UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PREVOR,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 11-1187 (RMC)**
	)	
FOOD AND DRUG ADMINISTRATION,	)	
	)	
Defendant.	)	
	)	

OPINION

PREVOR, a French company, developed a product called Diphoterine™ Skin Wash ("DSW") to mitigate chemical burn injuries in the industrial workplace. PREVOR sues the Food and Drug Administration for declaratory and injunctive relief to change FDA's designation of DSW as a drug-device combination product with a "drug" primary mode of action. PREVOR claims that FDA erred and thereby violated the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act. FDA maintains that its determination was based on the clear language of its governing statute and was not in violation of the APA. The parties cross-move for summary judgment.

The Court concludes that FDA acted arbitrarily and capriciously in designating DSW as a drug-device combination product with a drug primary mode of action. Accordingly, the Court will grant PREVOR's motion for summary judgment and deny the cross-motion of the FDA.

I. FACTS

A. DSW

PREVOR developed DSW to prevent and minimize chemical burn injuries that occur in the industrial workplace due to accidental exposure to chemicals. It has been marketed outside the United States as a device since 1996 and is registered/licensed as a medical device in Europe, Canada, Brazil, and Australia. When a water shower is not available, DSW provides an alternative "first-response" to chemical exposure. "DSW consists of a liquid substance contained in a canister propelled by pressurized gas." AR 001. The liquid substance is colorless and ordorless and is comprised of roughly 96% water and 4% diphoterine. *Id.* at 003. "DSW is used by spraying the pressurized contents of the canister on to the skin to physically and mechanically remove splashes of acids and bases off the skin by washing them away." *Id.* at 001. "DSW is intended to: (1) remove splashes of acidic or basic substances off the skin by physically and mechanically washing the chemicals away from the skin, and (2) neutralize and dilute acids and bases." *Id.* at 002. PREVOR states that "[t]he first use is a physical/mechanical mode of action (comprises approximately 90% of DSW's overall effect), while the second one is a chemical mode of action (comprises approximately 10% of DSW's overall effect)." *Id.* "Dissolution of the acids and bases has a minor, incidental effect, comprising less than ½% of DSW's overall effect." *Id.* at 001.

B. Statutory Framework

The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, gives FDA jurisdiction over, *inter alia*, the regulation of drugs and devices. The statute defines "drug" to mean, in part, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to

affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B) & (C). It defines "device" to mean

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
>
> **(1)** recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> **(2)** intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> **(3)** intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Id. at § 321(h). The critical distinguishing element applicable in this case is that a product that "achieve[s] its primary intended purposes through chemical action within or on the body" is excluded from the definition of a device.

The FFDCA recognizes that a product may be both a drug and a device, which the law labels a "combination product." 21 U.S.C. § 353(g). A combination product is defined by regulation as: "A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity." 21 C.F.R. § 3.2(e)(1). FDA considers the DSW canister/liquid solution, as a whole, to be a combination product. "PREVOR believes that DSW is a single-entity product with two modes of actions [sic] – physical and chemical – where the physical mode of action is primary and the most predominant in achieving the product's intended use." AR 001.

Pursuant to the FFDCA, FDA has designated agency components to regulate combination products. *See* 21 U.S.C. § 353(g)(1); 21 C.F.R. § 3.4. To determine which agency component will regulate a given combination product, FDA assesses a product's primary mode of action ("PMOA").[1] *See* 21 U.S.C. § 353(g)(1). Each constituent part of a combination product contributes a "mode of action" – "the means by which a product achieves an intended therapeutic effect or action." 21 C.F.R. § 3.2(k). "A constituent part has a device mode of action if it meets the [FFDCA] definition of device . . . and it does not achieve is primary intended purposes through chemical action within or on the body of man or other animals . . . ." 21 C.F.R. § 3.2(k)(2). "A constituent part has a drug mode of action if it meets the [FFDCA] definition of drug . . . and it does not have a . . . device mode of action." 21 C.F.R. § 3.2(k)(3). A primary mode of action is defined as:

> [T]he single mode of action of a combination product that provides the most important therapeutic action of the combination product. The most important therapeutic action is the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

21 C.F.R. § 3.2(m).

For those combination products whose primary mode of action is that of a drug, the Center for Drug Evaluation and Research ("CDER") has jurisdiction. *See* 21 C.F.R. § 3.4(a)(1). For those combination products whose primary mode of action is that of a device, the Center for Devices and Radiological Health ("CDRH") has jurisdiction. *See* 21 C.F.R. § 3.4(a)(2). Assignment to a specific agency component will determine the regulatory requirements for that product and the cost of approval. *See* Definition of Primary Mode of Action of a Combination Product, 70 Fed. Reg. 49,848, 49, 849 (Aug. 25, 2005) (codified at 21

[1] For clarity's sake, the Court generally avoids the plethora of acronyms used by the parties but provides them for the reader as they are used in direct quotes.

C.F.R. pt. 3) ("The purpose of the Office of Combination Products is to ensure the prompt assignment of combination products to agency components, the timely and effective premarket review of such products, and consistent and appropriate postmarket regulation of combination products.").

C. FDA Classification of DSW

On August 13, 2009, PREVOR submitted a Request for Designation ("RFD") to the Office of Combination Products ("OCP") at FDA, requesting that it "confirm that DSW is a device to be regulated by the Center for Devices and Radiological Health." AR 001. Alternatively, PREVOR asked that if the Office of Combination Products determined DSW to be a combination product, "OCP confirm that DSW should be regulated as a device by CDRH." *Id.* PREVOR informed FDA that DSW is intended to: "(1) remove splashes of acidic or basic substances off the skin by physically and mechanically washing the chemicals away from the skin, and (2) neutralize and dilute acids and bases." *Id.* at 002. With its Request for Designation, PREVOR included summaries of two studies that "were conducted to compare and quantify the relative contributions of the physical/mechanical effect and the chemical effect of DSW in achieving its intended use." *Id.* at 005. PREVOR also described products that the Center for Devices and Radiological Health regulates as devices "that have similar modes of action to DSW." *Id.* at 008.[2]

On October 16, 2009, the Office of Combination Products sent a letter to PREVOR designating DSW as a combination product assigned to the Center for Drug Evaluation and Research for regulation. *Id.* at 675. The Office of Combination Products concluded:

[2] FDA also received supplemental information from PREVOR. *See* AR 19-22.

> The liquid appears to have two primary intended purposes: to wash the chemical off the skin and neutralize the chemical that is on the skin. Since this liquid achieves its primary intended purposes, at least in part, through chemical action, it does not meet the definition of device. The liquid does, however, meet the definition of drug at section 201(g) of the Act (21 U.S.C. 321(g)). Accordingly, we have concluded that the liquid is a drug.

Id. at 676. The Office of Combination Products also concluded that the pressurized canister that delivers the DSW solution constitutes a device. Thus, "because the product is comprised of both drug and device constituent parts," the Office of Combination Products determined that DSW is a combination product. The Office of Combination Products also determined that the drug constituent part of DSW "provides the greater contribution to the overall therapeutic effect of the combination product and, thereby, the product's PMOA," so it assigned DSW to the Center for Drug Evaluation and Research. Finally, the Office of Combination Products rejected the comparison PREVOR sought to draw to other products because "each differ[s] from [DSW] in significant respects, including with regard to intended use, components, and/or ingredients." *Id.*

PREVOR timely sought review of this determination from FDA's Office of Special Medical Programs ("OSMP") on March 24, 2010.[3] PREVOR asserted that the Office of Combination Products erred by "[c]ontradicting established agency precedents, disregarding information provided in the RFD, and applying a novel review standard not found in or supported by law or regulation" in reaching its decision. *Id.* at 725. PREVOR again argued that DSW is a device or a combination product with a device primary mode of action (expulsion of the solution from the canister by compressed gas), and that it should be assigned to the Center for Devices and Radiological Health for regulation. *Id.* at 727. PREVOR cited the same studies it had referenced in its Request for Designation that assessed DSW's mode of action. *Id.* at 730-

[3] *See* 21 C.F.R. § 10.75.

31. It also contended that "CDRH regulates as devices products that have similar modes of action to DSW." *Id.* at 731.

On April 25, 2011, the Office of Special Medical Programs "affirm[ed] OCP's designation of DSW as a combination product to be assigned to CDER" for regulation. *Id.* at 785. It rejected PREVOR's argument that "the solution meets the definition of a device because . . . the chemical action is secondary and the physical action (washing effect) is primary. . . . [A] PMOA analysis does not apply to the solution because it is not a combination product." *Id.* Noting that the Request for Designation had indicated that "'the diphoterine molecule must be in solution in order for it to exhibit any chemical activity'" and that PREVOR had stated that it is "DSW, the product in finished, final form, that has the ability to interact with acids and bases,'" the Office of Special Medical Programs concluded that "it is the solution as a whole that is responsible for the chemical action rather than any particular component in the solution." *Id.* at 785-86.[4]

The FDA reviewers noted that "OCP determined that because the solution's primary intended purposes are achieved in part through chemical action, the solution does not meet the device definition . . . ." *Id.* at 786. Agreeing with that analysis, the Office of Special Medical Programs added:

> In determining whether an article is a "device," FDA must consider whether or not the article achieves its *primary intended purposes* through chemical action within or on the body of man. 21 U.S.C. § 321(h). . . . [I]f an article depends, *even in part*, on chemical action within or on the body to achieve *any* of its primary intended purposes, it does not meet the definition of a device . . . .

[4] The Office of Special Medical Programs addressed PREVOR's two studies in a footnote, rejecting them as "flawed because they do not simulate the conditions of use and therefore do not appear to measure or reflect the actions of the solution on the body." AR 786 n.1. FDA also indicated that the "lack of a control" in one of the studies made it "difficult to draw any conclusions from th[e] study." *Id.*

> Based on the information provided, the solution achieves its primary intended purposes through both physical action and chemical action within or on the body. In addition to washing harmful chemicals off the body, the solution is intended to neutralize harmful chemicals on the body . . . . Neutralizing the acids and bases in harmful chemicals is one of the solution's primary intended purposes. Because the solution depends on chemical action within or on the body to achieve one of its primary intended purposes, the solution is not a device within the meaning of section 201(h) of the Act.

Id. (emphases added).

The Office of Special Medical Products further concluded that DSW has a drug primary mode of action because "[i]t is the solution that directly acts on the body to help prevent or mitigate chemical burn injuries. Therefore, the solution provides the most important therapeutic action of the combination product." *Id.* at 787. As such, the Office stated that DSW is "appropriately assigned" to the Center for Drug Evaluation and Research for regulation. *Id.* ("Because the PMOA is that of the drug constituent, DSW is appropriately assigned to CDER for premarket review and regulation."). As to the products regulated as devices that PREVOR claimed were analogous to DSW, the Office of Special Medical Products found them to be distinguishable "because they differ from DSW, including with respect to intended use, components, and/or ingredients." *Id.* at 787.

In sum, FDA found that DSW is a combination product: the canister is a "device" and the solution is a "drug," and the "drug" provides the most important therapeutic action. FDA did not address the necessary action of the compressed gas in the canister to expelling the solution under pressure.

II. SUMMARY JUDGMENT STANDARD

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted "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." Fed. R. Civ. P. 56(a); *accord Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Moreover, summary judgment is properly granted against a party who "after adequate time for discovery and upon motion . . . fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true. *Anderson*, 477 U.S. at 255. A nonmoving party, however, must establish more than "[t]he mere existence of a scintilla of evidence" in support of its position. *Id.* at 252. In addition, the nonmoving party may not rely solely on allegations or conclusory statements. *Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999). Rather, the nonmoving party must present specific facts that would enable a reasonable jury to find in its favor. *Id.* If the evidence "is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted).

III. ANALYSIS

PREVOR brought its challenge to FDA's determination that DSW is subject to regulation by the Center for Drug Evaluation and Research under the APA, 5 U.S.C. § 701 *et*

seq.[5] A reviewing court may set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of U.S.v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). At the same time, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)); *see also Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) ("The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result."). While the agency action under review is "entitled to a presumption of regularity[,] . . . that presumption is not to shield [an] action from a thorough, probing, in-depth review." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977).

"An agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is entitled to considerably less deference than a consistently held agency view." *INS v. Cardoza-Fonesca*, 480 U.S. 421, 446 n.30 (1987) (internal quotation marks and citation omitted); *see also Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993) ("[T]he consistency of an agency's position is a factor in assessing the weight that position is due."). "One of the core tenets of reasoned decision-making is that an agency [when] changing its course . . . is obligated to supply a reasoned analysis for the change." *See Republic*

[5] The Court has federal question jurisdiction over PREVOR's claims. *See* 28 U.S.C. § 1331. The Court has personal jurisdiction over FDA because it resides in the District, and venue is proper pursuant to 28 U.S.C. § 1391(e)(1).

Airline Inc. v. Dep't of Transp., 669 F.3d 296, 300 (D.C. Cir. 2012) (internal quotation marks and citations omitted). "Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action." *Cnty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) (internal quotation marks and citation omitted).

PREVOR first claims that FDA misapplied the statutory definition of device. Under the statute, a product is not a device if it "achieve[s] its primary intended purposes through chemical action within or on the body of man." 21 U.S.C. § 321(h). FDA has interpreted "primary intended purposes" to permit an article to have more than one primary intended purpose. PREVOR does not dispute this interpretation of the statute. Instead, PREVOR disagrees with FDA's conclusion that DSW has more than one *primary* intended purpose. Specifically, PREVOR disagrees with FDA's conclusion that the neutralization of chemicals is one of the DSW solution's primary intended purposes.

In review, the Court looks for a reasoned basis for FDA's classification decision. *See State Farm*, 463 U.S. at 43. FDA states that it determines whether an intended purpose for a product is primary "by qualitatively evaluating an article's intended purposes." Def.'s Reply [Dkt. 22] at 3. FDA makes this determination "based on scientific information . . . on a case-by-case basis, as it is dependent on the specific characteristics of the article being examined." *Id.* at 4. Here, however, FDA failed to provide any details regarding its "qualitative evaluation" or the "scientific information" on which it based the particular decision that one of the *primary* purposes of the DSW solution is achieved through chemical action.

In the initial letter of designation issued by the Office of Combination Products, FDA summarily concluded that "[t]he liquid appears to have *two primary intended purposes*,"

citing only PREVOR's description of DSW's chemical action in its Request for Designation. AR 676 (emphasis added). But there is no dispute that DSW has *some* chemical effect, and FDA failed to address or explain what makes the chemical effect here a "primary intended purpose" of DSW. The Court does not ignore the name of the product – Diphoterine™ Skin Wash – but finds that FDA's reliance on extraordinarily expansive language ("at least in part" or "even in part") demonstrates the agency's own recognition that without such an interpretation of "primary intended purpose," DSW could be designated a "device."

FDA's letter of review from the Office of Special Medical Programs provided little additional insight. Again there is no dispute, as the FDA noted, that "[i]n addition to washing harmful chemicals off the body, the solution is intended to neutralize harmful chemicals on the body." *Id.* at 786. FDA then addressed *how* the DSW solution neutralizes chemicals, another point that is not contested. The Office of Special Medical Programs concluded, without explanation, that "[n]eutralizing the acids and bases in harmful chemicals is one of the solution's *primary* intended purposes." *Id.* (emphasis added). The agency's *ipse dixit* cannot substitute for the "qualitative analysis" or "scientific information" on which FDA says it acted, and the Court can find none in its classification letters or in the Administrative Record.

Courts defer to FDA "when it is evaluating scientific data within its technical expertise." *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 216 (D.D.C. 1996); *see also Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 142 (3d Cir. 1987) ("We are mindful that in evaluating scientific evidence in the drug field, the FDA possesses an expertise entitled to respectful consideration by this court."). This norm is difficult to apply here. While FDA rejected the studies that supported PREVOR's position that neutralization of chemicals is not a

primary intended purpose of the DSW solution, FDA did not rely on any studies or other scientific analysis in its classification letters to support its contrary conclusion.

This lack of scientific analysis may be explained by FDA's substitution of a new expansive interpretation of an exclusion from the statutory term "device." The Office of Combination Products decided, "Since this liquid achieves its primary intended purposes, *at least in part*, through chemical action, it does not meet the definition of device." AR 676 (emphasis added). The Office of Special Medical Programs agreed that "if an article depends, *even in part,* on chemical action . . . to achieve any of its primary intended purposes, it does not meet the definition of a device." AR 786 (emphasis added). PREVOR contends that the added language – "at least in part" or "even in part" – marks a departure from the statute and FDA's prior precedents. FDA responds that its language does not change its own interpretation of the statute but merely recognizes that the DSW solution has both a physical (washing) and chemical (neutralizing) action. FDA maintains that this language still leaves room for a product with a *de minimus* chemical effect to be classified as a device.

A product is not a "device" if it "achieve[s] its primary intended purposes through chemical action within or on the body of man." 21 U.S.C. § 321(h). Inasmuch as the statute seeks to identify *primary* intended purposes that are achieved through chemical action, it would be magnificently expanded if a *primary* purpose could automatically be achieved "at least in part" or "even in part" by chemical action. Primary means principal, first among others, foundational. *See* Merriam-Webster Dictionary Online, http://merriam-webster.com/ dictionary/primary (last visited Sept. 19, 2012) (defining "primary" as "of first rank, importance, or value"); Oxford English Dictionary Online, http://www.oed.com/ search?searchType= dictionary&q=primary (last visited Sept. 19, 2012) (defining "primary" as "of the highest rank or

importance; principal, chief"). Even when more than one primary purpose is contemplated, contrary to the Latin origin of the word,[6] the word does not readily include a purpose that occurs "*at least* in part" or "*even* in part" with other actions. It may not be a *non sequitur* in all situations to include an action achieved only "in part" within a "primary purpose," but here FDA offers nothing more than its say-so. The addition of such language when applying the statute substantively modifies the standard to be applied by expanding the reach of the exclusionary language. The Court agrees with PREVOR's argument that "FDA now prevents a device from having even a *de minimus* chemical effect because the 'at least in part' or 'even in part' language is so encompassing." Pl.'s Mot. for Summ. J. [Dkt. 12] at 14. While FDA protests that its new verbiage would not cover *de minimus* effects, it offers no reasoned basis either to interpret the statute's demand for "primary intended purposes" to include even "partial" purposes or to limit its new interpretation in any way.

While FDA asserts that its interpretation of "primary intended purposes" is "not new," Def.'s Opp'n [Dkt. 13] at 29, the case it cites in support states only that a product can have more than one primary intended purpose, which is not in dispute, not that the standard includes the language "even in part" or "at least in part." *See* Letter from Suzanne O'Shea, Product Jurisdiction Officer, FDA, to LuAnn Elrich, Senior Director of Pharmaceutical and Computer Services, Apotex Corp. (Sept. 8, 2003), *available at* http://www.fda.gov/downloads/CombinationProducts/JurisdictionalInformation/RFDJurisdictionallDecisions/RedactedDecisionLetters/UCM113771.pdf (last visited Sept. 19, 2012). Indeed, FDA fails to cite a single prior instance in which it has applied an "even in part" standard.

[6] "Primary" comes from the classical Latin word *prīmārius*, meaning "of the first rank or importance, chief, principal." Oxford English Dictionary Online, http://www.oed.com/search?searchType=dictionary&q=primary (last visited Sept. 19, 2012).

The fact that FDA has changed its interpretation becomes most apparent when examining products that are analogous to DSW but regulated as devices by FDA. "An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so." *Indepen. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996). *Compare Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 24, 27-28 (D.D.C. 1997) (concluding that FDA had treated products that were "identical in all material respects" differently "for no apparent reason"), *with Sanofi-Aventis U.S. LLC v. FDA*, 733 F. Supp. 2d 162, 172 (D.D.C. 2010) (holding that "the FDA provided 'legitimate reason[s]' for deciding that enoxaparin should be treated differently than the drugs cited by Sanofi." (alteration in original)). "The disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious." *Bracco Diagnositcs, Inc.*, 963 F. Supp. at 28.

PREVOR listed a number of products in its Request for Designation that FDA regulates as devices that PREVOR contended are substantially similar to DSW. PREVOR highlighted Reactive Skin Decontamination Lotion ("RSDL") as the product most like DSW that FDA regulates as a device. "RSDL consists of a drug constituent (lotion) and a device constituent (sponge applicator) and is intended to remove and/or neutralize chemicals . . . from the skin." AR 787. FDA concluded that the sponge (device) provides the primary mode of action, not the lotion, so it regulates RSDL as a combination product with a device primary mode of action. *Id.* To distinguish RSDL from DSW, the Office of Special Medical Programs stated:

> The sponge applicator is not only used to apply the drug (lotion) but it is also physically scrubbed over the contaminated skin and through this action, loosens and removes toxic chemicals from the skin . . . . [W]hile the sponge applicator in RSDL directly removes chemicals from the body, with DSW, it is not the canister that directly removes chemicals from the body but the solution. It is the solution in DSW that washes off the chemicals from the body as well as neutralizes and dilutes the chemicals.

AR 787-88.

The Court does not question FDA's expertise, but this explanation makes a most ephemeral distinction. Both the sponge applicator in RSDL and the canister in DSW are used to apply the relevant material *and* to remove chemicals from the skin. FDA recognizes that "the canister sprays the solution onto the body," but then ignores the necessary force of propulsion in washing off harmful chemicals. AR 787. Given the almost identical roles played by the device (sponge) in RSDL and the device (canister) in DSW, FDA's attempt at distinguishing them appears to treat similar products differently without a reasoned explanation. *See Babbitt*, 92 F.3d at 1258; *Bracco Diagnostics, Inc*, 963 F. Supp. at 28 ("FDA is not free to . . . permit two sets of similar products to run down two separate racks, one more treacherous than the other, for no apparent reason.").

FDA repeatedly states that the use of the language "even in part" or "at least in part" does not mark a change in its interpretation of the statute, but its issuance of new draft guidance documents following its designation decision for DSW undermines this assertion. In June 2011, FDA issued two draft guidance documents regarding the classification of products as drugs and devices. *See Guidance for Industry and FDA Staff: Classification of Products as Drugs and Devices & Additional Product Classification Issues, Draft Guidance* (June 2011), http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM258957.pdf (last visited Aug. 29, 2012) ("Classification Guidance Document"); *Guidance for Industry and FDA Staff: Interpretation of the Term "Chemical Action" in the Definition of Device under Section 201(h) of the Federal, Food, Drug, and Cosmetic Act* (June 2011), http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM259068.pdf (last visited Aug. 29, 2012). When issuing its guidance, FDA stated that they "provide the Agency's current thinking on approaches for

classifying products as drugs and devices." 76 Fed. Reg. 36,133, 36,133 (June 21, 2011). The Classification Guidance Document uses the same language that FDA used in its designation and review letters for DSW:

> In contrast, a product that depends, *even in part*, on chemical action within or on the body of man to achieve *any one* of its primary intended purposes, would not be a device. In addition, if a product has multiple therapeutic effects, each of these would be a "primary intended purpose" of the product, and the product would not meet the device definition if it achieves *any one* of these primary intended purposes through chemical action within or on the body of man.

Classification Guidance Document at 4-5 (emphases added). Although the Court does not reach the question of the guidance's compliance with the requirements of the APA, the issuance of this guidance is indicative of the scope and importance of the change FDA has made to its interpretation of "device" and already has applied to DSW.

FDA's designation decision here relied on a doubly grandiose interpretation of the phrase "primary intended purposes" from 21 U.S.C. § 321(h). First, FDA treated *any* purpose of DSW as a *primary* intended purpose, contrary to the more limited language of the statute and the agency's distinction between primary and secondary in prior precedent. *See* AR 098 (concluding that "the medical maggots exert their primary intended use by a physical, not chemical, action" because the proteolytic enzymes only "secondarily" aid in the debridement). Second, FDA treated achievement *even in part* of *any* purpose through chemical action as achievement of a primary intended purpose through chemical action. There may be solid scientific reasons for FDA's new approach but these remain unexplained, at least without defining "primary" in a manner consistent with the law. FDA insists that it does not need to explain because it has not changed its interpretation of "device." The record demonstrates otherwise.

Whether FDA would come to the same conclusions without resort to its extra-statutory interpretations remains to be seen. The case will be remanded for the agency to make that determination in compliance with this Opinion.

IV. CONCLUSION

For the foregoing reasons, PREVOR's motion for summary judgment [Dkt. 12] will be granted. FDA's motion for summary judgment [Dkt. 13] will be denied. The FDA's decision to designate DSW as a drug-device combination product with a drug primary mode of action will be vacated, and the case will be remanded to the FDA for further action consistent with this Opinion. A memorializing Order accompanies this Opinion.

Date: September 25, 2012

/s/
ROSEMARY M. COLLYER
United States District Judge