LEXIS 2372, at *19 (D. Kan. Feb. 26, 1997) ("[A] plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation. . . . Moreover, claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA . . . .").

The Court's review of the numerous cases cited by the parties and its own independent research leads the Court to agree with other decisions that have remarked that this doctrine is not subject to a "bright-line" rule of decision. *See, e.g.*, *Stratus*, 273 F. Supp. 2d at 786-87. Further complicating the Court's decision is the lack of binding precedent—whether from the Supreme Court or the Second Circuit—that provides a rule of decision or general guidance for the Court in approaching this doctrine. In light of this void, the Court is confronted with an array of diverse fact patterns in numerous cases, none of them authoritative, in which courts have applied or

refused to apply preclusion. Firm rules arising from these cases are elusive, but the Court observes some broad trends that guide its inquiry.

The Court's starting point is to briefly review the statutory and regulatory structure pertinent to the Weeks Estimator. Starting with the statutory regime, the FDCA provides that a device may be misbranded based on, among other things, a misleading or false label, insufficiently conspicuous words or statements, and failure to provide adequate directions for use. *See* 21 U.S.C. § 352(a), (c), and (f). Moreover, the 510(k) process as a whole turns on determining the "substantial equivalence" of a device to a previously marketed predicate based on the fact that it has the "same intended use" as the predicate device. 21 U.S.C. § 360c(i)(1)(A); *see also* 21 C.F.R. § 807.92 (2014) (requiring, in a 510(k) submission, a statement of intended use). As particularly pertinent to this matter, the FDCA provides that in conducting this review the FDA may require a statement that "provides appropriate information regarding a use of the device not identified in the proposed labeling" if the FDA determines "(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and (II) that such use could cause harm." 21 U.S.C. § 360c(i)(1)(E)(i).

Likewise, the FDA's regulatory scheme demonstrates that the FDA is responsible for controlling the marketing of medical devices with respect to their intended uses. For instance, 21 C.F.R. § 801.5 (2014), defining what constitutes "adequate directions for use" of a medical device, provides that such directions shall allow a layman to "use a device safely and for the purposes for which it is intended." *See also* 21 C.F.R. § 801.4 (2014) (defining "intended use"). It further specifies that directions may be "inadequate because . . . of . . . incorrect specification of . . . all conditions, purposes, or uses for which the device is intended, including conditions,

purposes or uses for which it is . . . suggested in its oral, written, printed or graphic advertising." § 801.5; *see also* 21 C.F.R. § 801.61 (2014). And 21 C.F.R. § 801.15 (2014) regulates the prominence of required label statements.

Finally, looking to the Clearance Letter, the FDA found that there was a reasonable likelihood that the device would be "used for an intended use not identified in the proposed labeling" and, as a result, imposed limitations on how SPD could market the device. Compl. Ex. A at 1. The FDA specifically provided that "[p]erformance of the Weeks Estimator should not be displayed" on the box labeling and that users should be directed to the package insert for more information on that point. Compl. Ex. A at 1. As to the package insert, the FDA set forth a number of requirements, including that the Weeks Estimator result "should not be expressed as 'weeks pregnant' and should be explained as the number of weeks . . . since ovulation," the form in which to describe the performance of the Weeks Estimator feature, and that doctors may date pregnancy differently. Compl. Ex. A at 2. It also required prominent display of the indications for use—which the FDA drafted and contain two paragraphs on how the Weeks Estimator features worked—in all labeling and in all promotional materials. Compl. Ex. A at 3.

In light of this structure, SPD's argument that C&D's claims involve the application of the FDA's regulatory regime is not wholly without force. The FDA has significant authority over the marketing of the Weeks Estimator, particularly as to its intended uses. As a result, the potential for overlap in adjudicating C&D's Lanham Act claims is not trivial, and there is an arguable view of these claims—a view urged by SPD—in which they simply ask the Court to apply the regulatory regime just discussed.

However, a close reading of C&D's Complaint reveals that its claims are not so simple and that resolving them need not involve the direct application of the FDA's regulations. In

particular, the focus of C&D's Lanham Act claims is that SPD is falsely marketing the Weeks Estimator as capable of estimating the duration of pregnancy, *i.e.*, that SPD is falsely claiming that the Weeks Estimator may be used for a purpose that, in fact, it cannot fulfill.[3] Although portions of C&D's Complaint suggest that its false advertising claim relies on the FDA's findings on this point, *see, e.g.*, Compl. ¶¶ 4-5, 20, 22-25, 34, 38, 40, 42, C&D argues that this was not its intention. *See, e.g.*, MTD Opp. at 11. In particular, in its opposition to the Motion to Dismiss, C&D describes the basis of its claim as follows:

> SPD's advertising *is false because (i) the Weeks Estimator cannot measure pregnancy duration*; instead it measures the length of time since ovulation . . . and (ii) if a woman used SPD's product to estimate pregnancy duration, she would get a very different result from what her doctor would tell her.

MTD Opp. at 11 (emphasis in original). Thus, according to C&D, its references to the FDA's determination that the Weeks Estimator does not measure the duration of pregnancy based on time of last menstruation is evidence that SPD's marketing of the product for this use is false, but C&D's claim would exist even in the absence of the FDA's determination. *Id.*

On this view of C&D's Complaint, its claims are directed at the simple factual falsity of SPD's marketing of the Weeks Estimator. In that case, the Court's task in adjudicating C&D's claims would be essentially two-fold: determine the message conveyed to consumers by SPD's marketing and then determine whether that message is either literally false or likely to mislead and confuse consumers. *See Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010) (noting the elements of a Lanham Act false advertising claim). Put in the concrete terms of this case, the Court would be required to decide (1) whether SPD's marketing conveyed to consumers that the Weeks Estimator measures the duration of pregnancy based on the medically

[3] The exception is C&D's Lanham Act claim based on SPD's representation about the 93% accuracy of the Weeks Estimator. This component of SPD's advertising has not been the focus of the parties' briefing, but the Court notes that essentially the same analysis as conducted below applies to this aspect of C&D's claims.

accepted standard (*i.e.*, date of last menstrual period) and (2) that this message is false or misleading.

Based on the current record, it does not appear that either task requires the Court to interpret, apply, or enforce the FDCA, the FDA's regulations, or the Clearance Letter. For example, to decide that the Weeks Estimator was falsely advertised in violation of the Lanham Act as capable of measuring pregnancy based on the standard applied by healthcare professionals, the Court need not look to the FDA's regulations governing labeling medical devices with their intended uses. Nor need the Court make a determination whether the Weeks Estimator is in compliance with the FDA's regulations or the restrictions imposed by the Clearance Letter. In this respect, C&D' claim is independent of the FDCA and FDA regulations and would exist even in their absence. *See Epogen & Aranesp*, 590 F. Supp. 2d at 1291-92; *Grove Fresh Distribs., Inc. v. Everfresh Juice Co.*, Nos. 89 C 1113 et al, 1989 U.S. Dist. LEXIS 14147, at *7-8 (N.D. Ill. Nov. 27, 1989) ("Striking all reference to the FDCA regulations leaves a still valid (if hard to prove) complaint."); *Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 716 (N.D. Ill. 1989) (finding that the claim at issue was not precluded because plaintiff did "not base its claim solely on the FDCA or FDA regulations. . . . Even without the FDA regulation defining 'orange juice from concentrate,' Grove Fresh could attempt to establish a violation of section 43(a). Grove Fresh would simply need to provide other evidence establishing the proper market definition of 'orange juice from concentrate'.").

This perspective that preclusion would not apply to C&D's Lanham Act claims is consistent with the Court's review of numerous cases applying this doctrine. *See Merck Eprova AG v. ProThera, Inc.*, No. 08 Civ. 35 (RMB) (JCF), 2010 U.S. Dist. LEXIS 142372, at *11-13 (S.D.N.Y. Oct. 20, 2010) (allowing a Lanham Act claim alleging that defendant misrepresented

that its product contained pure L-5-methyltetrahydrofolic acid because it did not assert a violation of an FDA regulation or the FDCA, but was merely claiming that the advertising was false under accepted scientific standards; references to the FDA approval process were only a source of evidence on this point); *Sciele Pharma, Inc. v. Brookstone Pharms., LLC*, No. 1:09-CV-3283-JEC, 2010 U.S. Dist. LEXIS 142408, at *14-17 (N.D. Ga. June 23, 2010) (accepting the plaintiff's argument that its claim that defendant falsely represented that certain vitamins contained "L-MTHF, when they actually contain D,L-MTHF" would be proved by reference to a well-established scientific standard, rather than by reference to any provision of the FDCA or FDA); *Epogen & Aranesp*, 590 F. Supp. 2d at 1291-92 (holding that FDCA preclusion did not bar claims that "allege[d] fraud not dependent on the FDCA's prohibition on off-label promotion," even if "the deceptive statements may have been made in order to promote off-label uses of EPO").

As to C&D's reference in its Complaint to the FDA's scientific findings, a number of courts have held that courts may consider the FDA's positions on a matter as evidence of falsity in considering a Lanham Act claim. *See Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 469 (D.N.J. 2009) ("[C]ourts have consistently held that the FDA's scientific findings are not only relevant, but entitled to significant deference.") (citations omitted); *Iams Co. v. Nutro Prods.*, No. C-3-00-566, 2004 U.S. Dist. LEXIS 31136, at *15 (S.D. Ohio July 17, 2004) ("The FDA's conclusion is obviously relevant to the controversy between the parties . . . ."); *Zeneca, Inc. v. Eli Lilly & Co.*, No. 99 CIV. 1452 (JGK), 1999 U.S. Dist. LEXIS 10852, at *99-100 (S.D.N.Y. July 15, 1999) (explaining that FDA's position was not sufficient to prove a Lanham Act claim, but was "persuasive evidence" of the falsity of the advertising statements given the agency's expertise).

And courts have likewise been clear that the mere fact that the FDA regulates in an area does not inevitably lead to preclusion. *See, e.g.*, *Epogen & Aranesp*, 590 F. Supp. 2d at 1291; *Ivax*, 459 F. Supp. 2d at 932-944 ("So long as courts are not required to perform authoritative interpretation and direct application of FDA regulations, then the simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim under the Lanham Act.") (internal citations omitted). Indeed, were courts unable to look to agency expertise in this fashion or if the mere fact that an agency had regulatory authority in an area was sufficient to invoke preclusion, the doctrine of primary jurisdiction, discussed below, would be incoherent. The entire premise of that doctrine involves courts waiting to adjudicate claims that implicate issues within an administrative agency's expertise until the agency has had an opportunity to express its position. As a result, the mere facts that C&D's Complaint cites actions taken by the FDA and that the FDA has some authority to act in this area do not counsel in favor of applying preclusion.

Turning to the cases that SPD cites in favor of applying preclusion, the Court finds that the cases SPD relies on are distinguishable from the case at hand. For instance, this does not appear to be a case in which resolving C&D's claims would necessarily require the Court to apply an FDA regulation to test the veracity of the advertising at issue, as is the case in many of the decisions cited by SPD. *See, e.g.*, *PhotoMedex*, 601 F.3d at 921-22, 927-28 (explaining that "[t]esting the truth of PhotoMedex's claim would . . . require a court to usurp the FDA's prerogative to enforce the FDCA" because the question of whether the laser device at issue required an affirmative clearance by the FDA was contingent on a factual determination, one to be made by the FDA, as to whether the device was significantly modified from a previously

approved device); *PDK Labs v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (noting briefly, in addressing standing to sue, that the plaintiff's "dogged insistence that PDK's products are sold without proper FDA approval suggests . . . that Friedlander's true goal is to privately enforce alleged violations of the FDCA"); *Sandoz*, 902 F.2d at 230-31 (resolving Lanham Act claim that an ingredient on a product label was "inactive" was false because the ingredient would be considered "active" under 21 C.F.R. § 210.3(b)(7) would have required the Court to "determine preemptively how a federal administrative agency will interpret and enforce its own regulations") (citations omitted); *Stratus*, 273 F. Supp. 2d at 787 ("It is for the FDA to exercise its discretion to determine whether Accuzyme, Panafil White, Kovia and Ziox are on the market lawfully, whether it be because they are grandfathered or are exempt from the FDA pre-clearance process.")[4]; *Summit Tech. v. High-Line Med. Instruments*, Co., 933 F. Supp. 918, 934 (C.D. Cal. 1996) (finding claim focused on allegedly false representations regarding the legality of importing certain lasers precluded because "the FDA has not yet determined whether to take action against Hi-Line for its importation of used Summit lasers"); *Braintree Labs.*, 1997 U.S. Dist. LEXIS 2372, at *20-21. Here, C&D's claims appear to be premised simply on the alleged factual falsity of SPD's advertisement statements under prevailing scientific and medical standards. Therefore, the decisions just cited raised claims that are fundamentally distinguishable from C&D's claims.

Likewise, also distinguishable are those cases in which there existed an actual conflict between an FDA action or regulation and the plaintiff's claims. For instance, although the FDA has regulatory authority over the intended uses of medical devices, this case is unlike *POM*

[4] *Stratus* held precluded a number of claims on essentially this theory. *See* 273 F. Supp. 2d at 787-88 (finding precluded claims that implicated questions of "what federal law does or does not require for [the products] to be marketed legally"; whether new drug applications were required; whether a party complied with good manufacturing practice; whether a product required an FDA approval or rating; and other similar issues; and whether the products were "misbranded" or "adulterated" under the FDA's standards).

Wonderful, which is now pending before the Supreme Court, because the regulatory scheme governing the Weeks Estimator does not—in itself—provide a basis to conclude that the Weeks Estimator box, label, or advertising has been authorized by the FDA. *See POM Wonderful*, 679 F.3d at 1176-77 (holding that plaintiff's claim based on the name and label of the product was barred because FDA regulations authorized the name that Coca-Cola had chosen, such that "Pom's challenge to the name 'Pomegranate Blueberry Flavored Blend of 5 Juices' would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading."). In other words, while the court in *POM Wonderful* was able to find that the FDA had essentially blessed the name and label of the juice product at issue by promulgating regulations that plainly authorized the name and label, the current record before the Court demonstrates merely a general prohibition against the misbranding of medical devices as to their intended uses. *See POM Wonderful*, 679 F.3d at 1176-77. In general terms, the same is true with respect to the other cases that SPD relies on in which there was such an existing and actual conflict. *Compare Rita Med. Sys.*, 2006 U.S. Dist. LEXIS 52366, at *8-11 (precluding claims based on an alleged misrepresentation that one of defendants' medical devices was "compatible" for use with the plaintiff's device because in the course of the 510(k) process, defendants described the device at issue as designed for use with the relevant devices manufactured by plaintiffs and FDA cleared the defendants' device for marketing; explaining that the court would not "unduly convert[ ] the Lanham Act claim into a review of an FDA action"), *Cytyc Corp. v. Neuromedical Sys.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (holding that "representations by Cytyc that comport substantively with statements approved as accurate by the FDA cannot supply the basis for NSI's claims") (citations omitted), *and Am. Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144-46

(S.D.N.Y. 1987) (dismissing Lanham Act claim targeting product's assertion that it provided "safe" pain relief because "the FDA expressly found that there was a need for uniformity in RS warnings on the labels of aspirin-containing products and expressly preempted all conflicting regulations" and had specifically inspected and approved the packaging at issue),[5] *with PhotoMedex*, 601 F.3d at 924-25 ("If, for example, it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued . . . . "), *and In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 U.S. Dist. LEXIS 95500, at *70-71 (N.D. Cal. Aug. 16, 2006).

In this case, no such conflict is apparent from the current record. Specifically, viewed in the light most favorable to C&D, the Clearance Letter—standing alone—does not demonstrate that the FDA has reviewed the Weeks Estimator box and labeling actually sold by SPD and determined it will not mislead consumers as to the capabilities of the Weeks Estimator. First, the Clearance Letter's statement that it should not be viewed as a determination that the Weeks Estimator complies with other requirements of the FDCA or other federal law cautions against such a finding without the benefit of the materials explaining what, precisely, was before the FDA. In short, the Court simply cannot determine, at this stage, the precise nature of any conclusions the FDA may have made as to the Weeks Estimator. Second, as C&D pointed out at

[5] SPD argues that *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, No. 95 Civ. 7011 (HB), 1996 U.S. Dist. LEXIS 7257 (S.D.N.Y. May 24, 1996), also follows this logic. It does not: in that case the court did not hold that it could not consider the truth of the advertising at issue without intruding on the FDA's domain; rather, it held that the alleged misrepresentations were not facially false or misleading. *SmithKline Beecham*, 1996 U.S. Dist. LEXIS 7257, at *40-42. Specifically, the challenged advertisement was not false because it merely claimed that, when used according to the product label, PEPCID AC must be administered an hour before the onset of expected heartburn whereas the label for TAGAMET HB provided for administration a half-hour before the onset of expected heartburn. *Id.* at *21 n.10, *40-42. The court did, however, suggest it would not substitute its "discretion for that of the FDA in approving package labelling for over-the-counter medications" by second-guessing the accuracy of those labels. *Id.* at *21 n.10, *41.

oral argument, the Clearance Letter requires that many of the disclosures about the Weeks Estimator's uses be included on the package insert, rather than the box. MTD Hr'g Tr. 30:8-20. As a result, it may be that the box—even if approved by the FDA when taken in conjunction with the package insert—is misleading to the consumer at the time of purchase due to the unavailability of the package insert at that time.[6] Moreover, on a related point, although the potential for conflict between the FDA's views and a hypothetical judgment for C&D in this case exists, particularly given the Clearance Letter's directive that "[p]erformance of the Weeks Estimator should not be displayed on your box labeling," this statement is ambiguous. Read in context with the FDA's surrounding concerns that the Weeks Estimator "will be used for an intended use not identified in the proposed labeling," the FDA's directive not to display "[p]erformance of the Weeks Estimator" could mean many things, including a directive that SPD remove specific product claims it had made in the proposed labeling. Finally, even assuming that the Clearance Letter reflected the FDA's approval of *some* package design by SPD as not misleading, nothing in the Clearance Letter demonstrates that the FDA, in fact, approved the box and labeling that SPD *actually* placed on the market. The Clearance Letter does not describe or attach copies of the box or labeling that (according to SPD) the FDA approved, and the Court therefore has no basis at this stage to accept SPD's claim that the Clearance Letter reflects approval of the materials that SPD has actually marketed and sold.[7]

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[6] Here, the different purposes of the FDCA and Lanham Act are thrown into stark contrast: from the perspective of the FDA, so long as the consumer is adequately informed about the use of the Weeks Estimator post purchase and does not misunderstand its results, the FDA's safety concerns are addressed. But from the perspective of a competitor concerned about the consumer's purchasing decision, at that stage the harm that the Lanham Act seeks to prevent will already have been accomplished if the consumer was misled into purchasing the Weeks Estimator with a mistaken belief as to its function.

[7] The same fundamental point applies all the more strongly to SPD's other advertising or promotional materials, as there is nothing to suggest that the FDA had viewed, let alone approved, any such promotional materials. Instead, the Clearance Letter simply imposes the general requirement that SPD's promotional materials for the Weeks Estimator must include the indications for use statements drafted by the FDA. Compl. Ex. A at 3. Viewed in the light most favorable to C&D, the Court cannot view this portion of the Clearance Letter as preemptive approval by

In sum, and recognizing that this is a doctrine that does not lend itself to a simple application, the Court concludes that the materials before the Court do not, at this time, warrant preclusion of C&D's claims. The Court notes, however, that the questions raised by this doctrine are often fact-intensive, and are frequently resolved after the pleadings stage. *See, e.g.*, *PhotoMedex*, 601 F.3d at 928 (addressing appeal grant of summary judgment); *Merck Eprova AG v. Gnosis S.P.A.*, No. 07 Civ. 5898 (RJS), 2011 U.S. Dist. LEXIS 30683, at *18-21 (S.D.N.Y. Mar. 17, 2011); *Iams*, 2004 U.S. Dist. LEXIS 31136, at *15. As a result, it may be that SPD is able to re-raise this argument at a later stage, if appropriate given the development of the proceedings.

IV. Primary Jurisdiction

SPD also contends that C&D's claims are subject to dismissal under the doctrine of "primary jurisdiction." Primary jurisdiction is "concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties" and with "maintaining uniformity in the regulation of an area entrusted to a federal agency," particularly by allowing administrative agencies the first opportunity to address issues in their expertise. *Ellis v. Tribune TV Co.*, 443 F.3d 71, 81-82 (2d Cir. 2006) (internal citations omitted). In particular, courts look to whether the claim requires resolution of issues that have been placed within the special competence of an administrative agency and courts in the Second Circuit focus on four factors in making this inquiry:

> (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of

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the FDA of any advertisement for the Weeks Estimator—no matter how misleading that advertisement may be as to the product's capabilities—so long as it includes this indications for use statement. The Court cannot, at this time, find C&D's claims precluded due to a conflict with the FDA's position on such a thin basis.

inconsistent rulings; and (4) whether a prior application to the agency has been made.

Id. at 81-83. Courts are also required to balance the advantages of applying the doctrine against the potential costs that may arise from delay and complications in administrative proceedings. *Id.* at 83 (citations omitted).[8]

Based on the facts before the Court in assessing the motion to dismiss, the Court concludes that the doctrine of primary jurisdiction does not counsel in favor of dismissing this action. First, it bears mention that primary jurisdiction is a doctrine of deferral, not dismissal—courts do not invoke this doctrine to wholly refrain from hearing a claim but rather merely to provide an agency the *first* chance to weigh in if the claim implicates matters within the agency's special competence. *See United States v. Philip Morris USA Inc.*, 686 F.3d 832, 837 (D.C. Cir. 2012) (explaining that primary jurisdiction involves "suspend[ing] the judicial process pending referral . . . to the administrative body for its views") (internal citations omitted); *Ellis*, 443 F.3d at 81 (primary jurisdiction allocates "initial decisionmaking responsibility"); *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 60 (2d Cir. 2006) (primary jurisdiction allows courts to refer issues to an agency for "resolution in the first instance") (citations omitted); *Bernhardt v. Pfizer, Inc.*, Nos. 00 Civ. 4042 (LMM) et al, 2000 U.S. Dist. LEXIS 16963, at *5-6 (S.D.N.Y. Nov. 16, 2000) ("If a court finds that an administrative agency has primary jurisdiction over the claim, the court stays the matter and directs plaintiff to file a complaint with the agency.") (citations omitted); *In re Genentech, Inc.*, No. C-88-4038-DLJ, 1989 U.S. Dist. LEXIS 14819, at *2-4 (N.D. Cal. July 7, 1989).

It appears that the FDA has already provided its views as to the principal scientific

[8] This is a prudential doctrine, *see, e.g.*, *Imagenetix, Inc. v. Frutarom USA, Inc.*, No. 12CV2823-GPC(WMC), 2013 U.S. Dist. LEXIS 173193, at *9 (S.D. Cal. Dec. 9, 2013), but because it merely assigns to the agency the first opportunity to address an issue, the Court does not believe it implicates the same concerns as those raised in *Lexmark*.

question that this Court might refer to it: whether the Weeks Estimator can measure the duration of pregnancy based on the last menstrual cycle. The answer, according to the FDA, is no. Indeed, the materials before the Court suggest that the FDA has gone one step further and also provided its opinion on whether a measure of pregnancy based on date of ovulation is the standard most commonly applied by physicians. Again, the FDA's answer is no.

With this in mind, the Court's task is to assess the potential consumer confusion caused by the manner in which the Weeks Estimator has been marketed. Numerous courts have held that invoking the doctrine of primary jurisdiction is inappropriate in such contexts, as this task lies within the Court's core competence. *See, e.g.*, *Goldemberg v. Johnson & Johnson Consumer Cos.*, No. 13-cv-3073 (NSR), 2014 U.S. Dist. LEXIS 47180, at *16-17 (S.D.N.Y. Mar. 27, 2014); *In re Colgate-Palmolive Softsoap Antibacterial Hand Soap Mktg. & Sales Practices Litig.*, Nos. 12-md-2320-PB et al, 2013 U.S. Dist. LEXIS 37152, at *17 (D.N.H. Mar. 28, 2013); *Jovel v. I-Health, Inc.*, No. 12-CV-5614 (JG), 2013 U.S. Dist. LEXIS 139661, at *20-21 (E.D.N.Y. Sept. 27, 2013); *In re Frito-Lay N. Am., Inc.*, No. 12-MD-2413 (RRM)(RLM), 2013 U.S. Dist. LEXIS 123824, at *27 (E.D.N.Y. Aug. 29, 2013); *Karhu v. Vital Pharms., Inc.*, No. 13-60768-CIV-COHN/SELTZER, 2013 U.S. Dist. LEXIS 112613, at *11-12 (S.D. Fla. Aug. 9, 2013); *Ackerman v. Coca-Cola Co.*, No. CV-09-0395 (JG) (RML), 2010 U.S. Dist. LEXIS 73156, at *54 (E.D.N.Y. July 21, 2010). The Court has the agency's answer on the primary matter for which its technical expertise may be invoked, strongly suggesting primary jurisdiction is not applicable.

As to the second factor, based on the regulatory structure discussed above, it appears that the FDA has some discretion as to how SPD markets the Weeks Estimator as to its intended use, particularly as to the box and labeling. *Cf. Bernhardt*, 2000 U.S. Dist. LEXIS 16963, at *8-9

("The above review of the relevant regulatory scheme convinces this Court that whether the notice requested by plaintiffs is warranted is a decision that has been squarely placed within the FDA's informed expert discretion [to address labeling of drugs as part of the drug approval process]."). Again, however, based on the materials presently before the Court, it appears that the FDA has completed the 510(k) process as to the box and labeling, issuing the Clearance Letter imposing the limitations it believes are necessary.[9] As a result, the Court concludes that this factor does not favor applying the doctrine of primary jurisdiction.

The same holds true for the third factor, the danger of inconsistent rulings. The Clearance Letter ameliorates much of the danger that the Court might rule inconsistently with the FDA's requirements. Although, as the Court has suggested, this letter is not wholly unambiguous when viewed in the context of the limited materials before the Court on the motion to dismiss, it provides the Court with guidance as to the FDA's position on the proper packaging and labeling of the Weeks Estimator. This factor also does not favor applying the doctrine of primary jurisdiction. *Goldemberg*, 2014 U.S. Dist. LEXIS 47180, at *20 (no danger of inconsistent rulings because agency was not simultaneously contemplating the same issue).

As to the fourth factor, C&D has made an informal application to the FDA requesting that it review SPD's compliance with the Clearance Letter as to the product packaging, labeling, and certain other promotional materials. *See Ellis*, 443 F.3d at 89 (noting that a prior application to the agency will usually support applying the doctrine of primary jurisdiction). The FDA has responded that it will review C&D's request to determine the best course of action, but does not indicate that it intends to take action or provide a timeline for any such response. As a result, the

[9] Although, as the Court explained in discussing FDCA conflict preclusion, the materials before the Court at this stage are limited on this point and render the Clearance Letter somewhat ambiguous, this does not change the fact that, based on the materials properly considered at this point, it appears that the FDA has made its determination on this point.

Court has little information as to what delay might be attendant to waiting for the FDA to respond to C&D's request.

Weighing these considerations, the Court concludes that the doctrine of primary jurisdiction does not favor deferral to the FDA at this time. The Court notes, however, that the litigation is in an early stage and its determination on this matter is based merely on the allegations of the Complaint and associated materials. As a result, the Court's determination on this point should not be viewed as precluding SPD from raising this argument at a later stage.

V. State Law Claims

SPD argues that C&D's state law claims should be dismissed on the same rationale as the dismissal of the Lanham Act claims.[10] MTD at 19. C&D does not argue that its state law claims are not subject to dismissal on the same basis as the Lanham Act claims, but merely contends that its Lanham Act claims are not subject to dismissal. MTD Opp. at 10 n.8. Thus, to the extent that the Lanham Act claims are dismissed, it appears C&D has not argued a basis for maintaining its parallel state law claims.

VI. The Preliminary Injunction

Pursuant to the Court's discussions with the parties following the initial pretrial conference in this matter, the Court indicated that it intended to address the issues discussed above in the context of both SPD's motion to dismiss and C&D's preliminary injunction request. Based on oral argument, a number of factors have convinced the Court that the proper course, for now, is to decide these issues only in the context of the motion to dismiss, and turn to them again at the consolidated trial on the merits.

First, given the absence of controlling precedent, or even substantial guidance, on the

[10] SPD also argues the Court should not exercise supplemental jurisdiction over these claims, but as C&D points out, even absent the Lanham Act claims there appears to be diversity jurisdiction in this matter. Moreover, because C&D's Lanham Act claims survive the motion to dismiss, federal question jurisdiction also remains.

issue of FDCA preclusion in the Second Circuit, the Court concludes it would be prudent to await the Supreme Court's decision in *POM Wonderful* before attempting to make a further determination on this doctrine. Having reviewed that case and considered the parties positions at oral argument, the Court views it as likely that any decision in *POM Wonderful* will inform the Court's analysis and may set forth a controlling rule to be applied in this case. Second, at oral argument C&D stated its position that, in fact, there is no preliminary injunction pending in this matter due to consolidation of this motion with the expedited schedule for addressing the merits. MTD H'rg Tr. 4:13-16, 45:1-4. In light of this representation, the Court sees little utility in deciding a component of a motion that the movant now believes is no longer in effect. Finally, in a similar vein, when the Court inquired into whether it should reserve decision on the pending motions until after the Supreme Court issues its decision in *POM Wonderful*, although SPD requested an immediate decision on the motion to dismiss, C&D suggested that the Court should wait for that decision. MTD H'rg Tr. 44:11-15, 45:7-9. As a result of these developments at oral argument, the Court has reconsidered its approach and determined that the efficient course for this matter is to resolve, at this time, only the motion to dismiss.

VII. Conclusion

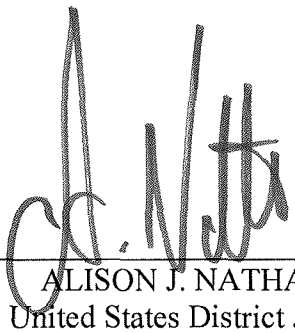
SPD's motion to dismiss is DENIED. C&D's motion for a preliminary injunction is moot by virtue of the consolidation of that motion with a trial on the merits in this case. This resolves docket numbers 19, 58, and 73.

Despite their submission of a letter on May 8, 2014, stating that they would provide proposed trial dates to the Court, the parties have not yet submitted any concrete proposed trial dates to the Court. The parties are directed to submit a letter no later than one week following the date of this order proposing mutually agreeable trial dates, as well as a proposed schedule for

the completion of discovery in this matter. If the parties fail to do so by that date, the Court will set a schedule without the parties' input and will expect the parties to conform their schedules to that set by the Court.

SO ORDERED.

Dated: June 3, 2014
New York, New York



ALISON J. NATHAN
United States District Judge