

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MIMEDX GROUP, INC.,

Plaintiff,

v.

U.S. FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

CIVIL ACTION NO.
1:24-cv-01287-TRJ

ORDER

Plaintiff MiMedx Group, Inc. (“MiMedx”) is a biomedical company based in Marietta, Georgia. (Doc. 46 at 10). In 2022, MiMedx began manufacturing a wound-care product called AXIOFILL which needed approval from the U.S. Food and Drug Administration (the “FDA”) before it could be sold to the general public. (*Id.*) On March 22, 2024, the FDA classified AXIOFILL as a “biological” product, a classification that carries heightened regulatory requirements. (Doc. 46-1 at 138–39). MiMedx argues the FDA should have classified AXIOFILL as a “361 HCT/P,” a classification that has less stringent regulatory requirements, and the FDA’s failure to do so was arbitrary and capricious under the Administrative Procedure Act (the “APA”), 5 U.S.C. § 706(2)(A). (Doc. 67 at 6–7). After a hearing and two rounds of briefing, the Court agrees, in part.

BACKGROUND

A. FDA Regulatory Overview

This case turns on the interpretation of the Public Health Service Act (the

“PHSA”), 42 U.S.C. § 201, *et seq.*, the Food, Drug, and Cosmetic Act (the “FDCA”), 21 U.S.C. § 301, *et seq.*, and the promulgating regulations. Before turning to the parties’ claims, a discussion of the regulatory context is helpful.

1. Biological Products and Devices

The FDA regulates biological products under the PHSA. (Doc. 46-1 at 131–32). A biological product is “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product . . . applicable to the prevention, treatment, or cure of a disease. 42 U.S.C. § 262(i)(1). Companies must obtain the FDA’s approval before marketing a biological product. *Id.* § 262(a)(1).

The FDA regulates devices under the FDCA. Generally, a device is an instrument “intended for use in the diagnosis of diseases or other conditions, or in the cure, mitigation, treatment, or prevention of disease,” which “does not achieve its primary intended purposes through chemical action within or on the body” and “which is not dependent upon being metabolized for the achievement of its primary intended purposes.” 21 U.S.C. § 321(h)(1). Companies must obtain the FDA’s approval before marketing a device. 21 U.S.C. §§ 360(k),(l),(m).

2. Human Cells, Tissues, or Cellular Tissue-Based Products

The FDA also regulates certain human cells, tissues, and cellular and tissue-based products, known as “HCT/Ps.” (Doc. 46-2 at 131). HCT/Ps are “articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.” (*Id.* (citing 21 C.F.R.

§ 1271.3(d))). Because “different HCT/Ps may present different concerns,” the FDA established a “tiered, risk-based approach” to regulating them. (*Id.* at 131–32); Human Cells, Tissues, and Cellular and Tissue-Based Products, Establishment Registration and Listing, 66 Fed. Reg. 5447, 5449 (Jan. 19, 2001) (codified at 21 C.F.R. § 1271). Under this approach, HCT/Ps that meet the four criteria listed in 21 C.F.R. § 1271.10 enjoy lighter regulatory burdens, including exemption from premarket review, and are commonly referred to as “361 HCT/Ps.” (*Id.* at 132); *see also United States v. U.S. Stem Cell Clinic, LLC*, 998 F.3d 1302, 1305 (11th Cir. 2021) (“361 HCT/Ps . . . are regulated under § 361 of the PHSA . . . only to prevent the spread of infectious disease.”). Pursuant to 21 C.F.R. § 1271.10(a),

[a]n HCT/P is regulated solely under section 361 of the [PHSA] and the regulations in this part if it meets all of the following criteria:

- (1) The HCT/P is minimally manipulated;
- (2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer’s objective intent;
- (3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
- (4) Either:
 - (i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
 - (ii) The HCT/P has a systemic effect or is dependent

upon the metabolic activity of living cells for its primary function, and:

- (a) Is for autologous use;
- (b) Is for allogeneic use in a first-degree or second-degree blood relative; or
- (c) Is for reproductive use.

21 C.F.R. § 1271.10(a). An HCT/P that fails to satisfy one or more criteria is instead regulated as a biological product under the PHSA, or as a drug or device under the FDCA, and subject to heightened regulatory burdens. (Doc. 46-2 at 132–33); *see U.S. Stem Cell Clinic*, 998 F.3d at 1305.

Here, two of the four criteria are relevant: (1) the minimal manipulation criterion and (2) the homologous use criterion (Doc. 33 at 7; Doc. 38 at 13); 21 C.F.R. § 1271.10(a)(1), (2). “Minimally manipulated” means “processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement.” *Id.* § 1271.3(f). “Homologous use” is defined as “the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with an HCT/P that performs that same basic function or functions in the recipient as in the donor.” 21 C.F.R. § 1271.3(c).

B. MiMedx’s Product: AXIOFILL

In 2022, MiMedx launched its wound-care product AXIOFILL, a dry powder consisting of extra-cellular matrix (“ECM”) from human placental tissue. (Doc. 46-1 at 123). “ECM is a network of native macromolecules that provide structural support to surrounding cells and tissue components.” (*Id.*) To make AXIOFILL, MiMedx collects donated human placental tissue from mothers delivering healthy babies via

C-section and isolates the placental disc ECM through a series of processing steps. (Doc. 46-2 at 30). These steps include soaking and rinsing the tissue to wash away other cells so that only the ECM remains. (Doc. 46-1 at 127–28). Then, the ECM is cut and ground into particles approximately 1mm in diameter, and the resulting powder can be applied to irregular shaped wounds. (Doc. 46-1 at 129).¹ Specifically, AXIOFILL is intended to “replace or supplement damaged or inadequate integumental tissue,” which “refers to the body’s outermost layer and protective covering, in particular the skin” that is “anything less than healthy, intact skin.” (Doc. 46-1 at 129). In other words, AXIOFILL provides a physical scaffold on wounds to support the growth of new cells. (Doc. 46-1 at 129).

It is undisputed that AXIOFILL is an HCT/P. (*Id.*) The parties, however, dispute whether AXIOFILL should be classified as a 361 HCT/P, a biological product, or a device. (Doc. 33 at 6; Doc. 38 at 7).

C. MiMedx’s Pre-Request for Designation and the FDA’s Evaluation

On March 22, 2023, MiMedx submitted a Pre-Request for Designation (“Pre-RFD”) to the FDA seeking a preliminary classification of AXIOFILL as a 361 HCT/P. (Doc. 46 at 5). A Pre-RFD is submitted by a sponsor, like MiMedx, to “obtain preliminary feedback” from the FDA as to whether a product is classified as a 361 HCT/P or as a drug, device, or biological product. (Doc. 46-2 at 153–54). In its Pre-

¹ To better understand ECM and AXIOFILL’s manufacturing process, MiMedx provides a useful analogy: ECM is the “structural support for cells throughout the body,” like “the frame of a house”—MiMedx collects placental disc tissue, and it “processes the tissue to remove the cells and isolate the ECM (like stripping a house down to its frame).” (Doc. 33 at 6; Doc 46-1 at 116).

RFD, MiMedx asserted that AXIOFILL satisfied the four criteria required to be regulated as a 361 HCT/P under 21 C.F.R. § 1271.10(a) because it is: (1) minimally manipulated; (2) intended for homologous use; (3) not combined during manufacturing with another article; and (4) does not have a systemic effect or depend upon the metabolic activity of living cells for its primary function. (Doc. 46 at 5, 20–22).

On October 18, 2023, the FDA issued its Pre-RFD evaluation, responding that AXIOFILL appeared to be an HCT/P that “does not meet all the criteria” for a 361 HCT/P, specifically the first and second criteria. (Doc. 46-1 at 22–23). First, the FDA preliminarily found that AXIOFILL does not meet the minimal manipulation criterion because the manufacturing process “alters the original structural characteristics” of the placental disc tissue’s “utility to act as a selective barrier that provides a transport function between circulatory systems (e.g., the fetal maternal systems).” (*Id.* at 24). In other words, the FDA concluded that the placental disc tissue is “likely altered by the processing described” by MiMedx and thus is not minimally manipulated. (*Id.* at 25). Second, in a footnote, the FDA stated that AXIOFILL “also does not appear to meet the other criteria in 1271.10(a), including, for example, [the homologous use criterion].” (*Id.* at 27 n.16). The FDA declined to elaborate further because failure to meet one criterion—here, minimal manipulation—is disqualifying for classification as a 361 HCT/P. (*Id.*)

Instead, the FDA preliminarily concluded that AXIOFILL “appears to be a biological product.” (*Id.* at 27). As defined above, a biological product is “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative,

allergenic product, protein, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.” 42 U.S.C. § 262 (i)(1). Relying on the fact that AXIOFILL “is comprised of placental ECM proteins . . . which are intended to treat injured skin by replacing or supplementing missing or damaged ECM,” the FDA concluded a biological product classification was proper. (*Id.*) The FDA also explained that “AXIOFILL does not appear to meet the device definition” because a device must “not achieve its primary intended purposes through chemical action within or on the body of man,” and “[t]he available information indicates that AXIOFILL achieves its primary intended purposes through chemical action within or on the body.” (Doc. 46-1 at 27).

D. MiMedx’s Request for Designation

On January 12, 2024, MiMedx submitted a Request for Designation (“RFD”) to the FDA. (*Id.* at 123). An RFD is a written request submitted by a sponsor, like MiMedx, to “obtain formal Agency decision regarding the regulatory identity or classification of an HCT/P.” (Doc. 46-2 at 154). In its RFD, MiMedx again asserted that AXIOFILL meets all the criteria to be a 361 HCT/P. (Doc. 46-1 at 129). Additionally, MiMedx responded to the FDA’s position that AXIOFILL failed to meet the minimal manipulation and homologous use criteria. (*Id.* at 130–32).

MiMedx challenged the FDA’s Pre-RFD conclusion that AXIOFILL was not minimally manipulated on three grounds. (*Id.*) First, it argued the FDA focused on the “wrong unit of analysis” by evaluating whether the whole placental disc was minimally manipulated instead of evaluating whether the placental disc tissue ECM

was minimally manipulated. (*Id.* at 131). Second, MiMedx argued that “even if the placental disc as a whole were the proper unit of analysis, the ability of the placental disc to act as a selective barrier that provides a transport function would not be a ‘relevant’ characteristic that must be preserved in order for the tissue to be minimally manipulated.” (*Id.*) Third, MiMedx argued that the FDA’s assessment of AXIOFILL was inconsistent with its treatment of similar products. (*Id.* at 133–34). For example, in 2004, the FDA classified “essentially the same” product as a 361 HCT/P and classified a similarly functioning product—“demineralized bone matrix (DBM) powder”—as a 361 HCT/P. (*Id.* at 134–37).

MiMedx argued further that the FDA seemed to be “led astray by the same errors” in its brief footnote regarding homologous use. (*Id.* at 132). MiMedx reiterated that AXIOFILL is intended for homologous use because the ECM performs the same basic function—providing structural support for surrounding cells—in the tissue donor and the recipient. (*Id.* at 132–33).

E. The FDA’s Final Decision

On March 22, 2024, the FDA issued its final decision via Designation Letter that AXIOFILL is a biological product rather than a 361 HCT/P. (Doc. 46-1 at 138). In its Designation Letter, the FDA reiterated that for AXIOFILL to be minimally manipulated, it must retain the original characteristics of “the placental disc as a whole” that relate to “how [the placental disc] functions in the donor”—not the characteristics of the ECM intended for implantation in the recipient. (*Id.* at 141). The FDA, therefore, concluded that AXIOFILL is not minimally manipulated, as its

processing likely alters “the native placental disc’s . . . ability to act as a selective barrier that provides a transport function between . . . the fetal and maternal circulatory systems.” (*Id.* at 144). The FDA also denied AXIOFILL was similarly situated to other products that were classified as 361 HCT/Ps. (*Id.* at 145).

In addition to finding that AXIOFILL is not minimally manipulated, the FDA again stated in a footnote that the product “does not appear to meet” the homologous-use criterion. (*Id.* at 149–50 n.27). And because AXIOFILL “must meet all the criteria” to be regulated as a 361 HCT/P, the agency noted “it is not necessary to address the other criteria . . . including [the homologous use criterion].” (*Id.*)

F. This Action

On March 25, 2024, MiMedx filed suit under the APA, claiming that the FDA’s classification of AXIOFILL must be set aside as arbitrary, capricious, and contrary to law. (Doc. 1). On May 28, 2024, the parties filed a joint motion for an order setting a summary judgment briefing schedule, requesting that the Court decide the merits of the case on cross-motions for summary judgment “[b]ecause review of an agency action is generally limited to the administrative record.” (Doc. 25 at 2–3). The Court granted the parties’ joint motion on June 11, 2024, suspending the requirements under Local Rule 56.1(B)(1) and ordering any factual assertions in the parties’ summary judgment briefing to be accompanied by a citation to the administrative record. (Doc. 27 at 2). Both parties moved for summary judgment and filed a joint appendix containing those portions of the administrative record cited in the briefing. (Docs. 33, 36, 38, 46). On September 25, 2025, the Court denied the cross-motions

without prejudice and directed the parties to file new briefs applying the standard outlined in *Kisor v. Wilkie*, 588 U.S. 558 (2019). (Doc. 60). On December 26, 2025, the parties filed their renewed motions for summary judgment. (Docs. 64, 67).

LEGAL STANDARDS

A. Summary Judgment

A “court shall grant summary judgment if the movant shows 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). However, “[w]hen a party seeks review of agency actions under the APA, the district judge sits as an appellate tribunal. The entire case on review is a question of law.” *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083–84 (D.C. Cir. 2001) (citation modified). Thus, “the normal rules of summary judgment do not apply,” and instead, summary judgment is “the mechanism for deciding whether as a matter of law the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review.” *In re ACF Basin Water Litig.*, 554 F. Supp. 3d 1282, 1294 (N.D. Ga. 2021).

B. APA Review

The APA provides that “[a] person suffering legal wrong because of agency action, or adversely aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.” 5 U.S.C. § 702. Courts may “hold unlawful and set aside agency actions, findings, and conclusions” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). As the Supreme Court recently explained, “[o]ur well-worn arbitrary-

and-capricious standard ensures that an administrative agency examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *Food & Drug Admin. v. Wages & White Lion Invs, L.L.C.*, 604 U.S. 542, 567 (2025) (quoting *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)) (citation modified).

Though “well-worn,” the Supreme Court has refined its guidance on the proper scope of a district court’s review of agency action with respect to statutes and regulations. In *Kisor v. Wilkie*, the Supreme Court held that courts may not defer to an agency’s interpretation of its own regulations “unless the regulation is genuinely ambiguous.” 588 U.S. 558, 574 (2019). In deciding whether there is genuine ambiguity, a court “must exhaust all the traditional tools of construction,” and “cannot wave the ambiguity flag just because it found the regulation impenetrable on first read.” *Id.* at 575 (citation modified). If after “carefully consider[ing] the text, structure, history, and purpose of a regulation” a court finds “genuine ambiguity remains, . . . the agency’s reading must still be reasonable” for it to enjoy deference. *Id.* (citation modified).

DISCUSSION

The question before the Court is whether the FDA’s decision to classify AXIOFILL as a biological product—rather than a 361 HCT/P or device—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. (Docs. 64, 67); 5 U.S.C. § 706.

A. The FDA’s Decision that AXIOFILL is More than Minimally Manipulated

In its Designation Letter, the FDA determined that AXIOFILL is not a 361 HCT/P because it does not meet the minimal manipulation criterion under 21 C.F.R. § 1271.10(a)(1) and § 1271.3(f). (Doc. 46-1 at 140). MiMedx argues that, based on the plain language of these regulations, AXIOFILL is minimally manipulated and that the FDA’s conclusion otherwise was contrary to law and arbitrary and capricious. (Doc. 67 at 18–30). The FDA, however, maintains its findings were proper under the plain meaning of its unambiguous regulations. (Doc. 65 at 7–8, 18). Put differently, the parties dispute the meaning of the minimal manipulation criterion in 21 C.F.R. § 1271.10(a), as further defined in § 1271.3(f). (Doc. 67 at 21; Doc. 65 at 20, 25). Because this dispute raises an issue of regulatory interpretation by an agency, *Kisor* applies. 588 U.S. at 575; (Doc. 60).

Before beginning the *Kisor* analysis, it is helpful to provide an overview of the regulations at issue. Under 21 C.F.R. § 1271.10(a), “[a]n HCT/P is regulated solely under section 361” if “[t]he HCT/P” is, among other things, “minimally manipulated.” And, pursuant to 21 C.F.R. § 1271.3(f)(1), “minimal manipulation means . . . processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement.” Specifically, the parties disagree on:

- (1) the unit of analysis—i.e., what “[t]he HCT/P” and “the tissue” refers to—under 21 C.F.R. § 1271.10(a) and in the content of § 1271.3(f); and
- (2) the “original relevant characteristics” of a tissue “relating to the tissue’s

utility for reconstruction, repair, or replacement” under § 1271.3(f).

(Doc. 65 at 20–27; Doc. 67 at 22).

Because the meaning of “the HCT/P” in 21 C.F.R. § 1271.10(a) and “the original relevant characteristics” in § 1271.3(f) present an issue of regulatory interpretation, the Court must decide whether the terms, as used in the regulations, unambiguously supports either party’s interpretation. *U.S. Stem Cell Clinic*, 998 F.3d at 1308. “[I]f there is only one reasonable construction of [the] regulation[s],” courts simply apply that meaning without any deference to the agency. *Kisor*, 588 U.S. at 575. To determine if regulatory language has more than one reasonable construction, courts must examine “text, structure, history, and purpose” of the regulation. *Id.* at 590. In conducting this analysis, courts afford “the agency’s view no special weight except to the extent it has the power to persuade.” *U.S. Stem Cell Clinic*, 998 F.3d at 1308 (citation modified). Only after “exhaust[ing] all the traditional tools of construction” may a court deem a rule genuinely ambiguous and invoke agency deference under *Kisor*. 588 U.S. at 590 (citation omitted).

1. Unit of Analysis

MiMedx argues that the plain text of 21 C.F.R. § 1271.10(a) and § 1271.3(f) “make[] clear that the proper unit of analysis is the specific HCT/P that FDA is classifying for regulation, not any larger organ from which that HCT/P was isolated.” (Doc. 67 at 23). In other words, rather than asking whether the *whole placental disc* was minimally manipulated, as the FDA did here, MiMedx argues that the FDA should have asked whether *the ECM* itself was minimally manipulated under the

unambiguous regulations. (*Id.* at 22–24).

The Court “begin[s], as always . . . with text and structure” of the relevant regulations. *Callahan v. U.S. Dep’t of Health & Human Servs.*, 939 F.3d 1251, 1259 (11th Cir. 2019) (citation modified). Section 1271.10(a) provides that, to be classified as a 361 HCT/P, “[t]he HCT/P” must be “minimally manipulated.” An HCT/P is defined as an “article[] containing or consisting of human cells or tissues that are intended for implantation” into a human patient. 21 C.F.R. § 1271.3(d). Here, the article “containing or consisting of human . . . tissues that are intended for implantation” is AXIOFILL, which is comprised of ECM from placental disc tissue. (Doc. 46-1 at 123). Therefore, the plain text of § 1271.10(a) suggests, upon first reading, that “[t]he HCT/P” that must be “minimally manipulated” is AXIOFILL.

But the analysis does not end there. The text of the regulations under § 1271.3(f)(1) provide additional context for § 1271.10(a). “Minimal manipulation” means “[f]or structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement.” 21 C.F.R. § 1271.3(f)(1). Here, “the tissue” that is processed is the placental disc. MiMedx repeatedly admitted as much in its RFD. (Doc. 46-1 at 123, 128 (“AXIOFILL is made from human placental disc The placental disc is processed in a series of steps.”)).

There is also no precedent indicating that an HCT/P, post-processing, is the proper unit of analysis for minimal manipulation. Nonetheless, MiMedx cites *U.S. Stem Cell Clinic* for the proposition that the FDA should “compare stem cells to stem

cells.” 998 F.3d at 1311. In *United States v. U.S. Stem Cell Clinic, LLC*, the company seeking FDA classification isolated stem cells from fat tissue and injected those stem cells into patients. *Id.* at 1304. The FDA argued that, “to satisfy the homologous use criterion,” the injected stem cells must serve the same “basic function” as the fat tissue, namely providing “cushioning and support.” *Id.* at 1310 (citation modified). The Eleventh Circuit found that the proper unit of analysis was the stem cells rather than the fat tissue, and that the FDA must “compare stem cells to stem cells.” *Id.* at 1310–11. MiMedx argues that, “[b]y the same logic, here, [the] FDA should have compared the post-processing ECM to the pre-processing ECM, not the placental disc from which the ECM was isolated.” (Doc. 67 at 27). But *U.S. Stem Cell Clinic* only analyzed the homologous use criterion under § 1217.10(a)(2)—which is a wholly separate criterion from minimal manipulation defined under § 1217.10(a)(1)—and it addressed stem cells rather than structural tissue. 998 F.3d at 1311. Under the minimal manipulation regulatory definition, structural tissue (like ECM) and cells (like stem cells) are defined differently. *Compare* 21 C.F.R. § 1271.3(f)(1) (defining minimal manipulation “[f]or structural tissue” as “processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement) *with* 21 C.F.R. § 1271.3(f)(2) (providing that, “[f]or cells” minimal manipulation means “processing that does not alter the relevant biological characteristics”). Because *U.S. Stem Cell Clinic* considered a wholly separate definition under § 1271.3(f)(2), it does not demand an ECM-to-ECM interpretation of the minimal manipulation standard here. 998 F.3d at 1311. Thus,

U.S. Stem Cell Clinic, while potentially relevant to the FDA’s homologous use evaluation, is inapposite to the question before the Court.

Moreover, beginning the minimal manipulation inquiry with a post-processed tissue like AXIOFILL that does not exist in nature would also undermine the purpose of the regulations. *Kisor*, 588 U.S. at 575. The FDA promulgated the 361 HCT/P criteria as the “dividing line between HCT/Ps that present a lower degree of” risk and those that “may present a greater degree of . . . risk and therefore should be subject to premarket review requirements to help ensure safety and effectiveness.” (Doc. 46-1 at 142); *see also* Human Cells, Tissues, and Cellular and Tissue-Based Products, Establishment Registration and Listing, 66 Fed. Reg. 5447, 5449 (Jan. 19, 2001) (codified at 21 C.F.R. § 1271) (The regulation . . . will further the goal of preventing the transmission of communicable disease.”). The minimal manipulation criterion serves that purpose because “HCT/Ps whose original relevant characteristics have been meaningfully altered present heightened risk and require greater regulation.” (Doc. 46-1 at 142). Therefore, analyzing the placental disc ECM alone, which is the result of multi-step processing and decellularization, would undermine the purpose of the minimal manipulation criterion by neglecting to account for potential alterations. (*See id.*) Thus, while AXIOFILL may be “the HCT/P” that must be “minimally manipulated” under § 1271.10(a), the definition of minimal manipulation under 21 C.F.R. § 1271.3(f)(1) demands starting with the original tissue: here, the placental disc tissue.

2. The FDA's Identification of "Relevant Characteristics"

Next, MiMedx argues that, even if the whole placental disc tissue were the proper unit of analysis, the FDA's decision would still be contrary to law because it misidentified the "relevant characteristics" of a placental disc under 21 C.F.R. § 1271.3(f)(1). This again raises a question of regulatory interpretation, so *Kisor* applies. *Kisor*, 588 U.S. at 575.

An HCT/P is minimally manipulated if processing "does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement." 21 C.F.R. § 1271.3(f)(1). The parties dispute what the placental disc's "relevant characteristics" are under the minimal manipulation criterion. (Doc. 65 at 28; Doc. 67 at 25). According to the FDA, "relevant characteristics" are those "relating to the tissue's utility for reconstruction, repair, or replacement" *in the donor*—here, the placental disc's ability to act as a "selective barrier . . . between . . . the fetal and maternal circulatory systems." (Doc. 46-1 at 141; Doc. 65 at 29). Conversely, MiMedx maintains the "relevant characteristics" are those that contribute to the tissue's utility *in the recipient*—here, the ECM's ability to provide a scaffold for cellular growth on a patient's wound. (Doc. 67 at 25).

Based on the plain text of the regulation, the "relevant characteristics" of the placental disc tissue under § 1271.3(f)(1) are those relating to its function in the recipient—not the donor. *Kisor*, 588 U.S. at 589–90. Again, § 1271.3(f)(1) provides that an HCT/P is minimally manipulated if processing "does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction,

repair, or replacement.” The phrase “original . . . characteristics of the tissue” references the placental disc tissue as it appears in the donor. 21 C.F.R. § 1271.3(f)(1). *Original*, THE MERRIAM-WEBSTER DICTIONARY, <https://merriam-webster.com/dictionary/original> (last visited July 13, 2026) (defining “original” as “of, relating to, or constituting an origin or beginning”). But that phrase is expressly qualified by limiting “original . . . characteristics” to only those that are “relevant to” a tissue’s “utility for reconstruction, repair, or replacement.” 21 C.F.R. § 1271.3(f)(1); *Relevant*, THE MERRIAM-WEBSTER DICTIONARY, <https://merriam-webster.com/dictionary/relevant> (last visited July 13, 2026) (defining “relevant” as “having significant and demonstrable bearing on the matter at hand”). “Utility” is defined as “fitness for some purpose or worth to some end or something useful or designed for use.” *Utility*, THE MERRIAM-WEBSTER DICTIONARY, <https://merriam-webster.com/dictionary/utility> (last visited July 13, 2026). And it is the recipient, not the donor, who *utilizes* the tissue for “reconstruction, repair, or replacement.” *See Vitti Labs, LLC, v. U.S. Food & Drug Admin.*, No. 4:25-cv-00011-BCW, Doc. 47 at 7 (W.D. Mo. Mar. 18, 2026) (holding that reconstruction, repair, or replacement “occurs only in a recipient”)²; Doc. 74-1 at 8.

² The Court takes judicial notice of the Western District of Missouri action *Vitti Labs, LLC, v. U.S. Food and Drug Administration*, No. 4:25-cv-00011-BCW, which MiMedx provided in its notices of supplemental authority. (Doc. 75 (the *Vitti Labs* decision); Doc. 76 (the *Vitti Labs* order denying a motion for reconsideration)). *Vitti Labs* is not yet available on Westlaw or Lexis. *See United States v. Raygoza-Garcia*, 902 F.3d 994, 1001 (9th Cir. 2018) (“A court may take judicial notice of undisputed matters of public record, which may include court records available through PACER.”). Nonetheless, the Court finds *Vitti Labs* helpful and persuasive in its analysis of the “relevant characteristics” language in 21 C.F.R. § 1271.3(f)(1). Indeed, it is the only case this Court is aware of that has directly addressed this issue.

Thus, the proper inquiry is whether the placental disc tissue maintains original characteristics that are relevant to its “utility for reconstruction, repair, or replacement” in the recipient—not the donor. *Id.* (concluding that “the FDA is required to consider all function of the umbilical cord that may benefit a recipient”).

The FDA’s interpretation that the only original characteristic is the placental disc’s ability to act as a “selective barrier . . . between . . . the fetal and maternal circulatory systems” is, therefore, erroneous. (Doc. 46-1 at 141). Indeed, 21 C.F.R. § 1271.3(f)(2) “does not instruct the FDA to consider only identical uses.” *Vitti Labs*, Doc. 47 at 9. “If the FDA had intended to focus the analysis strictly on the donor, it could have written it accordingly, but it did not.” *Id.* at 7. Instead, the plain language of the regulation provides that the FDA must consider the original characteristics of the placental disc tissue that are useful for reconstruction, repair, or replacement in a recipient. *Id.* at 9; 21 C.F.R. § 1271.3(f)(1). This interpretation is consistent with the purpose and history of the regulations, too, which is “to improve protection of the public health without imposing unnecessary restrictions on research, development, or the availability of new products.” Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447 (Jan. 19, 2001). Requiring AXIOFILL to maintain a precisely identical function to the placental disc, despite retaining the placental disc’s ECM function for structural support, would make the minimal manipulation criterion nearly insurmountable for otherwise safe products. *Id.*; *see also Vitti Labs*, Doc. 47 at 8 (“The entire regulatory scheme for HCT/P’s revolves around sending safe products to patients, so it would not

be logical to cut out consideration of recipients in the minimal manipulation analysis.”).

Because the FDA concluded, based on an erroneous interpretation of 21 C.F.R. § 1271.3(f)(1), that the only original relevant characteristic of a placental disc is its function as a “selective barrier . . . between . . . the fetal and maternal circulatory systems,” the FDA’s interpretation of § 1271.3(f)(1) with respect to AXIOFILL is vacated and remanded. (Doc. 46-1 at 141); *Fed. Power Comm’n v. Transcont’l Gas Pipe Line Corp.*, 423 U.S. 326, 331 (1976) (“If the decision of the agency ‘is not sustainable on the administrative record made, then the . . . decision must be vacated and the matter remanded . . . for further consideration.”) (citation omitted). The FDA is instructed to revisit its determination that AXIOFILL is not minimally manipulated based on 21 C.F.R. § 1271.3(f)(1) consistent with the regulatory requirement that the placental disc tissue maintains original characteristics that are relevant to its “utility for reconstruction, repair, or replacement” in the recipient.

B. The FDA’s Footnote on Homologous Use

In its Designation Letter, the FDA concluded in a footnote that AXIOFILL “does not appear to meet other criteria” to be classified as a 361 HCT/P, “including, for example, 1271.10(a)(2) [the homologous use criterion].” (Doc. 46-1 at 148–49 n.27). MiMedx contends that this finding was ill-explained and that the FDA’s conclusory statement will lead the parties back to court shortly after remand on the homologous use criterion. (Doc. 67 at 36). The FDA maintains that its mention of the homologous

use criterion was not “final agency action” subject to judicial review. (Doc. 71 at 20).³

Under the APA, only “final agency action” is subject to judicial review. 5 U.S.C. § 704; *Holistic Candles & Consumers Ass’n v. Food & Drug Admin.*, 664 F.3d 940, 943 (D.C. Cir. 2012) (“The APA, however, only provides a right to judicial review of *final* agency action.” (citation modified)). For agency action to be final, it must: (1) “mark consummation of the agency’s decision making process . . . [and] it must not be of merely tentative nature,” and (2) determine “rights or obligations . . . from which legal consequences will flow.” *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (citation modified). Neither of the two requirements are met regarding the FDA’s homologous use criterion footnote. A single four-sentence footnote, in the context of a 13-page, single-spaced Designation Letter discussing other criterion cannot be said to “mark the consummation” of the FDA’s decision making process regarding homologous use. *Id.* Indeed, the FDA simply “[n]ote[d]” that AXIOFILL “does not *appear* to meet . . . for example, [homologous use criterion],” (Doc. 46-1 at 148–49 n.27); *Holistic Candles & Consumers Ass’n*, 664 F.3d at 943–45 (finding no final agency action where “letters at issue advise . . . that ‘it *appears* [the products] are intended to mitigate or treat,’ the listed disorders”). This comment is, at most, an observation rather than a final binding determination. *See id.* And although legal consequences flow from the Designation Letter as a whole, the FDA’s remark as to the homologous use criterion does not determine MiMedx’s legal rights or obligations.

³ Because there is no dispute regarding the FDA’s interpretation of the homologous use criterion under 21 C.F.R. § 1271.10(a)(2), *Kisor* does not apply.

DRG Funding Corp. v. Sec’y of Hous. & Urban Dev., 76 F.3d 1212, 1214 (D.C. Cir. 1996) (“Courts have defined a nonfinal agency order as one, for instance, that does not itself adversely affect complainant but only affects his rights adversely on the contingency of future administrative action.”) (citation modified). Because the FDA’s footnote on AXIOFILL’s potential failure to satisfy the homologous use criterion is a non-final agency action, it is not subject to this Court’s review. 5 U.S.C. § 704.

C. The FDA’s Classification of AXIOFILL as a Biologic Rather than a Device

Finally, MiMedx challenges the FDA’s classification of AXIOFILL as a biological product rather than a device. (Doc. 67 at 38).⁴ Specifically, MiMedx argues that the FDA, by classifying AXIOFILL as a biological product despite classifying similar products as devices, “acted arbitrarily and capriciously.” (*Id.*)

A “device” is an article intended for medical use that does “not achieve its primary intended purposes through chemical action within or on the body of man or other animals.” 21 U.S.C. § 321(h)(1). In its Designation Letter, the FDA explained that “[t]he primary intended purpose of [AXIOFILL] is treatment of injured skin by replacement or supplementation of missing or damaged ECM” which, according to “[t]he available information” and “the scientific literature,” involves “chemical action within or on the body.” (Doc. 46-1 at 149–51). But, according to MiMedx, the FDA has “classified as devices many similar ECM products with the same components.” (Doc. 67 at 39). MiMedx summarized these products in a chart:

⁴ The *Kisor* analysis does not apply to this issue because it concerns the application of a statute—not a regulation. *Kisor*, 588 U.S. at 563 (establishing guidelines for analyzing agency regulations).

	ECM components?	How does it achieve its primary intended purposes?
AXIOFILL	✓	"[S]upplying an ECM scaffold to permit the ingrowth of cells"
Integra Meshed Bilayer Wound Matrix	✓	"[P]rovides a scaffold for cellular invasion"
Integra Dermal Regeneration Template	✓	"[H]elps repair ... damaged tissue" by "provid[ing] scaffolding (support framework) for ... cells to regrow a new layer of dermis."
Integra Bilayer Matrix Wound Dressing	✓	"[P]rovides a scaffold for cellular invasion"
Integra Flowable Wound Matrix	✓	"[P]rovides a scaffold for cellular invasion"
AVAGEN Wound Dressing	✓	"[P]rovides a scaffold for cellular invasion"

(Doc. 67 at 39; Doc. 58-1 at 21). Despite containing “the same basic ECM components” and having “the same intended use,” the FDA classified each of the above products as a device, but classified AXIOFILL as a biologic. (Doc. 58-1 at 21; Doc. 67 at 39).

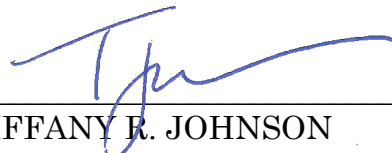
“Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld.” *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005). Here, as demonstrated in the above chart, the FDA classified similar products differently than AXIOFILL. (Doc. 58-1 at 12). And although the FDA explained that “the scientific literature” indicates that “AXIOFILL achieves its primary intended purpose through chemical action within or on the body,” it provided no explanation as to how, or why, AXIOFILL differs from otherwise similar products classified as devices. (*Id.*; Doc. 46-1 at 149–50). Nor did the FDA provide “substantial evidence in the record” to support its disparate treatment of AXIOFILL relative to these similar products classified as devices. *Surface Transp. Bd.*, 403 F.3d at 777. Because the FDA

applied “different standards to similarly situated entities” without “a reasonable explanation” or record evidence, its conclusion that AXIOFILL is a biological product was arbitrary and capricious under the APA. *Id.*; 5 U.S.C. § 706. The FDA’s decision that AXIOFILL is a biological product rather than a device is, therefore, vacated and remanded. *Fed. Power Comm’n*, 423 U.S. at 331. On remand, to the extent the FDA again concludes that AXIOFILL is a biological product, it must explain any differentiating features, with reasonable specificity, of AXIOFILL in light of the FDA’s classification of similar products as devices. *See id.*

CONCLUSION

For these reasons, the parties’ cross-motions for summary judgment (Docs. 64, 67) are **GRANTED IN PART and DENIED IN PART**. The FDA’s decisions that (1) AXIOFILL is not minimally manipulated, and (2) AXIOFILL is a biological product rather than a device are **VACATED and REMANDED** to the agency for further consideration in accordance with this Order. The Clerk is respectfully **DIRECTED** to **CLOSE** this case.

SO ORDERED, this 21st day of September, 2026.



TIFFANY R. JOHNSON
United States District Judge