PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 04-4481

NVE INC.,
Appellant

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES;
TOMMY G. THOMPSON, Secretary Department
of Health and Human Services; FOOD AND DRUG
ADMINISTRATION; *LESTER M. CRAWFORD, JR.,
Acting Commissioner, Food and Drug Administration;
JOHN DOES, 1-10 fictitious individuals
and ABC Agencies 1-10 fictitious agencies
and/or entities

*(Pursuant to Rule 43(c) F.R.A.P.)

Appeal from the United States District Court
for the District of New Jersey
(D.C. Civil No. 04-cv-00999)
District Judge: Honorable Joel A. Pisano

Argued September 26, 2005

Before: RENDELL, FUENTES and GARTH, Circuit Judges.

(Filed: February 7, 2006)

Walter F. Timpone [ARGUED]
McElroy, Deutsch, Mulvaney & Carpenter
1300 Mount Kemble Avenue
P.O. Box 2075
Morristown, NJ 07962
Counsel for Appellant

Douglas N. Letter
Christine N. Kohl [ARGUED]
U.S. Department of Justice
Civil Division
950 Pennsylvania Avenue, N.W.
Washington, DC 20530
Counsel for Appellees

OPINION OF THE COURT

RENDELL, Circuit Judge.

In 1994, Congress passed the Dietary Supplement Health and Education Act ("DSHEA"), declaring dietary supplements that "present[] a significant or unreasonable risk of illness or injury" to be "adulterated food" under the Food, Drug, and

Cosmetic Act ("FDCA"). DSHEA § 4, 21 U.S.C. § 342(f)(1) (2000). In 2004, the Food and Drug Administration ("FDA") promulgated a final regulation stating that dietary supplements containing ephedrine alkaloids ("EDS") were adulterated under the "unreasonable risk" standard of DSHEA. 21 C.F.R. § 119.1. The effect of the regulation was to prohibit the distribution of these supplements. NVE, a former manufacturer and distributor of EDS, brought this suit seeking to set aside the regulation.

Relying on a provision of DSHEA that states a "court shall decide any issue under [21 U.S.C. § 342(f)(1)] on a de novo basis," NVE sought to supplement the administrative record by offering affidavits, expert testimony, and other evidence. In orders dated August 4, 2004 and August 12, 2004, the District Court declined NVE's request, limiting its review to the 133,000-page administrative record for the challenged rule. However, pursuant to 28 U.S.C. § 1292(b), the District Court certified these orders for interlocutory appeal and identified four questions of law for our review:

> 1. May the party challenging the rule supplement the administrative record?
>
> 2. May the party challenging the rule present expert affidavits and/or testimony?
>
> 3. May the reviewing court conduct a trial or is its review limited to a review

of the administrative record?

4. May the party challenging the rule conduct discovery?

Because we conclude that the de novo standard of 21 U.S.C. § 342(f)(1) does not apply to a private action brought under the APA to challenge administrative rulemaking, we will answer the first, second, and fourth questions posed by the District Court in the negative and conclude with respect to the third question the District Court's review is limited to the administrative record.

We also address the District Court's ruling that it owed no deference in this case to the FDA's legal or factual conclusions. Though this issue was not one of the questions of law certified to us by the District Court, it was a part of the orders from which NVE appeals and is closely related to the question of whether NVE may supplement the record. Under 28 U.S.C. § 1292(b), we are not limited to the specific questions of law identified by the District Court when reviewing the orders certified for appeal. *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 424 F.3d 363, 368-369 (3d Cir. 2005). We therefore take up the question of deference here as part of our review of the District Court's orders of August 4, 2004 and August 12, 2004 and conclude that the normal rules for judicial deference regarding agency action apply in the instant suit.

I.

We begin with a discussion of the regulatory scheme at issue. The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated." 21 U.S.C. § 331(a). The United States enforces this provision through suits for injunctive relief, *id.* § 332, fines or imprisonment, *id.* § 333, or seizure of the adulterated food, *id.* § 334. It is well-established that the government bears the burden of proving that a food is adulterated in enforcement actions brought directly under the FDCA. *See United States v. Two Plastic Drums, More or Less of an Article of Food . . .*, 984 F.2d 814, 816 (7th Cir. 1993) (noting that the FDA has the burden of showing that food is injurious to health).

The FDCA also grants to the Secretary of Health and Human Services broad power "to promulgate regulations for the efficient enforcement of th[e] Act." 21 U.S.C. § 371(a). This provision authorizes the Secretary to issue substantive regulations, interpretive regulations, and statements of policy. *Pharmaceutical Mfrs. Ass'n v. FDA*, 484 F. Supp. 1179, 1182 (D. Del. 1980). Because courts owe deference to an agency's interpretation of the statute and regulations it administers, *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984), regulations validly promulgated under the FDCA normally have the force of law in enforcement proceedings, *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001). *See also United States v. Algon Chem. Inc.*, 879 F.2d 1154, 1159 (3d Cir. 1989) (deferring to FDA regulations in enforcement proceedings under the FDCA). Thus, where the FDA determines through rulemaking that a food is adulterated, the introduction of that food into interstate commerce violates the FDCA unless the rule is "procedurally defective, arbitrary

or capricious in substance, or manifestly contrary to the statute." *Mead Corp.*, 533 U.S. at 227; *see also United States v. Undetermined Quantities of Various Articles of Device . . .*, 800 F. Supp. 499, 502 (S.D. Tex. 1992) (determining, based on FDA regulations, that medical device was adulterated and misbranded under FDCA).

Congress passed DSHEA after a long-running dispute with the FDA about how strictly dietary supplements should be regulated. Members of Congress believed the FDA had "pursued a heavy-handed enforcement agenda against dietary supplements for over 30 years" prior to DSHEA's enactment. S. Rep. 103-410, at 15 (1994). Both Congress and the courts consistently resisted the FDA's regulation of dietary supplements, yet the FDA continued its course. *Id.* at 16-17. Senator Orrin Hatch summarized the attitudes of many in Congress in 1994 when he stated that, with respect to dietary supplements, "[i]t is the U.S. Congress versus the Food and Drug Administration." 140 Cong. Rec. S11708, 11711 (1994); *see also* 140 Cong. Rec. S14780-01 (1994) (statement of Sen. Harkin) (criticizing the FDA for restricting access to information about dietary supplements). In response to what it perceived as an "inappropriate regulatory strategy," S. Rep. 103-410, at 22, Congress passed DSHEA in October 1994 with strong bipartisan support.

DSHEA changed very little about the basic administrative tools available to the FDA for the regulation of dietary supplements. The Agency could still regulate dietary supplements through enforcement actions or rulemaking. However, DSHEA provided substantive and procedural limits

on the FDA's ability to restrict the use of dietary supplements. DSHEA identified the limited alternative conditions under which a dietary supplement or food containing a dietary supplement could be deemed adulterated. First, a dietary supplement is adulterated if it poses a significant or unreasonable risk of illness or injury. 21 U.S.C. § 342(f)(1)(A). Second, a dietary supplement is deemed adulterated if it is a new dietary ingredient for which there is inadequate information to establish that it does not pose a significant or unreasonable risk. *Id.* § 342(f)(1)(B). Third, the Secretary may declare that a dietary supplement is adulterated if it poses an imminent hazard to public health or safety, provided that the Secretary promptly initiates formal adjudication to affirm or withdraw the declaration. *Id.* § 342(f)(1)(C). Finally, a dietary supplement is deemed adulterated if it is poisonous or unsanitary. *Id.* § 342(f)(1)(D).[1]

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[1]Paragraph 342(f)(1) provides, in full, that a food is deemed adulterated:

> (f)(1) If it is a dietary supplement or contains a dietary ingredient that--
>
> (A) presents a significant or unreasonable risk of illness or injury under--
>
> (i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of Title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it

In addition to providing substantive limits on the circumstances under which dietary supplements may be considered adulterated, Congress imposed new procedural checks on the FDA's ability to regulate dietary supplements through the courts. After listing the ways in which a dietary supplement can be deemed adulterated, the provision states:

> In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide *any issue under this paragraph on a de novo basis*.

Id. § 342(f)(1) (emphasis added). Congress intended that these provisions would protect against "unreasonable regulatory barriers" limiting the flow of safe dietary supplements to consumers. DSHEA § 2(13) (codified in note to 21 U.S.C. § 321(ff)).

Beginning in 1997, the FDA began to consider

> adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

21 U.S.C. § 342(f)(1).

regulatory action with respect to certain products containing EDS. The FDA chose to regulate EDS through administrative rulemaking rather than through enforcement actions brought directly under the FDCA. The FDA proposed several alternatives, including regulation of items containing certain threshold amounts of EDS, limitations on the duration of use and daily uses of EDS, labeling requirements on products containing EDS, and prohibition of mixing certain ingredients with EDS. *See* Dietary Supplements Containing Ephedrine Alkaloids, 62 Fed. Reg. 30678, 30692-30705 (proposed June 4, 1997) (to be codified at 21 C.F.R. pt. 111). In 2000, the FDA withdrew most of these proposals and ceased activity aimed at regulatory action in the face of a negative public response and questions about the sufficiency of evidence that EDS was unsafe. 65 Fed. Reg. 17474 (April 3, 2000).

In 2002, the FDA received a report from the RAND Corporation calling for more study of the safety of EDS. The next year, the FDA reopened the comment period on the 1997 proposed rule in light of "new scientific evidence" about the effects of EDS on health. 68 Fed. Reg. 10417 (March 3, 2005). The FDA compiled an administrative record consisting of more than 48,000 comments and 133,000 pages. *See* Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788, 6792 (Feb. 11, 2004) (to be codified at 21 C.F.R. pt. 119). Based on "the well-known pharmacology of ephedrine alkaloids, the peer-reviewed scientific literature on the effects of ephedrine alkaloids, and the adverse events reported to have occurred in individuals following consumption of dietary supplements containing ephedrine alkaloids," *id.* at

6788, the FDA issued a final rule (the "EDS Rule") declaring that all dietary supplements containing EDS "present an unreasonable risk of illness or injury" and were therefore adulterated under the FDCA. 21 C.F.R. § 119.1.

NVE brought suit in March 2004 to enjoin the enforcement of the rule. It claimed that the FDA violated the Administrative Procedure Act ("APA") by: (1) acting arbitrarily, capriciously, and contrary to law, in violation of 5 U.S.C. § 706(2)(A); (2) exceeding its statutory authority, in violation of 5 U.S.C. § 706(2)(C); (3) acting in a manner that is unwarranted by the facts, in violation of 5 U.S.C. § 706(2)(F); and (4) failing to give proper notice of the FDA's intended actions, in violation of 5 U.S.C. § 553 and § 706(2)(D). NVE also claimed that the FDA violated its right to due process under the Fifth Amendment by failing to give NVE a reasonable opportunity to comment on the substance of the rule.

NVE contended that the de novo provision of § 342(f)(1) should apply to its suit such that the District Court must decide the issues NVE raised on a "de novo basis." 21 U.S.C. § 342(f)(1). NVE argued that under this standard the District Court should resolve all legal and factual issues anew, independent of any findings that the FDA made during its rulemaking. NVE claimed that a true de novo review gives the District Court the power to consider evidence outside of the administrative record. Consequently, NVE sought to submit evidence, such as expert testimony and affidavits, to aid the District Court in determining whether all dietary supplements containing EDS are adulterated, as the EDS Rule declared. NVE also sought to conduct discovery to the same extent as in

any other civil case proceeding under the Federal Rules of Civil Procedure.

The District Court requested that the parties submit briefs and present oral argument as to the proper standard of review and whether the parties were entitled to discovery. In an opinion and order dated August 4, 2004, subsequently clarified by an August 12, 2004 order, the District Court held that the case was brought under the APA and the APA therefore governed the scope of review. Because parties are typically not permitted to supplement the administrative record or engage in discovery in APA cases challenging rulemaking, the District Court ruled that the parties could neither supplement the record nor conduct discovery. However, the District Court also held that the de novo provision of DSHEA required that it give no deference to the FDA's factual and legal conclusions; rather, it could decide the issues anew. At NVE's request, the District Court certified its August 4, 2004 and August 12, 2004 orders for immediate appeal under 28 U.S.C. § 1292(b) and identified four controlling questions of law for our review. We granted NVE's Petition for Permission to Appeal on November 1, 2004.

II.

Before we conduct our analysis of the questions the District Court certified for review,[2] we must examine the nature

[2]As stated above, the four questions submitted to this Court for review are:

of the suit brought by NVE in the District Court. NVE's claims are brought under the APA. DSHEA does not provide a private cause of action, nor does it contain a waiver of sovereign immunity that would permit NVE to sue a federal agency. The only cause of action that NVE can maintain in order to challenge the EDS Rule arises under the APA, which provides both a waiver of sovereign immunity and a right of judicial review for any "person suffering legal wrong because of agency action." 5 U.S.C. § 702. NVE's complaint identifies the APA as the source of its claims, and NVE has not contended before this Court that it has a cause of action directly under DSHEA. Consequently, we agree with the District Court that the APA, not DSHEA, provides the mechanism for NVE's challenge of the EDS Rule. Because NVE's suit arises under the APA, the

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District Court must apply the APA's standards for scope of review and discovery, unless we conclude that Congress intended somehow to override the APA's standards when it enacted DSHEA and provided for de novo judicial review as to issues thereunder. We believe that the determination of the appropriate standard – whether under the APA or DSHEA – will dictate the answers to the questions posed to us.

III.

A.

Of the four questions certified to us for review, the first three comprise a single inquiry into whether NVE may supplement the administrative record. In a challenge to administrative action under the APA, the administrative record cannot normally be supplemented. *See Camp v. Pitts*, 411 U.S. 138, 142 (1973) ("In applying [the arbitrary and capricious] standard, the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court."); *Horizons Int'l, Inc. v. Baldrige*, 811 F.2d 154, 162 (3d Cir. 1987) (describing review of the existing administrative record as one of "the traditional limits of judicial review applied under section 10 of the APA"). The APA explicitly directs a reviewing court to "review the whole record or those parts of it cited by a party." 5 U.S.C. § 706.

Only one provision of the APA permits a reviewing court to look beyond the administrative record. Under 5 U.S.C. § 706(2)(F), a court may conduct a trial de novo to determine if

administrative action is "unwarranted by the facts." NVE alleged in its complaint that this provision applies here. The Supreme Court, however, has limited "trial de novo" review under the APA to two situations: (1) "when the action is adjudicatory in nature and the agency factfinding procedures are inadequate," and (2) "when issues that were not before the agency are raised in a proceeding to enforce nonadjudicatory agency action." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971). Neither of these situations exists in the instant case. NVE is challenging rulemaking, not adjudicative actions, and the FDA considered the issues raised in this suit during the administrative proceedings. Therefore, the scope of review standards contained in the APA would limit the District Court's review to the administrative record.

Congress may override the APA's rule that judicial review of administrative action is limited to the administrative record. *See United States v. Carlo Bianchi & Co., Inc.*, 373 U.S. 709, 715 (1963) (noting that Congress can "set[] forth the standards to be used or the procedures to be followed" during a court's review of the record); *Upjohn Mfg. Co. v. Schweiker*, 681 F.2d 480, 483 (6th Cir. 1982) ("When de novo review of agency action *is not expressly required by statute*, it is the exception rather than the rule." (emphasis added)). NVE argues that this is precisely what Congress did by including in DSHEA a provision requiring courts to "decide any issue under this paragraph on a de novo basis." 21 U.S.C. § 342(f)(1). We disagree and conclude that Congress did not intend reviewing courts to conduct de novo review in private-party challenges to FDA rulemaking under DSHEA.

B.

A challenge to administrative action under the APA raises a unique set of issues. Judicial review in such suits focuses on the agency's decision making *process*, not on the decision itself. "[A] court is not to substitute its judgment for that of the agency" in an APA challenge. *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Rather, it must ensure only that the agency has applied the procedures for rulemaking required by law and reached a rational conclusion.

In the instant case, NVE claimed that the defendants acted arbitrarily and capriciously, contrary to law, in excess of their statutory jurisdiction, and without adequate notice of, or opportunity to comment on, the proposed rule. Each of these claims under the APA is distinct from any substantive inquiry into whether dietary supplements containing EDS are actually adulterated under the FDCA.

The arbitrary and capricious standard focuses a court on the agency's process of reasoning. To determine whether an agency acted arbitrarily and capriciously, a court looks to whether the agency relied on factors outside those Congress intended for consideration, completely failed to consider an important aspect of the problem, or provided an explanation that is contrary to, or implausible in light of, the evidence. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. Reversal is appropriate only where the administrative action is irrational or not based on relevant factors. *Pennsylvania Dep't of Pub. Welfare v. United States Dep't of Health and Human Servs.*, 101 F.3d 939, 943

(3d Cir. 1996).

Likewise, in evaluating whether the FDA exceeded its statutory jurisdiction by promulgating the EDS Rule, a court must consider the scope of authority Congress granted to the Agency, in this case under 21 U.S.C. § 371(a), and compare it with the claimed excessive action. *Wilkinson v. Abrams*, 627 F.2d 650, 660 (3d Cir. 1980); *Western Union Tel. Co. v. FCC*, 541 F.2d 346, 354 (3d Cir. 1976). "What is important is that the reviewing court reasonably be able to conclude that the grant of authority contemplates the regulations issued." *Chrysler Corp. v. Brown*, 441 U.S. 281, 308 (1979). This review "is so basic that it rarely arises . . . as a meaningful challenge to agency action." 33 Charles Alan Wright & Charles H. Koch, Jr., *Federal Practice and Procedure* § 8381, p.335 (2006).

With respect to NVE's claim that the FDA failed to provide adequate public notice of its contemplated action, the District Court "must determine whether the notice given was sufficient to fairly apprise interested parties of all significant subjects and issues involved." *Am. Iron & Steel Inst. v. EPA*, 568 F.2d 284, 291 (3d Cir. 1977) (internal quotation marks omitted). It will concentrate on whether that notice provided either "the terms or substance of the proposed rule" or "a description of the subjects and issues involved," 5 U.S.C. § 553(b)(3), and whether interested parties had the opportunity to participate in the rulemaking process, *Fertilizer Inst. v. Browner*, 163 F.3d 774, 779 (3d Cir. 1998). In considering whether the notice was deficient because the final rule differed from the proposed rule, a reviewing court asks whether the final

rule was a logical outgrowth of the rulemaking proposal and record. *Aeronautical Radio, Inc. v. FCC*, 928 F.2d 428, 445-446 (D.C. Cir. 1991); *United Steelworkers of Am. v. Pendergrass*, 855 F.2d 108, 114 (3d Cir. 1988). The District Court will follow this same analysis in determining whether the FDA violated NVE's due process right to comment on the rule. *See Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524-25 (1979) (holding that where rulemaking fulfills basic APA standards for notice and procedure, a court will not impose additional process).

Thus, in this case the District Court should concern itself solely with whether the challenged administrative action followed the procedures for legitimate rulemaking. Nothing about DSHEA indicates that Congress intended the courts to consider on a de novo basis issues concerning the process of the agency's reasoning or the notice it provided to the public. To the contrary, Congress was clear that DSHEA's de novo standard applies only when a court is deciding an "issue under this paragraph." Used in this context, "this paragraph" refers to 21 U.S.C. § 342(f)(1). *See Koons Buick Pontiac GMC, Inc. v. Nigh*, 543 U.S. 50, 125 S. Ct. 460, 467 (2004) (describing the hierarchical scheme for subdividing statutory sections). Paragraph 342(f)(1) defines the conditions under which a dietary supplement may be deemed adulterated. An issue therefore arises under that paragraph only if it is probative of the question of whether a dietary supplement qualifies as an adulterated food. As discussed above, a dietary supplement may be deemed adulterated under DSHEA when one of four conditions is satisfied. *See* 21 U.S.C. §§ 342(f)(1)(A)-(D). Consequently, by its own terms, application of the de novo

provision is limited to judicial inquiries aimed at establishing the presence or absence of one of these conditions of adulteration. In the instant case, the District Court must not consider whether the FDA's determination that EDS is adulterated was correct, but rather if its action in rulemaking was arbitrary, capricious, contrary to law, in excess of the FDA's statutory jurisdiction, or preceded by inadequate notice. Congress did not state any intention that rulemaking was to be reviewed on a de novo basis. Indeed, as noted below, there is no mention in DSHEA of "review" of agency action.

There are other clues in the text of DSHEA that reinforce this conclusion. The de novo provision immediately follows the sentence stating that "the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated." 21 U.S.C. § 342(f)(1). The fact that the *United States* bears the burden of proof is significant for determining the type of "proceedings" to which Congress was referring in this context. It is the United States – not the FDA, its Commissioner, the Department of Health and Human Services, or its Secretary – that is the named party in enforcement actions. *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.") By contrast, private parties challenging agency rulemaking generally name as a defendant the agency or administrative officials responsible for the regulation, not the United States. *See* 5 U.S.C. § 702 (requiring any mandatory or injunctive decree under the APA to "specify the Federal officers or officers (by name or by title), and their successors in office, personally responsible for compliance"); 11B Am. Jur. Pl. & Pr. Forms Fed. Pract. & Proc.

§ 1364 (2005) (providing form of complaint under APA in which agency and agency officers, but not United States, are named defendants); 8 Fed. Proc. Forms § 21:18 (2005) (same); 10B Fed. Proc. Forms § 37:41 (2005) (same).[3] This strongly suggests that the "proceedings" in which the United States has the burden of proof under § 342(f)(1), and as to which the de novo standard is to apply, are enforcement proceedings brought by the United States to enforce DSHEA.

This view is bolstered by the fact that Congress made another provision of subsection 342(f) specifically apply to the Secretary of Health and Human Services. In § 342(f)(2), Congress distinguished between the Secretary and the United States attorneys, to whom the Secretary reports violations of § 342(1)(A), indicating that Congress did not use the terms "the

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[3]While it is common practice to name the agency or officers as defendants in APA actions, a plaintiff may name the United States directly. *See* 5 U.S.C. § 703 ("If no special statutory review proceeding is applicable, the action for judicial review may be brought against the *United States*, the agency by its official title, or the appropriate officer.") (emphasis added). We believe, however, that the fact Congress limited § 342(f)(1) to proceedings in which the United States is a party – rather than the "United States, the agency by its official title, or the appropriate officer," *id.* – indicates that it was referring to enforcement proceedings. Had Congress intended § 342(f)(1) to apply to private suits under the APA, it would have used broader language specifying that federal agencies or administrative officers would also bear the burden of proof.

Secretary" and "the United States" interchangeably in DSHEA. Had Congress intended the burden of proof provision to apply to APA actions as well as enforcement actions, it would have indicated that the provision applied to proceedings to which the Secretary was a party as well.

In light of our view that the United States bears the burden of proof only in enforcement actions, the most natural reading of the de novo provision – which immediately follows the burden of proof provision – is that it applies to the same "proceedings" in which the United States bears the burden of proof. *See Koons Buick Pontiac GMC*, 125 S. Ct. at 467 (noting that ambiguity can often be resolved by reference to "'the remainder of the statutory scheme'" (quoting *United Sav. Assn. of Tex. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988))); *Deal v. United States*, 508 U.S. 129, 132 (1993) ("[T]he meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used."). Thus, application of the de novo standard, like the burden of proof provision, is limited to enforcement actions brought by the United States.

We also note that DSHEA's de novo provision instructs courts to decide "issues" under § 342(f)(1) "on a de novo basis," rather than to conduct "de novo review." This distinction is highly significant given that a court's function in an APA suit is always *to review* administrative action. *See* 5 U.S.C. § 702 ("A person suffering legal wrong because of agency action . . . is entitled to judicial review thereof."); *id.* § 706 (defining standards under which a "reviewing court" may "set aside agency action, findings, and conclusions"). By

contrast, in an enforcement action under § 342(f)(1), a court's role is not to review an underlying administrative action, but rather to decide in the first instance whether a dietary supplement is adulterated. This choice of language in the de novo provision further suggests that the de novo standard does not apply in APA suits for judicial review of agency action.

NVE contends that differences between a draft of DSHEA passed by the Senate and the final bill suggest that Congress intended the de novo provision to apply to private challenges to rulemaking.[4] The version of DSHEA first passed

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[4]DSHEA's chief sponsors stated their intent that a joint Statement of Agreement would comprise the entire legislative history for DSHEA and that "no other reports or statement be considered as legislative history for the bill." 140 Cong. Rec. H11173, 11179 (1994); 140 Cong. Rec. S14798, 14801 (1994). The effect of such a disclaimer, even by the bill's sponsors, is debatable. *Compare Neutraceutical Corp. v. Crawford*, 364 F. Supp. 2d 1310, 1319 (D. Utah 2005) (citing legislative history not included in the Statement of Agreement), *with Whitaker v. Thompson*, 239 F. Supp. 2d 43, 51 (D.D.C. 2003) (limiting its analysis of the legislative history to the Statement of Agreement) and *United States v. Ten Cartons, More or Less, of an Article* . . ., 888 F. Supp. 381, 395 (E.D.N.Y 1995) (holding it could not rely on a Senate Report that the Statement of Agreement excluded from the legislative history). We withhold judgment about the overall effectiveness of this disclaimer, *see Pharmanex v. Shalala*, 221 F.3d 1151, 1158 (10th Cir. 2000) (refusing to rule "on the legitimacy or effectiveness of such a

by the Senate would have *required* the Secretary to promulgate regulations in order to declare that a dietary supplement posed an "unreasonable risk of illness or injury." The Senate draft did not include a provision that required courts to decide issues on a de novo basis.[5] In the final version of the bill, the FDA could

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disclaimer"), but assume that, despite the Statement of Agreement, previous drafts of DSHEA are indicative of congressional intent, *see United States v. Ten Cartons, More or Less, of an Article* . . . , 72 F.3d 285, 286 (2d Cir. 1995) (relying on previous version of DSHEA to interpret the enacted statute).

[5]The Senate draft of the DSHEA read, in pertinent part:

> (f) [A food shall be deemed to be adulterated i]f it is a dietary supplement that-
>
> (1) the Secretary finds, *after rulemaking*, presents a substantial and unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling;
>
> (2) the Secretary declares to pose an imminent and substantial hazard to public health or safety, except that the authority to make such

employ the "unreasonable risk" standard in both rulemaking *and* enforcement actions. *See* 21 U.S.C. § 342(f)(1)(A); *id.* § 342(f)(2). Along with this change, Congress added the de novo standard for judicial decision of "any issue under this paragraph."

> declaration shall not be delegated and the Secretary shall promptly thereafter convene rulemaking pursuant to section 701(e), (f), and (g) to affirm or withdraw the declaration; or (3) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.
>
> In any proceeding under this section, the United States bears the burden of proof on each element to show that a dietary supplement is adulterated.

DSHEA § 4, 140 Cong. Rec. S11708, 11713 (as passed by Senate Aug. 13, 1994) (emphasis added).

NVE argues that the changes from one legislative draft to the next demonstrate that the concept of rulemaking was clearly in the forefront of Congress's mind, and if it had wanted to exempt rulemaking from the de novo standard, it would have done so explicitly. NVE argues that because Congress did not trust the FDA, *see* 140 Cong. Rec. S11708, 11711 (1994) (statement of Sen. Hatch) ("It is the U.S. Congress versus the Food and Drug Administration."), it did not intend to make such an exception.

NVE's argument is unpersuasive for two reasons. First, we disagree with its reading of the legislative history. The de novo provision was added at the same time as Congress broadened the FDA's civil enforcement power under § 342(f)(1), suggesting that it was coupled with this additional power, and not the FDA's rulemaking authority. If Congress had intended the de novo standard to apply to judicial review of rulemaking, one might well have expected to find it along with the rulemaking language in the Senate's draft of the bill as well as the final version. Thus, we believe that the legislative history NVE cites could just as easily be interpreted as supporting our view that Congress intended DSHEA to require courts to apply the de novo standard *only* in enforcement actions.

NVE's argument is also unconvincing because it turns on its head the presumption that traditional APA standards should apply in APA suits. *See Carlo Bianchi & Co., Inc.*, 373 U.S. at 715. Overriding the normal rules for judicial review of administrative rulemaking would be a significant step for Congress to take, and one that we would not lightly read into a statute. Had Congress intended to supplant the well-established

procedures for APA challenges, it would have been clearer about its objective. NVE would have us conclude that the de novo provision applies to judicial review of rulemaking because Congress contemplated that the FDA would promulgate regulations under DSHEA and historically distrusted the FDA to regulate dietary supplements. These factors, however, do not convince us that Congress intended to overcome the presumption that APA standards apply in APA suits when it enacted DSHEA. Given that the text and drafting history of DSHEA indicates the de novo standard applies only to enforcement actions, we hold that the de novo provision of § 342(f)(1) has no application in a private-party challenge to rulemaking.

Finally, NVE has argued that our holding today will open a gaping loophole that eviscerates DSHEA's de novo provision. It contends that the FDA can simply avoid de novo judicial review by issuing regulations on dietary supplements instead of bringing individual enforcement actions. While we do not downplay the significance of this allegation, we cannot legislate to correct it, if that is in fact what is occurring here. If Congress perceives the agency's action to be an end-run around the standard it legislated for enforcement actions, surely it can amend DSHEA or the APA to remedy the situation. Furthermore, nothing we hold here does away with the congressional command in the text of § 342(f)(1) regarding de novo determination of issues in enforcement proceedings. It is only through enforcement proceedings that the EDS Rule, or any other regulation promulgated under DSHEA, is given effect. The de novo standard will apply when the FDA brings an enforcement action and a court is faced with the issue of

whether a specific supplement is adulterated. Thus, the de novo standard remains available when it matters most: when the United States singles out an individual or entity for violating the FDCA and seeks injunctive relief, seizure, or civil or criminal penalties.[6]

Because we conclude that the de novo standard does not apply in suits brought under the APA, we must answer the first three questions posed to us in the negative and hold that the District Court's review must be limited to the administrative record before the FDA.

IV.

NVE claims that, even if it cannot supplement the record, the de novo provision authorizes it to conduct discovery in order to determine what evidence the FDA considered in reaching its decision. NVE also seeks discovery to determine

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[6]Because we hold that the de novo provision does not apply to APA suits, we leave for another day the question of how precisely the de novo provision will operate in enforcement actions given the existence of an applicable regulation. *See, e.g.*, Stephen H. McNamara et al., *DSHEA Provisions Confine FDA's Authority to Issue Regulations That Concern Allegedly Adulterated Dietary Supplements*, 54 Food Drug L.J. 595, 597 (1999) (arguing that regulations promulgated under DSHEA do not have the force of law in enforcement proceedings like other regulations properly promulgated by agencies). This issue is not before us, and our holding today does not encompass it.

whether the administrative record is complete. Again, if NVE has the right to conduct discovery, it must derive this right from the APA, not DSHEA.

There are no grounds in the APA to permit discovery in this case. As we have noted in the past, "[i]t has long been recognized that attempts to probe the thought and decision making processes of judges and administrators are generally improper." *Grant v. Shalala*, 989 F.2d 1332, 1344 (3d Cir. 1993). There is a strong presumption against discovery into administrative proceedings born out of the objective of preserving the integrity and independence of the administrative process. We have carved out an exception to this rule only in cases involving alleged bias on the part of an agency. *See id.* (discussing the holding of *Hummel v. Heckler*, 736 F.2d 91 (3d Cir. 1984), which permits discovery on the issue of an ALJ's bias).

NVE alleges no such bias here, but nevertheless questions whether the 133,000-page administrative record is complete. FDA rules establish the contents of the administrative record for any promulgation of regulations, 21 C.F.R. § 10.40(g), and the administrative record is intended to be the sole basis for the Agency's decision, 21 C.F.R. § 10.45(f). NVE supports its call for discovery with nothing more than speculation that the FDA may not have produced the full record. In the absence of even a hint of evidence that the FDA failed to follow its own procedures for compiling the record, we will not permit discovery. To do so would undermine the presumption against discovery into administrative proceedings.

NVE cites for support *Dopico v. Goldschmidt*, 687 F.2d 644 (2d Cir. 1982). In that case, the Court of Appeals for the Second Circuit ordered discovery to determine whether an agency had submitted the full administrative record. However, *Dopico* differed from the instant case in two important respects. There, the plaintiffs were not challenging agency rulemaking, but rather an agency's decision to grant federal money to local transit authorities. Furthermore, the agency in that case submitted an administrative record that lacked the fundamental documents that would have formed the very basis for the agency's decisions about mass transit grants. Under these circumstances, the Court believed that discovery was appropriate. *Id.* at 654. NVE has not demonstrated the presence of any comparable factors in this case.

NVE's reliance on *Exxon Corporation v. Department of Energy*, 91 F.R.D. 26 (N.D. Tex. 1981), is similarly misplaced. That court was faced with a 126-page record that was incomplete on its face. *Id.* at 34. We agree with NVE that the size of the record alone is not dispositive of the question of whether discovery is appropriate. Nevertheless, the size of the record is certainly a factor that a court should consider in deciding whether to take the unusual step of permitting invasive discovery into administrative decision-making. NVE has pointed to nothing about the administrative record here that suggests it is incomplete. Given the breadth of the record submitted and the clarity of the FDA's own regulations regarding the content of the record, we agree with the District Court's decision not to permit discovery.

V.

Finally, we address the District Court's ruling that the FDA's factual determinations and legal conclusions are not entitled to deference in the instant suit. Though the District Court did not identify this issue as one of the four questions of law that we should address, our review in a § 1292(b) appeal is not limited to the specific questions certified by the District Court. *Howard Hess Dental Labs.*, 424 F.3d at 368. Rather, we may address "any issue fairly included within the certified order because it is the *order* that is appealable, and not the controlling question[s] identified by the [D]istrict [C]ourt." *Yamaha Motor Corp., U.S.A. v. Calhoun*, 516 U.S. 199, 205 (1996) (emphasis in original) (internal quotation marks omitted); *see also* 16 Charles Alan Wright et al., *Federal Practice and Procedure* § 3929, p. 388 (2d ed. 1996) ("The court may . . . consider any question reasonably bound up with the certified order, whether it is antecedent to, broader or narrower than, or different from the question specified by the district court."). Since the issue of what deference the District Court owes the FDA is unquestionably a component of the orders certified to us, we have authority to resolve it in this appeal.

The sole basis for the District Court's holding that it owed no deference to the legal and factual determinations the FDA made during rulemaking was its belief that the de novo standard applied in the instant case. Our conclusion that the de novo standard applies only in enforcement actions squarely implicates this holding. Because DSHEA's de novo standard is inapplicable in an APA challenge to administrative rulemaking, the normal rules for judicial deference regarding agency action apply in the instant suit. *See United States v. Mead*

Corporation, 533 U.S. 218, 226-27 (2001) (holding that administrative implementation of a particular statutory provision qualifies for *Chevron* deference when Congress delegated authority to agency "to make rules carrying the force of law"); *Southwestern Pennsylvania Growth Alliance v. Browner*, 121 F.3d 106, 117 (3d Cir. 1997) ("A reviewing court 'must generally be at its most deferential' when reviewing factual determinations within an agency's area of special expertise." (quoting *New York v. EPA*, 852 F.2d 574, 580 (D.C. Cir. 1988)). We therefore disagree with this aspect of the District Court's ruling in the August 4, 2004 order.

VI.

We hold that DSHEA's de novo provision does not apply to NVE's challenge to the EDS Rule. Because the APA limits judicial review of rulemaking to the administrative record and does not permit discovery under the circumstances before us, we will answer the first, second, and fourth questions posed by the District Court in the negative and conclude with respect to the third question the District Court's review is limited to the administrative record. In addition, we hold that the normal rules for judicial deference apply to NVE's challenge under the APA. Having reviewed the orders certified to us, we now remand the case to the District Court for further proceedings.