UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALLIANCE FOR NATURAL HEALTH US, *et al.*, Plaintiffs, v. KATHLEEN SEBELIUS, *et al.*, Defendants.	Civil Action No. 09-1523 (BAH)

MEMORANDUM OPINION

Dietary supplement producers and industry groups brought this lawsuit challenging several regulations adopted by the Food and Drug Administration ("FDA") to establish current good manufacturing practices for dietary supplements. The plaintiffs argue that the challenged regulations violate the Food, Drug, and Cosmetic Act ("FDCA") and the Administrative Procedure Act ("APA") because they exceed the regulatory authority that Congress granted to the FDA under the FDCA. The plaintiffs also argue that the challenged regulations violate the Due Process Clause of the Fifth Amendment to the U.S. Constitution because they are impermissibly vague, and that, for the same reason, they also constitute arbitrary and capricious agency action in violation of the APA. The plaintiffs ask the Court to reverse the regulations and remand to the FDA for further rulemaking. For the reasons explained below, the Court must deny the plaintiffs' motion and grant judgment for the FDA.

I. Background

Under the FDCA, 21 U.S.C. § 301 *et seq.*, a "dietary supplement" is a "product . . . intended to supplement the diet" that contains, *inter alia*, "a vitamin, a mineral, an herb or other botanical, an amino acid, or a dietary substance for use by man to supplement the diet by

increasing the total dietary intake." 21 U.S.C. § 321(ff). A dietary supplement also "is not represented for use as a conventional food or as a sole item of a meal or the diet" and is "labeled as a dietary supplement." *Id.*

In 1994, Congress passed the Dietary Supplement Health and Education Act ("DSHEA"), which amended the FDCA to add several specific provisions regarding the regulation of dietary supplements, including the definition cited above. Pub. L. No. 103-417, 108 Stat. 4325. Prior to that time, the FDA had attempted to regulate dietary supplements under its authority to regulate food additives. *See United States v. 29 Cartons of . . . an Article of Food*, 987 F.2d 33, 35-36 (1st Cir. 1993). Since DSHEA's enactment, dietary supplements have remained generally regulated as a subset of foods, rather than drugs, but several statutory provisions now govern the regulation of dietary supplements specifically. *See, e.g.*, 21 U.S.C. § 321(ff); 342(f)-(g).

As relevant here, DSHEA defined certain circumstances in which dietary supplements "shall be deemed to be adulterated" under the FDCA, including when a dietary supplement "has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations." 21 U.S.C. § 342(g). The law delegated authority to the FDA "to prescribe good manufacturing practices for dietary supplements." *Id.* The FDA had previously prescribed good manufacturing practices ("GMP" or "CGMP") for foods, drugs, and devices, so the GMP concept was a familiar one in the sphere of FDA regulation. *See*, *e.g.*, 21 C.F.R., Pt. 110 (food); Pt. 211 (drugs). DSHEA's delegation of authority to prescribe dietary supplement GMPs led to a decade-long process of administrative rulemaking that culminated in the regulations challenged in this action.

On February 6, 1997, the FDA published an Advance Notice of Proposed Rulemaking for dietary supplement GMPs. *See* Current Good Manufacturing Practice in Manufacturing,

Packing, or Holding Dietary Supplements, 62 Fed. Reg. 5700 (Feb. 6, 1997). The FDA solicited public input on whether it should adopt dietary supplement GMPs and, if so, what the regulations should include. *Id.* at 5707-08. The FDA received more than 100 comments in response. *See* Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, Proposed Rule, 68 Fed. Reg. 12158, 12159 (Mar. 13, 2003).

After considering the comments received in response to the Advance Notice of Proposed Rulemaking and conducting outreach efforts, including holding five public meetings and touring supplement manufacturing facilities to observe existing practices, the FDA drafted and issued a Proposed Rule in March 2003 suggesting GMPs for dietary supplements. *Id.* at 12158-61. Following announcement of the Proposed Rule, the FDA conducted three further public meetings and other outreach activities and received approximately 400 comments on the Proposed Rule. *See* Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, Final Rule, 72 Fed. Reg. 34752, 34756 (June 25, 2007).

The FDA issued the Final Rule establishing current good manufacturing practices for dietary supplements on June 25, 2007 ("GMP Final Rule"). *Id.* The GMP Final Rule establishes the requirements for activities related to dietary supplement manufacturing and includes sections related to personnel, physical plant and grounds, equipment and utensils, production process and control systems, holding and distributing, returned dietary supplements, product complaints, and records and recordkeeping. *See* 21 C.F.R., Pt. 111.

The FDA staggered the compliance date for the Final Rule based on company size. The compliance date was June 25, 2008 for large businesses; June 25, 2009 for businesses that

employ fewer than 500, but 20 or more full-time equivalent employees; June 25, 2010 for businesses that employ fewer than 20 full-time equivalent employees. 72 Fed. Reg. 34752.

Four plaintiffs brought this action challenging various regulations contained in the GMP Final Rule. Plaintiffs Duke Pearson and Sandy Shaw are scientists who formulate dietary supplements and license their formulations to dietary supplement manufacturers and retailers in exchange for royalties. *See* Declaration of Durk Pearson dated August 9, 2010 (hereinafter "Pearson Decl."); Declaration of Sandy Shaw dated August 9, 2010 (hereinafter "Shaw Decl."). The other two plaintiffs are organizations that claim an affiliation with dietary supplement industry participants – the Alliance for Natural Health USA and the Coalition to End FDA and FTC Censorship. The plaintiffs seek a declaration invalidating various provisions of the GMP Final Rule and enjoining their enforcement.

The defendants are Kathleen Sebelius, in her official capacity as Secretary of the United States Department of Health and Human Services, the United States Department of Health and Human Services, Margaret A. Hamburg, M.D., in her official capacity as Commissioner of the United States Food and Drug Administration, the Food and Drug Administration, and the United States of America (collectively, the "FDA" or the "defendants").

The plaintiffs brought this action on August 12, 2009. ECF No. 3. The FDA filed the administrative record ("A.R."), which is extremely voluminous, on April 1, 2010. ECF No. 16. On April 28, 2010, the plaintiffs moved for summary judgment on their claims. ECF No. 17. The FDA cross-moved for summary judgment on July 9, 2010. ECF No. 19.

The parties' cross-motions for summary judgment are now before the Court.

II. Standards of Review

A. Summary Judgment

Pursuant to Federal Rule of Civil Procedure 56, the Court will grant a motion for summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law" based upon the pleadings, depositions, and affidavits and other materials in the record. Fed. R. Civ. P. 56(a), (c); *Tao v. Freeh*, 27 F.3d 635, 638 (D.C. Cir. 1994). The Court must view all inferences in a light most favorable to the non-moving party. *Tao*, 27 F.3d at 638 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 255 (1986)). To the extent that the plaintiffs raise constitutional claims, this standard of review applies.

B. Administrative Procedure Act

For claims involving review of a final agency action under the Administrative Procedure Act, the standard set forth in Rule 56(c) does not apply because of the limited role of a court in reviewing the administrative record. *See* 5 U.S.C. § 706; *Cottage Health Sys. v. Sebelius*, 631 F. Supp. 2d 80, 89 (D.D.C. 2009); *see also* Local Civil Rule 7(h)(2) (in cases "in which judicial review is based solely on the administrative record," the parties are not required to submit statements of disputed or undisputed material facts). Summary judgment in the APA review context serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review. *Cottage Health Sys.*, 631 F. Supp. 2d at 90.

Under the APA, the Court is to set aside an agency action that is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2). "'The party challenging an agency's action as arbitrary and capricious bears the burden of proof.'" *City of Olmsted Falls, Ohio v. F.A.A.*, 292 F.3d 261, 271 (D.C. Cir. 2002) (quoting *Lomak Petroleum, Inc. v. FERC*, 206 F.3d 1193, 1198 (D.C. Cir. 2000)). While the "scope of

review under the 'arbitrary and capricious' standard is narrow," the agency must "articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of United States v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)); *see also CSI Aviation Servs., Inc. v. DOT*, No. 09-1307, 2011 WL 1229756, at *5 (D.C. Cir. Apr. 1, 2011) ("The agency must not only adopt a permissible reading of the authorizing statute, but must also avoid acting arbitrarily or capriciously in implementing its interpretation. . . . Among other things, this requires the agency to 'take whatever steps it needs to provide an explanation that will enable the court to evaluate the agency's rationale at the time of decision.'") (quoting *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 654 (1990)).

Under the APA, the Court also must set aside an agency action that is found to be in excess of the agency's statutory jurisdiction, authority, or limitations. 5 U.S.C. § 706(2)(C). To determine whether an agency has exceeded its statutory authority under the APA, the Court turns to the two-step process of analysis set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *See Colorado Wild Horse and Burro Coal., Inc. v. Salazar*, 639 F. Supp. 2d 87, 91 (D.D.C. 2009). First, the reviewing court must ask "whether Congress has directly spoken to the precise question at issue." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000) (quoting *Chevron*, 467 U.S. at 842). If so, the inquiry is at an end; the court "must give effect to the unambiguously expressed intent of Congress." *Id.* (quoting *Chevron*, 467 U.S. at 843). "But if Congress has not specifically addressed the question, a reviewing court must respect the agency's construction of the statute so long as it is permissible." *Id*; *see also Bhd. of R.R. Signalmen v. Surface Transp. Bd.*, No. 10-1138, 2011 WL 1120284, at *2 (D.C. Cir. Mar. 29, 2011).

III. Discussion

A. Standing

As a threshold question, the Court must address whether the plaintiffs have standing to bring this action. Under Article III of the Constitution, federal courts only have jurisdiction to resolve cases and controversies. *Fund Democracy LLC v. SEC*, 278 F.3d 21, 25 (D.C. Cir. 2002). "Therefore, in order to bring an action within our jurisdiction, the party must demonstrate that it has standing to bring that action." *Id.* (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). To satisfy this standing requirement, a plaintiff must "demonstrate that it has suffered a concrete and particularized injury that is: (1) actual or imminent, (2) caused by or fairly traceable to an act that the litigant challenges in the instant litigation, and (3) redressable by the court." *Id.* (quoting *Florida Audubon Soc'y v. Bentsen*, 94 F.3d 658, 663 (D.C. Cir. 1996) (en banc)); *see also Commuter Rail Div. of Reg'l Transp. Auth. v. Surface Transp. Bd.*, 608 F.3d 24, 30 (D.C. Cir. 2010) ("The irreducible constitutional minimum of standing contains three elements: (1) injury-in-fact, (2) causation, and (3) redressability.") (internal quotation marks omitted). At the summary judgment stage, a plaintiff asserting standing can no longer rest on "mere allegations," but "must set forth by affidavit or other evidence specific facts which for purposes of the summary judgment motion will be taken to be true." *Lujan*, 504 U.S. at 561 (internal quotation marks omitted).

The Court will begin by analyzing whether the individual plaintiffs, Durk Pearson and Sandy Shaw, have met their burden to establish standing. As explained below, the Court concludes that Pearson and Shaw do have standing in this action.

The regulations challenged in this action do not directly apply to Plaintiffs Pearson and Shaw, who are scientists that formulate dietary supplements and license their formulations to

manufacturers and retailers in exchange for royalties. *See* Pearson Decl.; Shaw Decl. Rather, the GMP regulations apply to third parties – the supplement manufacturers and retailers who are the individual plaintiffs' licensees. "[W]hen the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish." *Summers v. Earth Island Institute*, 129 S. Ct. 1142, 1149 (2009) (citing *Lujan*, 504 U.S. at 562). Even so, plaintiffs Pearson and Shaw have established standing here because this case is one "where the record present[s] substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress." *Nat'l Wrestling Coaches Ass'n v. Dept. of Educ*., 366 F.3d 930, 941 (D.C. Cir. 2004).

Pearson and Shaw submitted sworn declarations from themselves and from the CEO of one of their licensees, Life Enhancement Products, Inc. ("LEP"), to establish facts supporting their standing. Pearson and Shaw assert that they have been harmed by the GMP regulations because the increased compliance costs imposed by the GMP regulations have led their licensees to carry fewer of their products and have reduced their licensees' ability to pay royalty payments owed to them. Pearson and Shaw have licensing agreements with LEP for 60 supplement formulae. Pearson Decl.; Shaw Decl. LEP is a manufacturer, labeler, and retailer of dietary supplements and is regulated by the GMP regulations. Declaration of Will Block dated August 9, 2010 (hereinafter "Block Decl.") ¶¶ 2-3. LEP committed $112,166.56 to GMP compliance costs through the end of the 2010 fiscal year. Block Decl. ¶ 8. These expenses included salaries and benefits for compliance managers ($65,000), costs to construct upgrades in facilities (approx. $2,500), costs for testing procedures (approx. $8,000), costs for weekly quality meetings ($10,400), compensatory overtime ($6,000), label alterations ($4,000), and internal

auditing ($5,000). *Id.* As of August 9, 2010, LEP owed Pearson and Shaw $67,752.62 in unpaid royalties, a debt that LEP asserts began to accrue in March 2009, after the company began implementing changes to comply with the GMP rules. *Id.* ¶ 6; *see also* Pearson Decl.; Shaw Decl. According to LEP, "[b]ut for the additional costs for cGMP compliance, [LEP] would have funds to pay Durk Pearson and Sandy Shaw their royalties under our licensing agreement," and "[u]ntil [LEP] began implementing business changes to comply with the FDA cGMPs, it had paid Durk Pearson and Sandy Shaw their royalties in full." Block Decl. ¶¶ 11-12. The FDA has not disputed these assertions of fact.

The Court concludes that these facts constitute substantial evidence of a causal relationship between the GMP regulations and a reduction in the individual plaintiffs' licensees' ability to pay royalties. The injury to Plaintiffs Pearson and Shaw is also redressable because an injunction of the GMP regulations would likely reverse the cause of the injury. Plaintiffs Pearson and Shaw have thus satisfied their burden to demonstrate standing by showing a concrete and particularized injury that is (1) actual, (2) caused by or fairly traceable to the GMP regulations, and (3) redressable. *See Block v. Meese*, 793 F.2d 1303, 1308 (D.C. Cir. 1986) (film distributor had standing to challenge government classification of films as "political propaganda" because the classification would reduce his company's profits and the distributor had presented declarations from potential customers who declined to purchase the film based on the classification); *Tozzi v. U.S. Dept. of Health and Human Servs.*, 271 F.3d 301, 309 (D.C. Cir. 2001) (manufacturer had standing to challenge the government's classification of dioxin as a carcinogen because there was "little doubt" the classification would affect demand for the manufacturer's products).

Because Pearson and Shaw have standing, the Court need not address the independent standing of the organizational co-plaintiffs who assert the same claims as Pearson and Shaw. *See, e.g.*, *Tozzi*, 271 F.3d at 310 (declining to address Article III standing of remaining plaintiffs after finding a plaintiff with standing); *Clinton v. City of New York*, 524 U.S. 417, 431 n.19 (1998) (same).

Therefore, the Court now turns to the merits of the plaintiffs' challenge.

B. Plaintiffs' Challenge to the FDA Regulations

Plaintiffs object to the GMP regulations for two main reasons. First, plaintiffs claim that various GMPs exceed the FDA's statutory authority to regulate dietary supplement production. Second, plaintiffs assert that various GMPs are unconstitutionally vague because they contain imprecise qualifier terms like "adequate," "suitable," and "qualified." For instance, plaintiffs object to GMPs requiring manufacturers to maintain "adequate" bathrooms and plumbing and to hire "qualified" employees. Plaintiffs assert that the purported vagueness of the GMPs also constitutes arbitrary and capricious agency action in violation of the APA. The Court will address these arguments in turn.

1. Plaintiffs' Challenge to the FDA's Statutory Authority to Regulate Dietary Supplement Manufacturing

Plaintiffs argue that the FDCA does not authorize the FDA to issue many of the dietary supplement GMP regulations that the agency has adopted because of a statutory limitation prohibiting the FDA from issuing dietary supplement GMPs that impose "standards for which there is no current and generally available analytical methodology." Pls.' Mem. in Supp. of Mot. for Summ. J. ("Pls.' Mem.") at 5 (citing 21 U.S.C. § 342(g)(2)). The FDA contends that the plaintiffs' interpretation of this statutory limitation is flawed and that the FDA has not violated the statute. Mem. in Supp. of Defs.' Cross-Mot. for Summ. J. and in Opp'n to Pls.'

Mot. for Summ. J. ("Defs.' Mem.") at 21-26. For the reasons discussed below, the Court agrees with the FDA's position.

a. The Relevant Provisions of the FDCA

As noted above, in 1994, Congress enacted DSHEA, which amended the FDCA to add provisions specific to dietary supplements. Pub. L. No. 103-417, 108 Stat. 4325. Among them is Section 402(g), which provides that a dietary supplement "shall be deemed to be adulterated" under the following conditions:

> (g) Dietary supplement: manufacturing practices
>
> (1) If . . . it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations. . . issued by the Secretary under subparagraph (2).
>
> (2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment . . . .

21 U.S.C. § 342(g). Thus, Congress directed that dietary supplements that are "prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations" are "deemed to be adulterated," and Congress authorized the FDA to issue regulations that "prescribe good manufacturing practices for dietary supplements." *Id.* Congress then specified that those regulations "shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology." *Id.*

The dispute between the parties here turns on the interpretation of the second half of the second sentence in Section 402(g)(2): "Such regulations . . . may not impose standards for which

there is no current and generally available analytical methodology." 21 U.S.C. 342(g)(2). To paraphrase the dispute, the plaintiffs read this clause to mean that the FDA is *only* permitted to issue GMP regulations that are based on analytical methodologies and that these methodologies must also be current and generally available. *See* Pls.' Mem. at 11-12. By contrast, the FDA reads the clause to mean that *if and when* the FDA issues a regulation that incorporates a standard based on an analytical methodology, then that analytical methodology must be one that is current and generally available. *See* Defs.' Mem. at 25. Accordingly, the FDA believes that it may issue GMP regulations that are not based on analytical methodologies at all, while the plaintiffs disagree.

The term "analytical methodology" is not defined, but Congress has used the term "analytical method" in several other provisions in the FDCA, each time regarding testing to confirm the presence, absence, or quantity of a substance.[1] Since different sections of the same statute are ordinarily construed *in pari materia*, the Court concludes that the term "analytical methodology," as used in Section 402(g), means a method or process for analyzing or measuring a substance. *See Motion Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 802 (D.C. Cir. 2002) (citing *Erlenbaugh v. United States*, 409 U.S. 239, 244 (1972) (acknowledging "the principle that

[1] *See* 21 U.S.C. § 343(w)(6) (regarding petitions to exempt food from allergen labeling requirements, the "burden shall be on the petitioner to provide scientific evidence (including the *analytical method* used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health") (emphasis added); § 346a(d)(2)(A)(v) (a petition to establish, modify, or revoke a pesticide tolerance must include, *inter alia*, "full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the *analytical methods* used") (emphasis added); § 360b(a)(4)(B) ("If the Secretary finds that there is a reasonable probability that a use of an animal drug authorized under subparagraph (A) may present a risk to the public health, the Secretary may— (i) establish a safe level for a residue of an animal drug when it is used for such different use authorized by subparagraph (A); and (ii) require the development of a practical, *analytical method* for the detection of residues of such drug above the safe level established under clause (i).) (emphasis added).

individual sections of a single statute should be construed together.")). Thus, "analytical methodologies" are largely inapposite to regulations concerning matters like recordkeeping, the establishment of written procedures, the maintenance of facilities, and other general aspects of the manufacturing process addressed by the GMP Final Rule.

b. Plaintiffs' Claims

Based on their reading of Section 402(g), the plaintiffs argue that the FDA's GMP Final Rule overstepped the agency's authority by imposing various procedural, recordkeeping, and quality control requirements that are not based on any "analytical methodology."[2] For example, 21 C.F.R. § 111.25, which the plaintiffs object to, requires a manufacturer to "establish and follow written procedures" for, *inter alia*, "[c]alibrating instruments and controls [used] in manufacturing or testing a component or dietary supplement… [and] [m]aintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements." Other examples of provisions to which the plaintiffs object require recordkeeping of product complaints (§ 111.570), the routine inspection of mechanical equipment (§ 111.30(c)), and various quality control requirements (§§ 111.103-111.140). Pls.' Mem at 12-16. The plaintiffs contend that such regulations exceed the FDA's authority by imposing "standards" that are not linked "to proof of deviation from a current and generally available analytical methodology governing product production." Pls.' Opp'n to Defs.' Cross-Mot. for Summ. J. and Pls.' Reply to Defs.' Opp'n to Pls.' Mot. for Summ. J. ("Pls.' Reply") at 11-15.

[2] Specifically, the plaintiffs ask the Court to invalidate the following provisions: 21 C.F.R. §§ 111.8, 111.14; 111.16; 111.23; 111.25; 111.35; 111.8; 111.95; 111.103; 111.140; 111.153; 111.180; 111.205; 111.210; 111.255; 111.260; 111.303; 111.325; 111.353; 111.375; 111.403; 111.430 111.453; 111.475; 111.503; 111.535; 111.553; 111.570; 111.605-111.610; 111.12(a); 111.30(c), (d), (e); 111.60(b); 111.70(c)(3); 111.75(a),(c)(4), (d)(2); 111.160(c)(2)-(3); 111.165(c)(2)-(3); 111.260(l); and 111.315.

The FDA responds that the plaintiffs' reading of Section 402(g) is flawed and that the FDA has not violated Section 402(g) because it has not imposed any standards for which there is no current and generally available analytical methodology. Defs.' Mem. at 23-26. According to the FDA, the statutory language instructing that the GMP "regulations . . . may not impose standards for which there is no current and generally available analytical methodology," 21 U.S.C. § 342(g), means that "if and when [the] FDA imposes a standard that requires use of an analytical methodology, it must be one where the methodology is both current and generally available." Defs.' Mem. at 25. "So, for example, [the] FDA could not insist that manufacturers perform a test to confirm the absence of a particular contaminant if there is no current and generally available analytical methodology for detecting the presence of that contaminant." *Id.* According to the FDA, Congress did not mean that the FDA could *only* prescribe GMP regulations that are based on a "current and generally available analytical methodology," as the plaintiffs contend. *Id.* at 25-26. Indeed, such a limitation would render the GMP regulations "unable to address such basic requirements as employee qualifications, manufacturing facilities, sanitation requirements, and production and process controls, just to name a few." *Id.* at 24. According to the FDA, such a limitation would also contradict Section 402(g)'s explicit instruction that the GMP regulations be "modeled after current good manufacturing practice regulations for food," since "the vast majority of the food CGMP regulations are general requirements that do not impose a requirement to use any particular analytical methodology." *Id.* at 23-24.

c. Administrative Waiver

Before addressing the parties' conflicting interpretations of Section 402(g), the Court must consider the threshold question of administrative waiver. The FDA argues that the

plaintiffs waived their ability to argue that "[S]ection 402(g) should be construed to limit to the CGMP regulations to those based on current and generally available analytical methodologies" because they did not raise that argument during the rulemaking period, although they did submit comments to the proposed rule and joined in comments submitted by others. *See* Defs.' Mem. at 22-23; Defs.' Reply to Pls.' Opp'n to Defs.' Cross-Mot. for Summ. J. ("Defs.' Reply") at 10-12.

The D.C. Circuit has previously held that parties waive their right to raise issues in challenging an agency rule by failing to raise the issues during the notice-and-comment rulemaking period. *See Advocates for Highway and Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1148-50 (D.C. Cir. 2005); *see also Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297 (D.C. Cir. 2004) (per curiam) ("It is a hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review. . . .The rule applies with no less force to a statutory interpretation claim not brought to an agency's attention: '[R]espect for agencies' proper role in the *Chevron* framework requires that the court be particularly careful to ensure that challenges to an agency's interpretation of its governing statute are first raised in the administrative forum.'") (quoting *Natural Res. Def. Council v. EPA*, 25 F.3d 1063, 1074 (D.C. Cir. 1994)).

The plaintiffs assert that the "need for FDA's reliance on current and generally available analytical methodologies was indeed raised during the comment stage." Pls.' Reply at 20 (citing 72 Fed. Reg. 34805, 34852, 34854.) As the FDA points out, however, the comments cited by the plaintiffs do not appear to advance the plaintiffs' current interpretation of Section 402(g), which is that adulteration under Section 402(g) must be based on a showing that the "manufacturing practice contravenes a current and generally available analytical methodology." Defs.' Reply at 10 (citing Pls.' Reply at 12). Rather, the comments cited by plaintiffs primarily appear to

address how to define a "current and generally available analytical methodology" in the context of regulations requiring testing of a product for purity, composition, and other measurable indicators of the product's content. *See*, e.g., Pls.' Reply at 20 (citing 72 Fed. Reg. 34852, Comment 191 and Response) (addressing scientific methods for testing); *id.* (citing 72 Fed. Reg. 34805, Comment 59 and Response) (addressing appropriate level of precision in defining the terms "'test,' 'scientifically valid analytical method,' or 'scientifically valid method,'" but not suggesting all GMP regulations must incorporate such methods). The comment that is most helpful to the plaintiffs' waiver argument is this one:

> (Comment 194) One comment states the act prohibits us from imposing testing requirements for which scientifically valid methods are not generally available, and other comments believe that not all components have scientifically valid identification tests. Given the substantial ongoing efforts towards method development, the comments believe that the proposed requirements for testing would impose standards on many products and ingredients that cannot be met through current and generally available methods.
>
> (Response) We disagree that the statute prohibits us from imposing testing requirements. Section 402(g)(2) of the act states that dietary supplement CGMP regulations "may not impose standards for which there is no current and generally available analytical methodology." We are not imposing such standards. The manufacturer must establish specifications for its product and components, and we have provided flexibility for how the manufacturer can determine whether those specifications are met. The manufacturer can test, examine, rely on a certificate of analysis (other than to verify the identity of dietary ingredients), or, in the case of a specification that is exempted from periodic testing of a finished batch, rely on other information that ensures that such an exempted product specification is met.

72 Fed. Reg. 34853-54. The issue raised in this comment, however, is considerably narrower than the one raised by the plaintiffs. Here, the comment and the response appear to presume that Section 402(g)(2)'s limitation regarding analytical methodologies is directed to regulations involving the testing and analysis of substances. The comment does not address the plaintiffs' current, much broader contention that the FDA may not prescribe any GMP regulations – like

recordkeeping and maintenance requirements – that are not based on an "analytical methodology."

Plaintiffs Pearson and Shaw submitted comments both to the Advanced Notice of Proposed Rulemaking, 62 Fed. Reg. 5700 (Feb. 6, 1997), and to the Proposed Rule, 68 Fed. Reg. 12158 (Mar. 13, 2003), in which they objected to numerous aspects of the proposed regulations, but did not advance their current interpretation of the statute. *See* A.R. 336-359, 894-900, 8570-8844, 8964-8986. In those comments, the plaintiffs discussed analytical procedures, but did not argue that all GMP regulations must be rooted in an analytical methodology. *See*, *e.g.*, A.R. 899-900 (supplemental comments by, among others, Durk Pearson and Sandy Shaw) ("The proposed CGMPs would require extensive testing to determine the purity of herbs and botanicals. That requirement is illogical in light of the fact that laboratories lack the analytical procedures to establish the purity of many of the herbs and botanicals that are used as dietary ingredients. In cases where there are analytical procedures available, the techniques that must be used are so expensive that small companies would not be able to afford the testing as often as is required in the proposed CGMPs."); *see also* A.R. 8578-8579 (comments of Durk Pearson and Sandy Shaw addressing Section 402(g)).

Plaintiffs now ask the Court to invalidate more than 40 sections of the Final GMP Rule, which was the outcome of a lengthy agency rulemaking process that spanned a decade from the Advance Notice of Proposed Rulemaking in 1997 to the adoption of the Final Rule in 2007. *See* 62 Fed Reg. 5700; 72 Fed. Reg. 34752. There was extensive public participation in the rulemaking process, including participation by Plaintiffs Pearson and Shaw as well as other industry participants.

Under these facts, the Court concludes that the plaintiffs are precluded from contesting the FDA's regulatory authority by arguing that the FDCA only permits the agency to issue dietary supplement GMPs that are specifically linked to an analytical methodology because that argument was not advanced during the rulemaking process.[3] *See Advocates for Highway and Auto Safety*, 429 F. at 1148-50; *Nuclear Energy Inst., Inc*, 373 F.3d at 1297; *see also Military Toxics Project v. EPA*, 146 F.3d 948, 956-57 (D.C. Cir. 1998).

d. *Chevron* Analysis

Even if waiver did not preclude the plaintiffs' challenge to the FDA's statutory authority, the outcome would be the same because the FDA's interpretation of Section 402(g) reflects the statute's clear meaning. As noted above, the Court will apply the two-step analysis set forth in *Chevron* in reviewing the FDA's interpretation of its authority under the FDCA.

i. *Chevron* Step One

At the first step of the *Chevron* analysis, the Court must "exhaust the 'traditional tools of statutory construction' to determine whether Congress has spoken to the precise question at issue." *Natural Res. Def. Council, Inc. v. Browner*, 57 F.3d 1122, 1125 (D.C. Cir. 1995) (quoting *Chevron*, 467 U.S. at 843 n.9). Traditional tools of statutory interpretation include analysis of the statutory text, legislative history, and structure. *See S. Cal. Edison Co. v. FERC*, 116 F.3d 507, 515 (D.C. Cir. 1997).

Plaintiffs' argument that the statute bars the FDA from imposing any GMP regulation that is not based on a current and generally available analytical methodology relies on reading the second half of the second sentence in Section 402(g)(2) in isolation: "Such regulations. . . may not impose standards for which there is no current and generally available analytical

[3] To the extent that plaintiffs argue that some of their challenges to specific GMPs are properly premised on the cited objections reflected in the Administrative Record and discussed above, these challenges are nonetheless disposed of by the Court's explanation of the appropriate interpretation of Section 402(g) below.

methodology." *See, e.g.*, Pls.' Mem. at 1, 11, 14-16. Yet courts consider statutory language within the context of the statute as a whole. *See United States v. Morton*, 467 U.S. 822, 828 (1984) ("We do not . . . construe statutory phrases in isolation; we read statutes as a whole.").

Reading the statute as a whole, the Court concludes that the plain reading of Section 402(g) comports with the FDA's interpretation. The first sentence of Section 402(g)(2) states that: "The Secretary may by regulation prescribe good manufacturing practices for dietary supplements." 21 U.S.C. § 342(g). The statute then continues by stating that "[s]uch regulations shall be modeled after current good manufacturing practice regulations for food. . ." *Id.* When Congress chose to use the phrases "good manufacturing practices" and "current good manufacturing practice" in delegating authority to the FDA, it was necessarily aware of the prior application of theses phrases in the FDCA and its corresponding regulations. *FAIC Sec., Inc. v. United States*, 768 F.2d 352, 363 (D.C. Cir. 1985) (recognizing principle that "whenever Congress passes a new statute, it acts aware of all previous statutes on the same subject") (quoting *Erlenbaugh v. United States*, 409 U.S. 239, 244 (1972)). Both the drug GMPs and the food GMPs, upon which the dietary supplement GMPs are to be modeled, contain the type of requirements that the plaintiffs argue Congress has foreclosed in Section 402(g). Indeed, the vast majority of food GMPs consist of general requirements that do not specify the use of particular analytical methodologies.[4] The FDA argues convincingly that, if the plaintiffs were correct that

[4] *See, e.g.*, 21 C.F.R. § 106.100 (requiring recordkeeping for infant formula); § 110.20(b) ("Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes"); § 110.37(d) ("Each plant shall provide its employees with adequate, readily accessible toilet facilities."); § 110.40(a) ("All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained."); § 110.40(b) ("Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter . . . ."); § 114.10 ("All operators of processing and packaging systems shall be under the operating supervisions of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant

all dietary supplement GMPs had to be rooted in an analytical methodology, the resulting regulations would not be like "GMP" regulations at all because they would be "unable to address such basic requirements as employee qualifications, manufacturing facilities, sanitation requirements, and production and process controls, just to name a few." Defs.' Mem. at 24. In addition, recognized authorities on good manufacturing practices indicate that they embody the type of regulations contained in the GMP Final Rule. In issuing its dietary supplement GMPs, the FDA looked to "generally recognized principles underlying GMP." *See* 72 Fed. Reg. 34781 (citing Juran's Quality Control Handbook (4th ed. 1988) (Final Rule Ref. 9)). Such generally recognized principles of GMP emphasize process and procedural controls as the basis of GMP and deem it neither sufficient nor effective "to rely solely on end product testing" to assure quality. *Id.* at 34762.

The plaintiffs' interpretation of Section 402(g) is thus problematic for two key reasons. First, the purported requirement that all dietary supplement GMP regulations be tethered to an analytical methodology is difficult to reconcile with the Congressional directive to prescribe GMP regulations modeled on those for food and with the use of the phrase "good manufacturing practices" in the FDCA context generally. Internally inconsistent interpretations of statutes are disfavored. *See Am. Soc. of Travel Agents, Inc. v. Blumenthal*, 566 F.2d 145, 163-64 (D.C. Cir. 1977) (Bazelon, J., dissenting) ("[C]ontradictory interpretations of differing statutory sections are avoided on the assumption that statutes constitute the expression of a coherent purpose") (citing cases). At best, if plaintiffs' reading of the statute were correct, that would mean that the statute is ambiguous and must be analyzed under *Chevron* Step Two because it provides

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sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction."); § 129.20 (plant construction and design for bottled water processing facilities); *but see* 21 C.F.R. § 114.90 for an example of a food GMP regulation that does specify a particular analytical methodology for determining food acidity.

internally inconsistent directives. Second, and more fundamentally, the plaintiffs' interpretation of the statute defies common sense. It is not reasonable to assume that Congress would charge the FDA with prescribing good manufacturing practices for dietary supplements, and then cabin the agency's authority so narrowly that it could not regulate basic matters like facility maintenance and sanitation requirements. *See Brown & Williamson*, 529 U.S. at 133 (the Court "must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude") (citing *MCI Telecommunications Corp. v. American Telephone & Telegraph Co*., 512 U.S. 218, 231 (1994)).

Plaintiffs' arguments also frequently invoke Section 402(f) of the FDCA, but this section is not relevant to the dispute over the proper interpretation of Section 402(g). *See, e.g.*, Pls.' Mem. at 21 ("[T]he GMP Final Rule violates . . . 21 U.S.C. § 342(f);(g) of the FDCA [sic] by exceeding FDA's statutory authority . . ."); Pls.' Reply at 13 ("FDA prefers to operate without even acknowledging the existence of its Section 342(f) and 342(g)(2) burdens of proof."); Pls.' Reply at 11 (asserting that "[t]he FDA's GMP regulations are not lawful unless they satisfy one or the other statutory burdens placed on the agency [referring to Sections 402(f) and (g)]"). Section 402(f), *inter alia*, establishes that a dietary supplement that "presents a significant or unreasonable risk of illness" shall be deemed to be adulterated. 21 U.S.C. § 342(f). Sections 402(f) and (g) provide independent and parallel criteria for establishing adulteration under the FDCA. Section 402(f) is not implicated by the GMP regulations challenged in this action because those regulations were authorized under Section 402(g). Accordingly, Section 402(f) does not appear relevant to the plaintiffs' argument, especially in light of the plaintiffs' apparent concession that Sections 402(f) and (g) operate independently. *See* Pls.' Reply at 10-11, 14. To the extent that the plaintiffs argue that the two subsections do not operate independently and that

valid GMP regulations must comply with Section 402(f) in some way, there is no support in the statutory text for this argument because Section 402(f) does not reference GMP regulations at all, while they are precisely the subject of Section 402(g).

Plaintiffs also argue that the FDA's interpretation of the statute effectively reads Section 402(g)(2)'s limitation regarding analytical methods out of the statute entirely, violating the well-settled canon of construction favoring interpretations that give effect to all parts of a statutory text. *See* Pls.' Reply at 14. Plaintiffs' argument is incorrect. The FDA's interpretation does not read the restriction out of the statute. Rather, that interpretation gives the restriction a coherent meaning that, unlike the plaintiffs' interpretation, is also consistent with the overall text of the statute: "[W]hen [the] FDA imposes a standard that requires use of an analytical methodology, it must be one where the methodology is both current and generally available." Defs.' Reply at 9. Put another way, the FDA cannot require the use of an analytical methodology that is not current and generally available. If it were to do so, that would violate the statute.

The FDA's interpretation of the statute is also most consistent with the statute's legislative history, despite the plaintiffs' arguments to the contrary. Plaintiffs argue that the "express purpose of DSHEA was to ensure that 'the Federal Government erects no regulatory barriers that impede the ability of consumers to improve their nutrition through the free choice of dietary supplements.'" Pls.' Mem. at 19 (quoting 140 Cong. Rec. S11705-06, at S11706, 1994 WL 424971 (Aug. 13, 1994) (proposed draft for DSHEA submitted by Senators Hatch and Harkin)). Based on this proposed language and other legislative history, the plaintiffs argue that the FDA's interpretation of Section 402(g) "violates Congress's mandate in DSHEA by creating a regulatory burden that will destroy a significant portion of the dietary supplement market without regard to the ultimate safety of the products produced . . ." Pls.' Mem. at 20. This

argument is misplaced. First, the chief sponsors of DSHEA in both the Senate and the House of Representatives indicated that a joint Statement of Agreement "comprises the entire legislative history for [DSHEA]. . . It is the intent of the chief sponsors of the bill . . . that no other reports or statements be considered as legislative history for the bill." S. Rep. No. 103-410 (1994), *reprinted in* 1994 U.S.C.C.A.N. 3523, 1994 WL 724535. Second, even if the Court were to consider other legislative history beyond the Statement of Agreement, the plaintiffs' argument would not prevail. Plaintiffs conveniently ignore other language in the proposed draft of DSHEA submitted by Senators Hatch and Harkin that states that the purpose of DSHEA was also to "strengthen the current enforcement authority of the Food and Drug Administration by providing to the Administration additional mechanisms to take enforcement action against unsafe or fraudulent products." 140 Cong. Rec. at S11706. Moreover, the proposed statutory language cited by the plaintiffs is not reflected in the final version of DSHEA that was enacted. *See generally* Pub. L. 103-417, 108 Stat. 4325 (1994). In enacting DSHEA, Congress found that "the Federal Government should not take any actions to impose *unreasonable* regulatory barriers limiting or slowing the flow of *safe products and accurate information* to consumers," *Id.* § 2 (emphasis added). Thus, the legislative history indicates that Congress intended to authorize the FDA to enact reasonable supplement manufacturing regulations to promote product safety and quality, while also ensuring consumer access to supplements. In any event, these general conclusions about the statute's overarching purpose ultimately shed little light on the parties' dispute here.

Other parts of the legislative history, however, specifically support the FDA's interpretation of Section 402(g). In a Senate Report on DSHEA, the Section-by-Section Analysis of the bill described Section 12, which became Section 402(g), as follows:

> Section 12. Under current law, dietary supplements are regulated as foods and need comply only with the very general food GMP regulations. This section adds to FDA's enforcement authority the power to issue GMP regulations, after notice and comment, specific to dietary supplements. These shall be in accordance with the food, not drug, GMP concepts and shall not require analytical data that is not currently and practically available to industry companies.

S. Rep. No. 103-410 (1994), 1994 WL 562259, at *39. This report strongly supports the FDA's interpretation of Section 402(g) – i.e., that the intent of the "analytical methodology" limitation is to prohibit the FDA from enacting regulations that would require manufacturers to provide the agency with data through methods that are not currently and practically available to them. Significantly, the report does not in any way suggest that all GMPs must be based on an analytical methodology.[5]

Based on the statutory text, structure, and legislative history, the Court concludes that the clear meaning of Section 402(g) is the FDA's interpretation of the statute. If the FDA imposes a standard that requires the use of an analytical methodology, the methodology must be current and generally available to manufacturers. The statute does not mean that the FDA may only adopt GMP regulations that require the use of such an analytical methodology.

ii. *Chevron* Step Two

Even if the meaning of the Section 402(g) were determined to be ambiguous rather than clear, the Court would still uphold the FDA's interpretation of the statute. Under the second step of the *Chevron* analysis, if a statute is ambiguous with respect to a specific issue, the Court must uphold the agency's interpretation if it is "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. For all of the reasons discussed above that support the FDA's interpretation of the statute, the Court could not conclude that the FDA's construction of the

[5] The plaintiffs cite this same Senate Report to note the inclusion of the following statement: "Given the FDA's historical bias against dietary supplements, the Committee believes it is necessary to place the above limitations [i.e., the limitations reflected in Section 402(g)] on FDA's authority to promulgate GMP regulations." *See* Pls.' Mem. at 16. It is undisputed that Section 402(g) reflects limitations on the FDA's authority, however. The question here is the specific content of those limitations.

statute is impermissible here. Thus, the FDA's interpretation would prevail at the second step of the *Chevron* analysis as well.

The Court will now turn to the plaintiffs' vagueness arguments.

2. Plaintiffs' Argument That the FDA Regulations Are Unconstitutionally Vague Under the Due Process Clause

The plaintiffs argue that several sections of the GMP Final Rule violate the Due Process Clause of the Fifth Amendment and the APA prohibition on unconstitutional agency action because they are unconstitutionally vague and allow arbitrary and discriminatory enforcement. Specifically, the plaintiffs find fault with the use of qualifier terms like "adequate," "suitable," "qualified," and "appropriate." *See* Pls.' Mem. at 23-26. As explained below, the Court concludes that the challenged sections of the GMP Final Rule are not unconstitutionally vague.[6]

a. Legal Standards

When a regulation that does not implicate constitutionally protected conduct is challenged as unconstitutionally vague on its face, the regulation will be upheld unless it is impermissibly vague in all of its applications.[7] *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497-98 (1982); *United States v. Salerno*, 481 U.S. 739, 745 (1987); *Rancho Viejo, LLC v. Norton*, 323 F.3d 1062, 1077-78 (D.C. Cir. 2003) ("[T]o mount a successful facial challenge, 'the challenger must establish that no set of circumstances exists

[6] The sections the plaintiffs consider unconstitutionally vague are: 21 C.F.R. §§ 111.3; 111.10(b)(2), (9); 111.12(a), (c); 111.13; 111.15(a)(3), (a)(4), (e)(1), (f); 111.20(a), (b), (c), (d)(1)(i), (d)(iii), (d)(iii), (d)(v), (d)(2), (e), (h); 111.27(a); 111.70(a), (b)(3), (c), (d), (e); 111.90(b)(1); 111.410(a); 111.455; and 111.470. *See* Pls.' Mem. at 35 (listing provisions that plaintiffs seek invalidated on vagueness grounds). Certain of the challenged provisions appear to be cited incorrectly elsewhere in the plaintiffs' submissions. For example, plaintiffs' discussion of § 111.15(e) appears to refer to § 111.15(f) (physical plant plumbing requirements), while plaintiffs' discussion of § 111.25(a)(1) and (a)(2) appears to refer to § 111.27(a)(1) and (a)(2) (equipment and utensil requirements). *See* Pls.' Mem. at 23-25. In any event, the plaintiffs do not address all of these regulations individually in their memoranda, but instead argue that the challenged regulations share common defects. *See* Pls.' Mem. at 23-26.

[7] The parties agree that this standard applies to the plaintiffs' vagueness challenge. *See* Pls.' Reply at 29; Defs.' Mem. at 29.

under which the Act would be valid.'") (quoting *Salerno* at 481 U.S. at 745); *see also id.* at 1078 n.21 (noting that the D.C. Circuit has repeatedly invoked *Salerno*'s no-set-of-circumstances test to reject facial constitutional challenges) (citation omitted).

"The degree of vagueness that the Constitution tolerates . . . depends in part on the nature of the enactment." *Hoffman*, 455 U.S. at 498. For example, as relevant here, "economic regulation is subject to a less strict vagueness test," *id.*, but, on the other hand, where, as here, a regulation carries the potential for criminal sanctions, courts undertake a comparatively stricter vagueness review.[8] *Id.* at 498-99. "[R]egulations will be found to satisfy due process so long as they are sufficiently specific that a reasonably prudent person, familiar with the conditions the regulations are meant to address and the objectives the regulations are meant to achieve, would have fair warning of what the regulations require." *Freeman United Coal Mining Co. v. Fed. Mine Safety & Health Review Comm'n*, 108 F.3d 358, 362 (D.C. Cir. 1997). Regulations need not achieve "mathematical certainty" or "meticulous specificity," and may instead embody "flexibility and reasonable breadth." *Id.* (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)). Under these standards, the plaintiffs cannot shoulder the "heavy burden" required to prevail in a facial vagueness challenge. *Rancho Viejo, LLC*, 323 F.3d at 1078.

b. Analysis of the Plaintiffs' Vagueness Claims

Plaintiffs object to the use of terms like "adequate," "qualified," and "suitable" in the GMP Final Rule. For example, the plaintiffs assert that 21 C.F.R. § 111.15(h) "requires restrooms to be 'adequate' and 'readily accessible' but defines neither term such that the regulated class can discern its meaning." Pls.' Mem. at 24. Similarly, the plaintiffs contend that Section 111.15(f) requires "physical plant plumbing [be] 'of an adequate size and design and be

[8] Under 21 U.S.C. §§ 331 and 333, marketing an "adulterated" product is a strict liability criminal offense punishable by up to a year in jail and a $1,000 fine. Greater penalties are available if the violation is committed "with the intent to defraud or mislead." 21 U.S.C. § 333(a)(2).

adequately installed and maintained' but does not define the term 'adequate' such that the regulated class can discern its meaning." Pls.' Mem. 23-24. Plaintiffs raise similar objections to provisions requiring employees to be "qualified" (§ 111.12(a)), equipment and utensils to be "of appropriate design, construction, and workmanship" (§ 111.27(a)(1)), and so on. The Court concludes that these terms do not render the regulations unconstitutionally vague for several reasons.

While the plaintiffs only cite isolated snippets of the challenged regulations, many of the challenged regulations contain further details that flesh out the meaning of terms like "adequate," "suitable," and "qualified" in context. For example, as noted above, the plaintiffs object that Section 111.15(f) requires "physical plant plumbing [be] 'of an adequate size and design and be adequately installed and maintained'" without defining the term "adequate." Pls.' Mem. 23-24. Yet the full text of Section 111.15(f) reads:

> (f) Plumbing. The plumbing in your physical plant must be of an adequate size and design and be adequately installed and maintained to:
>
> (1) Carry sufficient amounts of water to required locations throughout the physical plant;
> (2) Properly convey sewage and liquid disposable waste from your physical plant;
> (3) Avoid being a source of contamination to components, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition;
> (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
> (5) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.

Thus, the full text provides numerous details clarifying what the FDA means by "adequately installed and maintained" plumbing. Other challenged sections of the GMP Final Rule also contain similar clarifying details. For example, the plaintiffs object to Section 111.15(i) because it requires hand-washing facilities that are "adequate, convenient, and furnish running water at a

suitable temperature" without defining "adequate," "convenient," or "suitable," Pls.' Mem. at 24, but the full text of the regulation explains further that hand-washing facilities should be "designed to ensure that an employee's hands are not a source of contamination of components, dietary supplements, or any contact surface." 21 C.F.R. § 111.15(i).

Even without the presence of additional explanatory details, the use of the terms like "adequate," "appropriate," "suitable," and "qualified," in the GMP Final Rule is not impermissibly vague because "a reasonably prudent person, familiar with the conditions the regulations are meant to address and the objectives the regulations are meant to achieve, would have fair warning of what the regulations require." *Freeman*, 108 F.3d at 362 (upholding mining regulation requiring that "structures . . . shall be maintained *in good repair* to prevent accidents and injuries. . .") (emphasis added). Courts recognize that "specific regulations cannot begin to cover all of the infinite variety of conditions which [regulated parties] must face," and that "by requiring regulations to be too specific courts would be opening up large loopholes allowing conduct which should be regulated to escape regulation." *Id.* (internal quotation marks and alteration omitted). Indeed, here, the FDA "was tasked with developing CGMP regulations that apply to a diverse industry . . . [and the] FDA [has] explained that using qualifying terms like 'adequate' is necessary to address the 'variety of conditions that exist at different companies.'" Defs.' Mem. at 43-44 (citing 72 Fed. Reg. 34788, 34767). When the challenged regulations are viewed within the overall regulatory scheme for dietary supplement manufacturing practices, the Court concludes that a "reasonably prudent person, familiar with the conditions the regulations are meant to address and the objectives the regulations are meant to achieve" would have "fair warning of what the regulations require."

The FDA's food and drug GMP regulations are also replete with provisions that are similar to the challenged dietary supplement GMPs.[9] These GMP regulations have been in place for decades and courts have previously rejected vagueness challenges against them. In *Nat'l Ass'n of Pharm. Mfrs. v. HHS*, 586 F. Supp. 740 (S.D.N.Y. 1984), the district court rejected a similar vagueness challenge to FDA drug GMP regulations based on use of words such as "adequate," "appropriate," "designed to assure," "proper," "sufficient," and "suitable" in those regulations. *Id.* at 753-54. The plaintiffs attempt to distinguish this case by pointing out various distinctions between the FDCA's treatment of drugs and dietary supplements, including the provisions of Section 402(g) discussed above, but these distinctions are not relevant to the vagueness inquiry. *See* Pls.' Reply at 32-33. To the extent that the plaintiffs rely on their restrictive reading of Section 402(g) to argue that there is a meaningful difference in the level of specificity required in food and drug GMPs versus dietary supplement GMPs, the Court has already explained that the plaintiffs' reading of Section 402(g) is incorrect.

Plaintiffs also raise the specter of FDA inspectors exploiting the flexibility in the regulations in abuse of their power. *See* Pls.' Reply at 27 ("FDA enforcement officers are capable of engaging in harassment and falling prey to bias"). In reviewing a facial challenge to a regulation, however, the Court must presume the agency will act in good faith. *See Shays v.*

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[9] *See, e.g.*, 21 C.F.R. § 110.20(b) ("Plant buildings and structures shall be *suitable* in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes") (food); § 110.37(d) ("Each plant shall provide its employees with *adequate, readily accessible* toilet facilities.") (food); § 110.40(a) ("All plant equipment and utensils shall be so designed and of such material and workmanship as to be *adequately cleanable*, and shall be *properly maintained*.") (food); 21 C.F.R § 211.63 ("Equipment used in the manufacture, processing, packing, or holding of a drug product shall be *of appropriate design, adequate size, and suitably located* to facilitate operations for its intended use and for its cleaning and maintenance.") (drugs); § 211.25(c) ("There shall be an *adequate* number of *qualified personnel* to perform and supervise the manufacture, processing, packing, or holding of each drug product") (drugs). (Emphases added).

FEC, 528 F.3d 914, 930 (D.C. Cir. 2008) ("Shays doubts whether the Commission will enforce the safe harbor provision in a way that actually requires meaningful firewalls, but as a court reviewing this facial challenge we must presume that the Commission will enforce its rule in good faith.") (citing *Sullivan v. Everhart*, 494 U.S. 83, 94 (1990)).

There are clearly many applications of the challenged GMP regulations under which the regulations would not be impermissibly vague. To take just one example, the plaintiffs object to Section 111.15(h), which requires manufacturers to provide "employees with adequate, readily accessible bathrooms." *See* Pls.' Mem. at 24; 21 C.F.R. § 111.15(h). A reasonably prudent manufacturer familiar with the objective of this requirement would be on fair notice that he has violated it if his facility's bathrooms lack running water, or if the bathroom doors are locked and employees can only open them with the permission of a supervisor. *See* Defs.' Mem. at 33. While the Court does not dismiss the possibility that the challenged provisions of the GMP Final Rule might be impermissibly vague in certain enforcement contexts, the plaintiffs have not established that "no set of circumstances exists under which the [regulations] would be valid.'" *Rancho Viejo, LLC*, 323 F.3d at 1077-78 (quoting *Salerno*, 481 U.S. at 745). Accordingly, the regulations are not facially unconstitutional.

3. Plaintiffs' Argument That the FDA Regulations Are Arbitrary and Capricious Under the APA

In a variation on the plaintiffs' claim that various sections of the GMP Final Rule are unconstitutionally vague under the Due Process Clause of the Fifth Amendment, the plaintiffs also argue that the same sections are arbitrary and capricious and an abuse of discretion under the APA because they "fail to implement clear standards or . . . fail to provide individuals with notice to alert them of how to conform their conduct to the law." Pls.' Mem. at 29. This facial challenge to the regulations under the APA also fails.

First, as noted above, courts have previously upheld similar GMP provisions. *See Nat'l Ass'n of Pharm. Mfrs.*, 586 F. Supp. at 753-54 (FDA drug GMP regulations using words such as "adequate," "appropriate," "designed to assure," "proper," "sufficient," and "suitable" are "sufficiently definite and precise to comport with constitutional standards and are not arbitrary or capricious on grounds of vagueness."). The fact that existing FDA regulations have similar wording also undermines the plaintiffs' dire warnings that the dietary supplement GMPs will "compel FDA inspectors to employ their own guesswork as to what is required, creating chaos, fear, and panic in the industry due to uncertainty." Pls.' Reply at 36.

Second, while the plaintiffs argue that the FDA could have adopted regulations with a greater degree of specificity, it is not the Court's role to dictate what level of specificity is appropriate. "When Congress has not specified the level of specificity expected of the agency, . . . the agency is entitled to broad deference in picking the suitable level." *Shays*, 528 F.3d at 930 (quoting *Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 217 (D.C. Cir. 2007). Congress has not specified a particular level of specificity here, although Congress did instruct the agency that the GMP regulations should be modeled on food GMPs, which contain regulations of similar specificity to those challenged by the plaintiffs. *See* 21 U.S.C. § 342(g); *see also supra* n.9 (listing similar food GMPs). In addition, the FDA has articulated a rational explanation for its selected level of specificity in the GMP Final Rule. *See* 72 Fed. Reg. 34787-88 (explaining that the agency could not "predict with mathematical precision how many inches or feet, for example, would be 'adequate space' to allow for cleaning a particular piece of equipment that could be applied to every size of facility and every operation. . . [D]efining such terms too precisely would unduly restrict the application of the regulation to a very narrow, limited set of circumstances and not provide industry with the needed flexibility to address the

number and variety of types of manufacturing operations that Congress intended for [the GMP Final Rule] to cover."). Thus, the FDA has "articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of United States*, 463 U.S. at 43 (internal quotation marks omitted).

Finally, the plaintiffs argue that even if Congress did not dictate a particular level of specificity for the GMP regulations, the regulations are nevertheless arbitrary because they lack a "comprehensible level of specificity." As discussed above regarding the plaintiffs' constitutional vagueness argument, when the challenged provisions of the GMP Final Rule are read in their full context and in light of the regulations' purpose, they are sufficiently comprehensible to the regulated class. Moreover, the cases cited by the plaintiffs do not support sustaining their pre-enforcement APA challenge on vagueness grounds. *See* Pls.' Mem at 30-31; Pls.' Reply at 36-37. For example, *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), a case heavily relied upon by the plaintiffs, involved a *post-enforcement* challenge to an FDA decision. In that case, the D.C. Circuit held that the APA required the FDA to provide additional "definitional content" to the standard the FDA had applied in rejecting certain proposed health claims that the plaintiffs had sought to use in marketing dietary supplements. *See id.* at 660. In explaining its ruling, the D.C. Circuit specifically noted that "[this holding] is not to say that the agency was necessarily required to define the term in its initial general regulation-or indeed that it is obliged to issue a comprehensive definition all at once." *Id.* Plaintiffs' cited authority is thus unavailing.

Accordingly, the Court concludes the challenged provisions of the GMP Final Rule are not arbitrary and capricious under the APA.[10]

[10] The plaintiffs also argue in a footnote that the GMP Final Rule violates Executive Order 12866, which requires "[e]ach agency shall tailor its regulations and guidance documents to impose the least burden on society, including individuals, businesses of differing sizes, and other entities, consistent with obtaining the regulatory objectives . . . Pls.' Mem. at 30 n.20 (citing Exec. Order No. 12,866, § 1(11) (Sept. 30, 1993)). According to the plaintiffs, the

IV. Conclusion

The plaintiffs' remaining contentions are without merit.

For the reasons stated above, the Court concludes that the challenged sections of the GMP Final Rule did not exceed the FDA's statutory authority, are not impermissibly vague under the due process clause, and are not arbitrary and capricious under the APA. Accordingly, summary judgment is GRANTED for the defendants and DENIED for the plaintiffs.

DATED: April 6, 2011

/s/ *Beryl A. Howell*
BERYL A. HOWELL
United States District Judge

GMP Final Rule violates Executive Order 12,866 because its burden on industry, particularly small business, is extreme, and is not outweighed by demonstrable benefits to society. *Id.* This argument fails because Section 10 of Executive Order 12866, entitled "Judicial Review," specifically provides: "This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person." By the terms of the Executive Order, the plaintiffs may not sue for any alleged violations. *See Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 9 (D.C. Cir. 1999) (equivalent language in another Executive Order precluded plaintiff from suing for violation of the order or invoking the order's provisions as evidence of arbitrary and capricious agency action); *see also Trawler Diane Marie, Inc. v. Brown*, 918 F. Supp. 921, 932 (E.D.N.C. 1995), *aff'd*, 91 F.3d 134 (4th Cir. 1996) (table) (Executive Order 12866 does not permit private lawsuits to challenge an agency's compliance).