IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PREVOR, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Case No. 1:11-cv-01187 (RMC)

DEFENDANT'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Prevor has challenged three aspects of FDA's determination that Diphoterine Skin Wash ("DSW") is a combination product and not a device under the Federal Food, Drug, and Cosmetic Act ("FDCA"): (1) FDA's construction of the exclusionary language in the device definition; (2) FDA's scientific and regulatory determination that the DSW solution is excluded from the device definition; and, (3) FDA's scientific and regulatory determination that DSW is a combination product that relies on a drug constituent to provide its "primary mode of action." Prevor urges the Court to reach different conclusions than FDA did on all of these issues and find that DSW is a device. Prevor's arguments are grounded in little more than bald assertions that the Court should substitute Prevor's judgments for that of the agency. All of these questions relate to complex scientific facts and application of FDA's statute and regulations. They are also within FDA's congressionally-delegated authority to regulate drugs, devices, and combination products. Therefore, FDA's determinations should be accorded deference. Prevor has not identified any statute, regulation, or scientific information that compels a different result.

DSW consists of two components – a pressurized liquid solution and a dispensing canister – and is intended to mitigate burns caused by hazardous chemicals. Prevor requested FDA to evaluate DSW and "confirm" that the product is a "device." A.R. 001. The agency disagreed with Prevor's assessment and concluded that DSW is a drug-device combination product with a drug "primary mode of action." A.R. 787. FDA reached its conclusion as a matter of statutory construction and regulatory and scientific evaluations.

The key statutory construction issue in this case relates to the device definition. Under the FDCA, the device definition excludes an article if it achieves its "primary intended *purposes*" through chemical action on the body. 21 U.S.C. § 321(h) (emphasis added). This plural language plainly shows that an article may have more than one "primary intended purpose." Although Prevor disputed this construction initially, it now concedes in its reply brief that "a product analyzed under the statutory device definition may have multiple primary intended purposes." Pl.'s Reply at 6.

The remaining issues in the case relate to FDA's application of the FDCA and FDA regulations to determine which center in the agency will have primary regulatory authority for DSW. First, FDA determined that the DSW solution has two primary intended purposes, one of which is achieved by chemical action, and therefore the solution is not a device under 21 U.S.C. § 321(h). Second, FDA determined that, although the DSW solution is a drug, the canister is a device, and therefore DSW is a "combination product" under 21 U.S.C. § 353(g)(1). Third, for combination products, FDA must assign the product to an agency center based on the product's "primary mode of action." 21 U.S.C. § 353(g)(1); 21 C.F.R. §§ 3.2(k), 3.2(m), 3.4. FDA applied its product-jurisdiction regulations and determined that DSW's drug constituent (the

solution) provides the product's "primary mode of action," and therefore DSW should be regulated by FDA's Center for Drug Evaluation and Research.

The undisputed facts in the record demonstrate that FDA, in making these determinations, thoroughly evaluated DSW's method of operation, its chemical and physical composition, and the means by which it achieves its primary intended purposes. See A.R. 015-016, 039-066, 675-677, 784-789. In reaching its decisions, FDA considered Prevor's arguments, including its assertion that certain other products should inform the agency's decision on DSW, and other information offered by Prevor, including the company's studies that purported to quantify the physical and chemical actions of the DSW solution. Id.

Accordingly, because it is undisputed that the statute recognizes that articles may have multiple primary intended purposes, and because the undisputed facts in the record demonstrate that FDA reasonably and properly applied the statute and made the scientific and regulatory determinations that Prevor challenges, the Court should defer to FDA's determinations and enter judgment for the government.

I. FDA Reasonably Determined that the DSW Solution Is Excluded From the Device Definition.

A. FDA's Interpretation of "Primary Intended Purposes" Is Correct.

Under the FDCA, the device definition excludes an article from its ambit if it "achieve[s] its primary intended purposes through chemical action within or on the body." 21 U.S.C. § 321(h). As explained in the government's opening brief, in light of the plural form of "purposes," FDA interprets "primary intended purposes" to allow an article to have more than one primary intended purpose. See Def.'s Mot. Summ. J. at 15-20. The agency gives effect to the word "primary" by qualitatively evaluating an article's intended purposes to determine which

comprise its "primary intended purposes." This evaluation is based on scientific information, and must be conducted on a case-by-case basis, as it is dependent on the specific characteristics of the article being examined.[1]

Prevor argued in its opening brief that FDA must choose one "primary intended purpose" between the purposes achieved by the DSW solution's two actions. See Pl.'s Mot. Summ. J. at 13-14. However, Prevor now concedes, as it must, that Congress's use of "purposes" in the plural forecloses that argument. Pl.'s Reply at 6 ("[A] product analyzed under the statutory device definition may have multiple primary intended purposes."). Nevertheless, Prevor still attempts to narrow the circumstances under which FDA could find that an article has two primary intended purposes. See id. at 6, 9. According to Prevor, "for two intended purposes to both be considered 'primary,' they must contribute comparably to the overall therapeutic effect" of the article. Id. at 9. Elsewhere in its reply, Prevor suggests that the test for "primary intended purposes" should be quantitative. See, e.g., id. at 11-12 (alleging that chemical action contributed at most 10% to the solution's effects and claiming that, as a result, neutralizing chemicals cannot be a primary purpose).

Prevor cites no authority for its "comparabl[e] contribut[ion]" or any other quantitative test, and FDA is aware of none. Congress gave no indication during the 1990 amendments that it intended to place such a restriction on "primary intended purposes" in the device definition. Neither the text of the statute nor its legislative history provides any support for Prevor's revised

[1] FDA recently published a draft guidance on product-classification issues that confirms this approach. Guidance for Industry and FDA Staff: Classification of Products as Drugs and Devices & Additional Product Classification Issues, Draft Guidance (June 2011), available at www.fda.gov/combinationproducts/default.htm. The draft guidance explains that "the applicable statutory criteria" for product classification requires FDA to make these determinations "based on the specific characteristics of the product, including its intended use(s), and the current state of scientific knowledge at the time the classification determination is made." Id. at 5.

interpretation. See Def.'s Mot. Summ. J. at 15-20, 30 (analyzing the legislative history of the device definition).

Contrary to Prevor's assertion that FDA must use a quantitative test to determine when an intended purpose is "primary," the term is not reducible to this type of calculation. Congress and the courts have used "primary purposes" to convey the concept of more than one purpose without any reference to numerical thresholds. See Def.'s Mot. Summ. J. at 19. Accordingly, as described above, FDA conducts a qualitative analysis based on the specific characteristics of each product to determine whether a purpose is "primary."

Prevor also argues that FDA must rely on the interpretation of "primary" in its definition of "primary mode of *action*" to construe "primary intended *purposes*." See Pl.'s Reply at 8-9 (emphases added). This argument does not consider that "primary" is used in different regulatory contexts. FDA regulations define a "primary mode of action" as:

> the *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) (emphases added). A definition that relates to determining the "single" factor making the "greatest contribution" has no logical bearing in construing the plural term "primary intended purposes." Prevor makes no attempt to reconcile this discrepancy.

B. FDA Did Not Change Its Interpretation of "Primary Intended Purposes."

Contrary to Prevor's assertions, Pl.'s Reply at 13-14, 16, FDA has not changed its statutory interpretation of "primary intended purposes." As discussed above, it is undisputed that the plain language of the statute compels the conclusion that, in determining when an article is excluded from the device definition, there may be more than one primary intended purpose. 21

U.S.C. § 321(h). FDA applies this definition by evaluating the specific characteristics of the article being examined on a case-by-case basis. This principle is consistent with long-standing FDA policy.

Prevor bases its claim that FDA changed its interpretation on a mischaracterization of the agency's position: that FDA "apparently" "presumes that all intended purposes are 'primary intended purposes,'" including a purpose achieved by a trivial or *de minimis* amount of chemical action. Pl.'s Reply at 7, 16. In particular, Prevor relies on a phrase, taken out of context, from the FDA Office of Special Medical Programs' ("OSMP") response to Prevor's request for review. That document stated, "if 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." A.R. 786 (emphasis added).

OSMP's use of the phrase "even in part" does not bear the weight that Prevor ascribes to it. The phrase "even in part" simply recognizes that both chemical and physical actions may be involved. The other language in the clause confirms that FDA does not endorse a standard by which a trivial or *de minimis* chemical effect would exclude an article from a device classification. Specifically, the emphasized terms in "if an article *depends* . . . on chemical action . . . to *achieve* any of its *primary intended purposes*" indicate that an insubstantial chemical effect would not satisfy the phrase. Thus, the quoted clause from OSMP's response does not represent any deviation from the statutory construction that Prevor concedes is correct – that there may be more than one primary intended purpose.

Second, when viewed in context of the entire response letter, it is clear that the agency was not creating, endorsing, or relying on a *de minimis* standard. OSMP explained that the DSW

solution "achieves its primary intended purposes through both physical action and chemical action":

> In addition to washing harmful chemicals off the body, the solution is intended to neutralize harmful chemicals on the body. Exposure to various chemicals can lead to chemical reactions on the body resulting in chemical burn injuries. *The solution inhibits such chemical reactions through another chemical action*, i.e., by neutralizing the acids and bases in harmful chemicals, *and through this chemical action, the solution helps prevent or mitigate chemical burn injuries.*

A.R. 786 (emphases added). Thus, OSMP's letter explains that the chemical action in the DSW solution was far from *de minimis*.

Prevor also bases its claim that FDA changed its interpretation of "device" on the agency's classification of blow fly larvae ("medical maggots") and Reactive Skin Decontamination Lotion ("RSDL"). Pl.'s Reply at 9-10, 13-14, 17-22. In its opening brief, the government explained why these products are not analogous to DSW. Def.'s Mot. Summ. J. at 25-27, 34-35. Medical maggots are animals that debride wounds by rasping and tearing necrotic tissue – readily distinguishable from a pressurized canister containing a chemical solution. See id. at 34-35. This difference, and the different classifications for these products, demonstrate the need for, rather than undermine, FDA's case-by-case approach to evaluating the specific characteristics of each article to determine the appropriate classification. And, as described below, unlike the DSW canister, RSDL's device constituent directly removes chemical agents from the skin. Id. at 25-26, 34-35. Because of this difference, the products do not have the same "primary mode of action" and therefore are not assigned to the same agency center for regulation.[2]

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[2] Prevor persists in contending that RSDL would be *classified* differently today under FDA's "new" statutory interpretation of the device definition. See Pl.'s Reply at 13-14. Prevor continues to conflate a product's classification (e.g., a drug, device, or combination product) with a combination product's "primary mode of action." The *classification* of DSW and RSDL is the

Finally, Prevor incorrectly asserts that FDA must offer a reasonable explanation for its change in interpretation, as well as engage in rulemaking to effectuate a new binding standard. Pl.'s Reply at 15-16, 23. These assertions confuse both the facts and the law. Although Prevor is correct that, when an agency changes its established statutory interpretation, it must provide a reasonable explanation for that change, there has been no such change here. As described above, Prevor has now conceded that FDA's interpretation of "primary intended purposes" allows for more than one primary intended purpose, and Prevor makes no argument that this interpretation has changed. The agency cannot be required to offer an explanation for a change in its statutory interpretation when there has been no change, and should not be required to offer an explanation for an undisputed issue.

A rulemaking obligation would be triggered only where the agency had issued a regulation, given that regulation an authoritative interpretation, and then changed its interpretation. Alaska Prof'l Hunters Ass'n, Inc. v. Fed. Aviation Admin., 177 F.3d 1030, 1034

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same, i.e., each product is a combination product with a drug constituent and a device constituent. Prevor's argument actually rests on the difference between the products' "primary mode of action," not their classification.

Additionally, Prevor's cite to statements of the Center for devices and Radiological Health's ("CDRH") reviewer and OCP's technical reviewer is a red herring. Prevor is referring to reviewers' opinions rather than the agency's final decision. The views of individual FDA reviewers that are not adopted as part of a final agency decision are not controlling determinations. See Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1320-21 (D.C. Cir. 1998).

Furthermore, the CDRH reviewer explained that, in her view, a re-analysis of the PMOA of RSDL and M291 (its predecessor product) would likely find that the products have a drug PMOA, not a device PMOA. A.R. 057-058; Def.'s Mot. Summ. J. at 34. This conclusion is based on the reviewer's opinion about the relative importance of the products' constituent parts, not on a new interpretation of the device definition. See A.R. 057-058. In the context of discussing M291, OCP's technical reviewer considered a hypothetical that assumed M291 acted through solubilization. That discussion is not interpreting "primary intended purposes," much less applying an allegedly new legal standard.

(D.C. Cir. 1999); Paralyzed Veterans of Am. v. D.C. Arena, L.P., 117 F.3d 579, 586 (D.C. Cir. 1997). Prevor does not cite to any authoritative agency interpretation of a regulation that has allegedly now been changed. This doctrine is therefore inapplicable.[3]

C. FDA's Application of "Primary Intended Purposes" to the DSW Solution Is Reasonable.

1. The Solution Is Not a Device.

FDA concluded: (1) the DSW solution's primary intended purposes are achieved in part by physical action and in part by chemical action; (2) one of the solution's primary intended purposes is achieved by chemical action on the body; and, (3) because the solution relies on chemical action on the body to achieve one of its primary intended purposes, it is excluded from the device definition. See Def.'s Mot. Summ. J. at 22, 28-30. FDA made this scientific and regulatory determination based on the evidence, and the Court should defer to that reasonable determination.

The record amply supports FDA's determination that one of the DSW solution's primary intended purposes is achieved through chemical action. In making its determination, FDA examined the documents Prevor submitted to the agency – a premarket notification (510(k)), a request for a designation for DSW, a request for review, and supplemental material to the review request – which describe the solution's neutralizing chemical action and its role in preventing or mitigating chemical burn injuries. See A.R. 123-127 (510(k) excerpt), 147-158 (same), 001-004

[3] Although the Washington Legal Foundation, in its amicus brief, argues that FDA's product-jurisdiction regulations "set forth its previous understanding of the meaning of the phrase 'primary intended purposes,'" WLF Amicus at 10, nothing in the text of the regulations supports that argument.

(excerpt of request for designation), 008 (same), 011-013 (same), 725 (excerpt of request for review), 728-731 (same), 773-774 (excerpt of first supplement to request for review).[4]

In determining that the DSW solution is not a "device," OSMP cited Prevor's information on the solution's ability to chemically inactivate acids and bases by turning them into a neutral salt. A.R. 786; Def.'s Mot. Summ. J. at 22-23. As OSMP noted, the solution's inactivating process, i.e., neutralization, helps to prevent or minimize injuries from chemical burns. Id. Prevor's submissions and product labeling make clear that the solution will not mitigate burn injuries almost exclusively by its physical action; the solution's chemical action plays an essential role. In fact, Prevor informed OSMP that "the benefit provided by the chemical action of DSW is valuable, by neutralizing the pH of any remaining offending chemical on the skin surface." A.R. 774 (first supplement to request for review).

In marketing its product, Prevor seeks to capitalize on both the solution's chemical and physical actions. DSW will be marketed "to physically and mechanically remove splashes of acids and bases off the skin by washing them away" *and* "to neutralize acids and bases." A.R. 001. Prevor's marketing objective is evident in Prevor's request for designation and its request for review, and also in DSW's proposed product label. A.R. 001-002 (noting, in the request for designation, the solution's two purposes); A.R. 002 (providing, in the request for designation,

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[4] Prevor faults the agency for considering material in the 510(k), which had been submitted by the company to seek FDA clearance to market DSW. See Pl.'s Reply at 7 n.2; Pl.'s Mot. Summ. J. at 35-36. But Prevor cites no authority for its contention that the agency is precluded from considering Prevor's earlier submission on the same product, nor could it. Notably, Prevor requested a decision on DSW's classification as a direct result of the FDA CDRH response to its 510(k). A.R. 002. The agency was entitled to review and consider the information in the 510(k) because it: (1) was relevant; (2) was provided to FDA by the company; and (3) described the product's physical and chemical actions, which were the very issues before the agency in Prevor's request for designation. Because of Prevor's conflicting representations, the agency had all the more reason to consider the 510(k).

DSW's proposed label bearing the solution's two purposes); A.R. 725 (noting, in the request for review, the solution's two purposes); Def.'s Mot. Summ. J. at 31-32.

Indeed, the proposed DSW label belies Prevor's attempt here to trivialize the solution's chemical action. The label's section entitled "Scope of effectiveness and known limitations" advised that DSW is "[n]ot recommended for use in splashes of hydrofluoric acid and its derivatives or fluorides in acidic milieu." A.R. 003; see A.R. 151. A CDRH reviewer recognized that this caution demonstrated the importance of the chemical action: removal by physical washing alone should work the same way on any type of acid, but chemical action may react adversely (or not react) with certain other chemicals. Thus, as the CDRH reviewer pointed out, if the solution's ability to neutralize chemicals on the skin were minimal, "it is somewhat surprising that *any* chemical would be excluded" from the scope of the product's effectiveness. A.R. 057 (emphasis added).

Finally, Prevor's 510(k) revealed the importance of the ingredient Diphoterine and the role of chemical neutralization when describing the disadvantage of using water alone: "[Water] does not neutralize the chemical; therefore any chemical left on the skin, even if diluted by water, can still penetrate and react with the tissue and cause burns." A.R. 148; Def.'s Mot. Summ. J. at 6-7. The 510(k) explained that the DSW solution "binds to, or reacts with, the chemical to neutralize it, thereby reducing the potency and reactivity of the chemical, as well as the chemical's ability to penetrate and damage skin tissue," because of the Diphoterine.[5] Id.

[5] Prevor's reply brief is so dismissive of the solution's neutralizing effect that it makes DSW seem no different from a container of water. See Pl.'s Reply at 12. At one point, Prevor asserts that one of its studies shows that "a similar amount of DSW liquid or water is required to reach a safe neutral pH of 9.0 pH" when confined to physical action only. Id. If the solution's chemical action were truly as minor as Prevor now claims, the presence of Diphoterine would be superfluous.

2. Prevor's Studies Are Irrelevant and Invalid.

Prevor's only support for asserting that neutralization is not one of the solution's primary intended purposes is the two studies ("Study 1" and "Study 2") described in its request for designation. Pl.'s Reply at 11-13. The studies' quantitative comparisons of the solution's physical and chemical actions are not relevant for determining whether the solution's washing and neutralizing purposes are *primary* intended purposes. See Def.'s Mot. Summ. J. at 23-24. And, after a rigorous evaluation of these studies, FDA determined that the studies did not even support Prevor's claim that the solution's effects are attributable to 90% physical action and 10% chemical action. Id. at 24. FDA concluded that the studies were flawed because they did not simulate the actual conditions of use. Additionally, FDA concluded that one study lacked a control. Id. FDA's thorough review of Prevor's studies is documented in the record.

CDRH's reviewer described Study 1 as "very problematic," A.R. 056, and stated that "neither of the two 'studies' . . . ma[de] any attempt to simulate the conditions of use of the DSW product," A.R. 057. OCP's technical reviewer agreed that the studies "are not appropriate for the proposed indications for use" because they tested the product "on inanimate objects (beakers) that would not absorb or interact in the same way as the skin with acids, bases, or the DSW solution." A.R. 043. OCP's reviewer also noted that Study 2 lacked proper controls because "a water control was not actually performed but was hypothetically calculated." A.R. 042.

CDRH's reviewer provided additional reasons why neither study supported Prevor's assertions about the quantitative relationship between the solution's actions and its effects. A.R. 056-057. Prevor had conducted Study 1 to "'simulate the physical removal and displacement of NaOH [sodium hydroxide]" by the DSW solution. A.R. 056. Among other things, the reviewer concluded that the pH measurements used to monitor the DSW solution's progress in physically

displacing the NaOH were likely inaccurate as a result of improper mixing when the solution was added to the NaOH in the collecting beaker. Id. The reviewer also noted that the study did not even require pH measurements of the "displaced" fluid in the larger collecting beaker but instead unjustifiably assumed that the fluid consisted entirely of NaOH. Id. The reviewer summarized: "I do not believe that this study accurately measured 'displacement' and so I do not see how it can accurately predict the percent" of physical or chemical action of the solution. Id. Regarding Study 2, the reviewer concluded that the pH measurements were likely unreliable for the same reason noted for Study 1, and the method described for Study 2 "is not that which would be used to perform a true neutralization study." A.R. 056-057.

Prevor's two laboratory studies, and Prevor's subjective and self-serving assessments of those studies, do not establish scientific fact, and do not bind the judgment and discretion of the agency to conduct an independent evaluation. FDA evaluated those studies along with all of the other evidence before it and reasonably concluded that chemical neutralization is one of the primary intended purposes of the DSW solution.

II. FDA Reasonably Determined that DSW Is a Combination Product with a Drug "Primary Mode of Action."

Having determined that the solution is not a device, FDA took two additional steps to determine that DSW is a combination product with a drug primary mode of action ("PMOA"). First, FDA determined that DSW is a combination product consisting of two constituent parts – a drug (the solution) and a device (the canister). A.R. 787. Second, based on a "PMOA" analysis required by the agency's product-jurisdiction regulations, FDA reasonably determined that DSW's drug constituent provides the product's PMOA because the solution is more important than the canister in fulfilling the product's therapeutic effects. Def.'s Mot. Summ. J. at 12, 25.

FDA determined that the DSW solution is a "drug" under the FDCA because its intended use is to prevent and minimize accidental chemical burn injuries. Id. Prevor agrees that the canister is a device, Pl.'s Mot. Summ. J. at 13, and does not contest the mechanics of determining whether a product is a combination product. Thus, with respect to FDA's determination that DSW is a combination product, the only contested issue is whether the DSW solution is a device – the same issue discussed in the previous section. If the Court defers to FDA's judgment that the solution is not a device but a drug, then DSW must be classified as a combination product with drug and device constituent parts.

Under the regulations, a PMOA is "the single mode of action of a combination product that provides the most important therapeutic action of the combination product" and "[t]he 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). The constituent parts each contribute a single "mode of action" to a combination product, 21 C.F.R. § 3.2(k); the types of "mode of action" are then compared in a PMOA analysis. Thus, DSW's drug constituent (the solution) contributes a "drug mode of action," its device constituent (the canister) contributes a "device mode of action," and the PMOA analysis determines which constituent part provides the "mode of action" that is DSW's "primary mode of action."

In conducting the PMOA analysis on DSW, OSMP explained, "While the canister sprays the solution onto the body, the solution washes off, neutralizes, and dilutes harmful chemicals that are splashed onto the body." A.R. 787; Def.'s Mot. Summ. J. at 12, 25. OSMP reasoned that "the solution provides the most important therapeutic action of the combination product" because it "directly acts on the body to help prevent or mitigate chemical burn injuries." Id. Therefore, OSMP concluded that DSW's PMOA "is that of the drug constituent." A.R. 787.

Prevor has never contended that the DSW canister provides the product's PMOA because it is expected to make a greater contribution than the solution in achieving the DSW's therapeutic effects.[6] Instead, Prevor takes issue with the divergent results between the agency's PMOA analyses on DSW and another product, RSDL, Pl.'s Reply at 21, which is intended to "remove and/or neutralize" chemical warfare agents and T-2 toxin from the skin, A.R. 787. Whereas DSW has a drug PMOA, the agency found that RSDL's PMOA is provided by its device constituent.[7] Def.'s Mot. Summ. J. at 25-26.

Although DSW and RSDL both have drug and device constituents, key differences between the products account for the different outcomes under the PMOA analyses. RSDL consists of a sponge applicator (its device constituent) and a lotion (its drug constituent) impregnated in the sponge. A.R. 787-788; Def.'s Mot. Summ. J. at 25-26, 33-34. As OSMP explained, RSDL's device constituent "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." A.R. 787. OSMP also noted that RSDL's device constituent "directly removes chemicals from the body." A.R. 788. In contrasting the DSW canister with

[6] Although Prevor's briefs state that the "force imparted by the nozzle provides the impetus to remove the chemical" and that "additional physical action [is] provided by forcible expulsion of the liquid from the canister," Pl.'s Mot. Summ. J. at 30 and Pl.'s Reply at 12 n.4, respectively, those comments do not purport to be a PMOA analysis. Even if they did, Prevor has "not demonstrated that [DSW's] canister provides the PMOA." Def.'s Mot. Summ. J. at 26.

[7] In its submissions to FDA, Prevor agreed that RSDL's device constituent provides the product's PMOA. A.R. 732; Def.'s Mot. Summ. J. at 26 n.7.

RSDL's sponge applicator, OSMP noted that the DSW solution, not its canister, directly removes chemicals from the body.[8] A.R. 787-788; Def.'s Mot. Summ. J. at 25-26.

Prevor argues that FDA should have noted common ground between the drug constituents in DSW and RSDL – that the drug constituents act both physically and chemically – and therefore reached the same conclusion in the PMOA analyses. See Pl.'s Reply at 20-22. But that factor alone is not enough to determine the outcome of a PMOA analysis; FDA's analysis is not as superficial and simplistic as Prevor urges. FDA examines more closely the specific mechanisms of action for each constituent and assesses the actions of the drug constituent in relation to other constituent parts of the product.

Similarly unavailing is Prevor's assertion, both in the context of the device definition and with respect to the PMOA analysis, that FDA did not adequately evaluate "analogous" products in the course of its decision-making on DSW. See Pl.'s Reply at 17, 20. As shown above, FDA closely examined medical maggots and RSDL, the products upon which Prevor chiefly relies, and determined that those products were not regulatory precedents. As the record demonstrates, FDA fully considered other products as well. See A.R. 787-789.

In any event, contrary to Prevor's assertions, FDA is not required to make a detailed record of all products that *Prevor claims* are analogous, when, in fact, they are not. The Administrative Procedure Act requires that an agency's decision is supported by the record and that, based on the agency's explanation, a court can discern the reasonableness of the decision. See Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); Pub. Citizen, Inc. v. Fed. Aviation Admin., 988 F.2d 186, 197 (D.C. Cir. 1993). An

[8] The FDA press release announcing RSDL's clearance, which Prevor cited, Pl.'s Reply at 21-22, did not assess the relative actions of the drug and device constituents and therefore does not refute OSMP's analysis. See A.R. 176.

agency is not required "to distinguish every precedent cited to it by an aggrieved party" where the past decisions "involve materially different situations." LeMoyne-Owen College v. NLRB, 357 F.3d 55, 60-61 (D.C. Cir. 2004) (citations omitted). The products regulated by FDA involve diverse and distinct characteristics and mechanisms of action and, for a particular product, there may not be an available precedent.

III. Conclusion.

As explained above and in the government's opening brief, FDA properly concluded, based on the undisputed facts in the administrative record and in the exercise of its scientific and regulatory expertise, that: (1) the DSW solution is not a device; (2) DSW is a drug-device combination product; and, (3) DSW's drug constituent provides its "primary mode of action." Therefore, DSW is properly assigned to CDER for regulation. Accordingly, the Court should defer to FDA's reasonable decision-making and should grant the government's motion for summary judgment, and deny Prevor's motion for summary judgment.

Respectfully submitted,

RONALD C. MACHEN JR.
United States Attorney

TONY WEST
Assistant Attorney General
Civil Division

MAAME EWUSI-MENSAH FRIMPONG
Acting Deputy Assistant Attorney General

MICHAEL S. BLUME
Director

MARK L. JOSEPHS
Assistant Director

Of Counsel:

WILLIAM B. SCHULTZ
Acting General Counsel
Food and Drug Division
Office of General Counsel
U.S. Dep't of Health and Human Services

ELIZABETH H. DICKINSON
Acting Chief Counsel

ERIC M. BLUMBERG
Deputy Chief Counsel for Litigation

CLAUDIA J. ZUCKERMAN
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
White Oak 31, Room 4550
Silver Spring, MD 20993-0002

By: /s/ JOHN W. M. CLAUD

JOHN W. M. CLAUD (D.C. Bar No. 497900)
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
202-307-5747

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CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing Reply Memorandum in Support of Defendant's Motion for Summary Judgment to be served via the District Court's electronic filing (ECF) system upon:

Jeffrey N. Gibbs (D.C. Bar No. 385294)
John R. Fleder (D.C. Bar No. 176123)
Anne K. Walsh (D.C. Bar No. 464858)
Jennifer M. Thomas (D.C. Bar No. 987518)
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
Phone: (202) 737-5600
Fax: (202) 737-9329
Attorneys for Plaintiff

By: /s/ JOHN W. M. CLAUD
JOHN W. M. CLAUD (D.C. Bar No. 497900)
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
202-307-5747

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