UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

EISAI, INC.,	)	
Plaintiff,	)	
v.	)	**Civil Action No. 14-cv-1346 (RDM)**
UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

A company that obtains approval from the Food and Drug Administration ("FDA") to market a drug, no active ingredient of which has been previously approved, is entitled to a five-year period of exclusivity during which would-be competitors cannot apply for approval of generic versions of that drug. *See* 21 U.S.C. § 355(c)(3)(E)(ii). This exclusivity period creates an incentive for pharmaceutical companies to undertake the lengthy and expensive process of developing, testing, and obtaining approval of new drugs. On occasion, however, some drugs effectively receive periods of exclusivity shorter than the five year period authorized by statute. When the Drug Enforcement Administration ("DEA") seeks to schedule a new drug under the Controlled Substances Act, it must request recommendations from the FDA; after the DEA receives the FDA's recommendation, it engages in notice-and-comment rulemaking culminating in a final rule that determines whether and at what level the drug will be scheduled. *See* 21 U.S.C. § 811. Because the FDA requires applicants for approval of new drugs to commit not to market those drugs until after the DEA makes its scheduling determination, the scheduling

process can delay the entry of new drugs into the market, sometimes by more than a year after their FDA approval. The central issue in this case is whether and under what circumstances the period of time drug manufacturers spend waiting for a final DEA scheduling determination counts against the five-year exclusivity period.

Plaintiff, Eisai, Inc. ("Eisai"), holds new drug approvals ("NDAs") for two drugs caught in this regulatory limbo. It contends—not without force—that its effective loss of months of market exclusivity while it waited for the DEA to schedule these drugs is at odds with the balance that Congress struck between incentivizing the development of new drugs and making affordable medications more broadly available to patients when it enacted the Hatch-Waxman Amendments in 1984. On the one hand, Congress streamlined the procedure for approval of typically cheaper generic drugs. On the other, it granted five years of market exclusivity to the developers of sufficiently innovative drugs, improving the chance that they would see returns on the significant investments required to bring new drugs to market. As Eisai stresses, requiring manufacturers of scheduled drugs to lose months—or more—of exclusivity while they await scheduling determinations might upset this balance and discourage pharmaceutical companies from pursuing promising drugs that are likely to require scheduling under the Controlled Substances Act.

This case, however, turns on the meaning, not the wisdom, of an FDA regulation implementing the Hatch-Waxman Amendments. Under that regulation—the validity of which Eisai does not challenge—the exclusivity period for a new drug begins when the FDA issues its letter approving the drug, even if the drug's manufacturer must await DEA's scheduling determination before it can bring the drug to market. The regulation does provide for an exception under limited circumstances. But the FDA has interpreted that exception narrowly,

and the Court is bound to defer to the agency's reasonable interpretation of its own regulation. Because Eisai's drugs do not qualify for the exception under the FDA's interpretation of its regulation, the FDA and its co-Defendants are entitled to summary judgment.

I. BACKGROUND

A. The Statutory and Regulatory Regime

The Drug Price Competition and Patent Term Restoration Act, Pub. L. 98-417 (1984), commonly known as the Hatch-Waxman Amendments, "emerged from Congress'[s] efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990). To achieve the first goal—encouraging investment in new drugs—the Hatch-Waxman Amendments provided a five-year period of market exclusivity for new drugs, no active ingredients of which have previously been approved. 21 U.S.C. § 355(c)(3)(E)(ii). Other companies are barred from seeking approval of generic versions of these new drugs—referred to as "New Chemical Entities" or "NCEs"—during this five-year window, which begins on "the date of the approval of the [New Chemical Entity] application." *Id.* To achieve the second goal—making it easier for competitors to bring cheap generics to the market—Congress created the Abbreviated New Drug Approval process, which allows producers of follow-on drugs to rely on the safety and effectiveness trials conducted by a drug's initial developer, streamlining the process of bringing generic drugs to market. *See* 21 U.S.C. 355(j).

The FDA has promulgated regulations implementing the Hatch-Waxman Amendments. Tracking the statute, these regulations bar manufacturers from applying for approval of follow-

on drugs for "a period of 5 years from the date of approval of the first approved new drug application." 21 C.F.R. § 314.108(b)(2). "Date of approval," in turn, is defined as:

> the date on the letter from FDA stating that the new drug application is approved, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required. "Date of approval" refers only to a final approval and not to a tentative approval that may become effective at a later date.

21 C.F.R. § 314.108(a).

The Controlled Substances Act creates five "schedules" for potentially addictive drugs or drugs that otherwise have "potential for abuse." 21 U.S.C. § 812. It authorizes the Attorney General—who, in turn, has delegated this authority to the DEA—to add, remove, or reassign drugs through notice-and-comment rulemaking. *Id.* § 811; 28 C.F.R. § 0.100(b). When the FDA determines that a drug in the approval process "has an abuse potential," it must forward that information to the DEA. 21 U.S.C. § 811(g). Before the DEA initiates a rulemaking to schedule a new drug, it must "request from" the FDA "a scientific and medical evaluation" of the drug, as well as "recommendations[ ] as to whether such drug . . . should be" scheduled as a controlled substance. *Id.* § 811(b). The FDA's recommendations—which it must provide "within a reasonable time"—are "binding . . . as to . . . scientific and medical matters." *Id.* If the DEA finds "substantial evidence of potential for abuse," it "shall initiate proceedings" to schedule the drug. *Id.* If the DEA determines that the drug should be scheduled under the Controlled Substances Act, the manufacturer must update the label with "the controlled substance symbol designating the schedule in which the controlled substance is listed." 21 C.F.R. § 201.57(a)(2); *see also id.* § 1302.04 (providing further labeling requirements).

The FDA's approval process for new drugs includes review of the drug's proposed labeling. *See* 21 U.S.C. § 355(b)(1), (d). If the DEA reaches its scheduling determination after the drug is approved, however, the label must be updated to indicate the drug's scheduling

designation. The parties agree that the label updating process under these circumstances is governed by 21 C.F.R. § 314.70(b), which requires a manufacturer to supplement its new drug application with any changes to the controlled substance labeling of its drug and to secure FDA approval of that supplement before marketing the product. Although the regulations thus require that a drug manufacturer obtain FDA approval of labeling changes that reflect DEA's scheduling of the drug before using the modified labeling, the producer may seek a waiver of that requirement under 21 C.F.R. § 314.90, and the FDA routinely grants these waiver requests. AR 13 n.71. As a practical matter, such a waiver permits the producer to begin marketing as soon as the DEA issues its final scheduling determination.

Neither the Food, Drug, and Cosmetic Act nor the FDA's regulations prohibit a producer from marketing an approved drug before that drug is scheduled. The FDA, however, requires new drug applicants to agree not to market drugs that the "FDA has proposed for scheduling under the Controlled Substances Act . . . until the Drug Enforcement Administration makes a final scheduling decision." U.S. Food and Drug Administration, FDA Form 356h, *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM082348.pdf (last visited Sept. 28, 2015). The upshot is that manufacturers of drugs that have been proposed for scheduling cannot market their drugs until, at the earliest, the DEA issues a final scheduling determination, even if the FDA approved the drugs at an earlier time. And if the FDA calculates the five-year exclusivity period beginning on the date of its approval, the producer is unable to market the drug during a portion of its exclusivity period, stripping that asset of some of its value.

B. Belviq and Fycompa

Plaintiff produces two recently approved drugs that lost portions of their window of market exclusivity while awaiting DEA scheduling. The first, Belviq, is a weight-loss drug that,

according to the complaint, "took fourteen years and cost over $300 million" to develop. Dkt. 1 ¶ 36. The FDA issued a letter approving Belviq on June 27, 2012. *Id.* ¶ 37. In the letter, which bore the caption "NDA APPROVAL," the agency reminded the drug manufacturer that it had "agreed not to market [Belviq] until the Drug Enforcement Administration has made a final scheduling decision." AR 68. Moreover, the agency advised:

> [W]hen the scheduling is finalized, you will need to make appropriate revisions to the package insert, the patient package insert and the carton and immediate-container labels through supplementation of your NDA. This would include the statements detailing the scheduling of Belviq in the labeling, as required under 21 C.F.R. §§ 201.57(a)(2) and (c)(10)(i).

Id. The FDA subsequently listed Belviq in Approved Drug Products with Therapeutic Equivalence Evaluations—the agency publication commonly known as the "*Orange Book*"—and determined that Belviq's five-year exclusivity period began on June 27, 2012, when the approval letter was issued.

The FDA submitted its scheduling recommendation to the DEA for Belviq on June 25, 2012, just two days before it approved the drug. The DEA issued its final rule scheduling Belviq almost a year later, on May 8, 2013. *See Schedules of Controlled Substances: Placement of Lorcaserin Into Schedule IV*, 78 Fed. Reg. 26701-02 (May 8, 2013).

The other drug at issue, Fycompa, followed a similar path. Fycompa is used to treat seizures in patients suffering from epilepsy. Dkt. 1 ¶ 11. The FDA issued a letter approving Fycompa on October 22, 2012. *Id.* ¶ 47. In language materially identical to that used in the Belviq approval, that letter stated:

> [Y]ou agreed not to market this drug until the Drug Enforcement Administration has made a final scheduling decision. We further note that, when the scheduling is finalized, you will need to make appropriate revisions to the package insert, the patient package insert and the carton and immediate-container labels through supplementation of your NDA. This would include statements detailing the scheduling of Fycompa in the labeling, as required under 21 § C.F.R. 201.57(a)(2) and (c)(10)(i).

AR 76-77. The FDA subsequently included Fycompa in the *Orange Book* and determined that its five-year exclusivity period began on the date of the approval letter.

The FDA recommended that the DEA schedule Fycompa on January 28, 2013—about three months after Fycompa was approved and the exclusivity period began. The DEA issued a final rule scheduling Fycompa on January 2, 2014—over fourteen months after the FDA issued its approval letter. After the DEA scheduled Belviq and Fycompa, Eisai had to submit for FDA approval revised labeling incorporating the scheduling. 21 C.F.R. § 314.70(b). As is typical, Eisai received waivers pursuant to 21 C.F.R. § 314.90 of the requirement that these changes be approved before the drugs could be marketed with the revised labeling. Arg. Tr. at 6:24-7:5. Thus, Eisai was authorized to begin marketing Belviq in May 2013 and Fycompa in January 2014.

C. Eisai's Petition and Lawsuit

On July 25, 2013, Eisai filed a petition with the FDA challenging the agency's calculation of the exclusivity periods for Belviq and Fycompa. *See* AR 20-143. In the petition, Eisai argued that the FDA's determination that the exclusivity periods for Belviq and Fycompa began before the company could market the drugs was arbitrary and capricious and violated the FDA's regulations. AR 31-46. In Eisai's view, exclusivity for new drugs subject to scheduling under the Controlled Substances Act should be "triggered only when FDA-approved labeling incorporating the final schedule permits commercial marketing of the products." AR 33.

The FDA denied Eisai's petition on April 30, 2014. AR 1-19. The agency read the petition to "ask FDA to decide that there are two approval dates for their drugs: (1) when FDA has completed its review of the [New Drug Application] and issues an approval letter, and (2) when DEA has completed its scheduling process, with only the latter being considered for purposes of 5-year NCE exclusivity." AR 14. It rejected Eisai's argument that Belviq and

Fycompa qualified for an exception to the general rule that a drug is approved on the date of the FDA's approval letter. *Id.* at 17-18.

Eisai filed this lawsuit on August 8, 2014. The company seeks a declaration that the FDA's determination of the exclusivity periods for Belviq and Fycompa violates the Administrative Procedure Act, 5 U.S.C. § 706(2), ("APA"), and an order requiring the FDA to recognize those periods as beginning on the date when the company was actually permitted to bring the drug to market. Dkt. 1 at 25. Eisai subsequently moved for summary judgment, arguing that the FDA violated 21 C.F.R. § 314.108(a), departed from its earlier practice, unfairly treated Eisai's drugs differently than similar products, and failed to provide a reasonable basis for its actions. Dkt. 14. The FDA filed a cross-motion for summary judgment, arguing that Belviq and Fycompa did not qualify for an exception to the FDA's general rule that five-year exclusivity begins to run on the date of the agency's approval letter, that the agency's practice has been consistent, and that the agency treats all drugs identically by beginning their exclusivity periods on the date of the FDA's approval letter. Dkt. 15. The Court held oral argument on the cross-motions on September 1, 2015.

II. LEGAL STANDARDS

The APA precludes agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency's decision, accordingly, must be the product of "reasoned decisionmaking." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983). An agency action will normally be set aside as "arbitrary and capricious" if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so

implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* at 43.

An agency must also, of course, "adhere to its own regulations." *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 536 (D.C. Cir. 1986). An agency has wide latitude to interpret its regulation, however, and its interpretation is "controlling unless plainly erroneous or inconsistent with the regulation." *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (citations and quotation marks omitted); *see also Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945). Thus, the Court must defer to the FDA's interpretation of its regulation "unless an alternative reading is compelled by the regulation's plain language or by other indications of the [agency's] intent at the time of the regulation's promulgation." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (citations and quotation marks omitted). And, although an agency enjoys significant leeway when interpreting its regulation, that interpretation must bear the mark of consistency, for "agency action is arbitrary and capricious if it departs from agency precedent without explanation." *Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003).

III. DISCUSSION

Eisai argues that the FDA violated the APA in multiple respects. First, the company alleges that the agency acted arbitrarily and capriciously by triggering the start of the five-year exclusivity period based on the date in the NDA approval letters. Eisai argues that the agency should have instead recognized that the NDA approval letters it issued fell within the regulatory exception. Even if they did not, the company contends, the FDA's interpretation of its own regulation is inconsistent with the text and both regulatory and congressional intent. Eisai also alleges that failing to recognize that it fell within the exception resulted in a departure from past

agency practice. Finally, Eisai asserts that the FDA violated the APA by treating Belviq and Fycompa differently than other, similarly situated products

A. Application of the FDA's Interpretation to Belviq and Fycompa

The Court will first consider Eisai's argument that, even accepting the FDA's interpretation of the "approval date" regulation, the company should prevail because the letters approving Belviq and Fycompa contained language that should have brought the drugs within the exception to the regulation and delayed the FDA's official approval date. To summarize the argument: The regulation provides that the "date of approval" is the date on the NDA approval letter "as long as approval of [final printed] labeling or materials is not expressly required," 21 C.F.R. § 314.108(a); the FDA has interpreted that exception as applying only when the "express[] require[ment]" that the FDA approve the final labeling appears in the actual approval letter that the FDA sends; and Eisai contends that even accepting that interpretation, the letters at issue here contained such a requirement and so Belviq and Fycompa should have fallen within the exception and received a later approval date.

If Eisai is correct about that, then the Court could resolve this case on the facts and avoid issuing a broader ruling on the FDA's interpretation of its regulation. The Court concludes, however, that the FDA reasonably concluded that the letters do not themselves expressly require subsequent label approval.

There is no question that Eisai had to finalize the labels on the packaging for Belviq and Fycompa after DEA scheduled the drugs. FDA regulations require that the label of any scheduled drug reflect the Controlled Substances Act schedule on which the drug is listed. 21 C.F.R. § 201.57(a)(2); *see also id.* § 201.57(c)(10)(i) (requiring the a drug's full prescribing information to include "the schedule in which [a drug] is controlled"). The proposed labels for

Belviq and Fycompa did not include any such designation because the FDA had not yet referred the drugs for DEA scheduling when Eisai submitted the NDAs, including the proposed labels, for the drugs. To cover this situation, FDA regulations set out the requirements for making various changes to drug applications and provide that "[a]ny change to the information required by § 201.57(a)" is a "major change" that "requir[es] supplement submission and approval prior to distribution of the product made using the change." 21 C.F.R. § 314.70(b), (b)(2)(v)(C). At oral argument, the FDA conceded that § 314.70(b) applied to the labeling changes that added scheduling information for Belviq and Fycompa. Arg. Tr. at 65:16-23. Thus, at the time Eisai received its NDA approval letters, FDA regulations mandated that Eisai update its labels once DEA made a scheduling determination and that it secure FDA approval of those updated labels.

The question here is whether the NDA approval letters themselves "expressly required" that approval. *See* 21 C.F.R. § 314.108(a). If so, then the drugs should have fallen within the exception in § 314.108(a), even as the FDA construes the regulation, and should have received an official approval date that reflected that later approval. This is a close question on the facts. The NDA approval letter for Belviq included a reminder to Eisai that the company would "need to make appropriate revisions to the package insert, the patient package insert and the carton and immediate-container labels through supplementation of [its] NDA." AR 68. The letter for Fycompa contained identical language. AR 76-77. As the Court reads the letters, both expressly require Eisai to revise the labels, but neither expressly requires that the FDA *approve* those edits. It is true that the letters require the sort of label revision that the FDA must presumptively approve under its regulations. 21 C.F.R. § 314.70(b)(2)(v)(C). But only an express requirement of FDA "approval" triggers the exception in 21 C.F.R. § 314.108(a), at least as the FDA

construes that exception, and the letters say nothing about approval. Although this distinction is a fine one, it is not without significance.

Even though the letters facially appear to trigger a sequence of events that should end with FDA approval of the updated labels *before* the drugs could go to market, the record reveals that the agency's practice is quite different. FDA regulations allow the agency to waive the requirement that it approve of labeling changes before products incorporating those changes can be brought to market. *See* 21 C.F.R. § 314.90(a) ("An applicant may ask the Food and Drug Administration to waive under this section any requirement that applies to the applicant under §§ 314.50 through 314.81."). In its administrative petition to the FDA, Eisai recognized that the FDA "routinely approves" those waivers and allows companies to amend their labels to reflect DEA scheduling through a "changes-being-effected (CBE) supplement after a determination by the [FDA's] review division that *a prior-approval supplement is not necessary*." AR 34 (emphasis added). In other words, the FDA's practice has been that, once it approves an NDA, a company may obtain a waiver and simply file a supplement reflecting the addition of the DEA scheduling information without obtaining FDA approval before going to market. *See Norwich Eaton Pharm., Inc. v. Bowen*, 808 F.2d 486, 492 (D.C. Cir. 1987) (noting that "'[s]upplements' effect changes in applications that have *already been approved*" (emphasis added)).

This practice makes sense. A label change to reflect DEA scheduling is often as simple as adding a small logo to the label with a Roman numeral that reflects the drug's schedule and a sentence that states the same information. It is such a simple and non-discretionary edit that the FDA generally treats it as ministerial and not worth further agency review. As a result of the FDA's "routine[]" practice of accepting these supplements, Eisai recognized that "the day the CBE supplement is submitted with the necessary label changes is the day the sponsor can

commercially market the product . . . ." AR 34. And, indeed, Eisai received such waivers for both Belviq and Fycompa.[1] Thus, the NDA approval letters Eisai received were, in reality, the final FDA approval necessary for market entry, and the DEA's scheduling determination was the only hurdle that remained. Because those letters did not facially contain an "express[] require[ment]" that the FDA approve of additional labeling requirements and because Eisai understood that, in fact, the FDA would not need to approve of any additional labeling requirements before the company could take the drugs to market, the Court concludes that the FDA's decision to consider the date of approval for both Belviq and Fycompa as the date found on their NDA approval letters was not arbitrary or capricious. *See Emily's List v. FEC*, 581 F.3d 1, 22 n.20 (D.C. Cir. 2009) ("Agencies generally do not violate the APA's deferential arbitrary-and-capricious standard when they employ bright-line rules for reasons of administrative convenience, so long as those rules fall within a zone of reasonableness and are reasonably explained.").

B. The FDA's Interpretation of the 21 C.F.R. § 314.108(a) Exception

The next question is whether the FDA has reasonably construed the exception to its regulation defining "date of approval," 21 C.F.R. § 314.108(a). This is a critical issue in this case because the agency initiates the five-year exclusivity period for a drug on "the date of approval of the . . . new drug application." 21 C.F.R. § 314.108(b)(2). Section 314.108 tracks the statutory language, which prohibits submission of applications for generic versions of a drug "before the expiration of five years from the *date of approval*" of the original new drug

[1] Only one of these waivers is in the record, *see* AR 107, but Eisai avers, and the FDA has not disputed, that both waivers were granted after the approval letters that triggered the start of the exclusivity periods here.

application. 21 U.S.C. § 355(c)(3)(E)(ii) (emphasis added). The statute does not define "date of approval," but an FDA regulation does:

> Date of approval means the date on the letter from FDA stating that the new drug application is approved, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required. "Date of approval" refers only to a final approval and not to a tentative approval that may become effective at a later date.

21 C.F.R. § 314.108(a). Thus, in run-of-the-mill cases, the date of approval is simply the "date on the letter from the FDA stating that the new drug application is approved." *Id.* There is little room for the agency to interpret this clear rule, and its interpretation is not at issue here.

There is room, however, to interpret the exception to the general rule, which applies when "approval of [final printed] labeling or other materials" is "expressly required." *Id.* The regulation is entirely silent as to *who* must "expressly require[ ]" labeling approval, *where* that requirement must appear, or even *what* constitutes an "express require[ment]." The FDA argues that the phrase "expressly required" refers only to the letter the agency issues advising that the new drug application is approved, and absent an express requirement of subsequent approval *in that letter*, the approval letter triggers the five-year exclusivity period. The Court must defer to that interpretation unless it is "plainly erroneous or inconsistent with the regulation." *Auer*, 519 U.S. at 461.[2]

1. *Text of the Regulation*

Eisai argues that "there is no requirement in the regulation's text that the 'express requirement' be in the approval letter, and the FDA cannot read such a requirement into the

[2] *Auer* has been the target of skepticism in recent years. *See Decker v. Nw. Envtl. Def. Ctr.*, 133 S. Ct. 1326, 1338-39 (2013) (Roberts, C.J., concurring in part and dissenting in part); *id.* at 1339-1342 (Scalia, J., dissenting); *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1210-1211 (2015) (Alito, J., concurring in part and concurring in the judgment); *id.* at 1213-1225 (Thomas, J., concurring in the judgment). This Court, however, is bound to follow *Auer* unless and until the Supreme Court modifies the relevant standard.

regulation." Dkt. 17 at 4. To prevail on this argument, Eisai must show that it would be "plainly erroneous or inconsistent with the regulation" for the FDA to interpret its regulation in this manner. *Auer*, 519 U.S. at 461; *see also Thomas Jefferson Univ.*, 512 U.S. at 512 ("[The Court's] task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." (internal quotation marks omitted)). The fact that 21 C.F.R. § 314.108(a) does not specify which document must "expressly require[]" subsequent approval renders the regulation ambiguous. It does not, however, render the FDA's reading plainly erroneous.

The FDA's interpretation of the regulatory text, moreover, is a reasonable one. Eisai reads too much into the fact that the phrase "expressly required" is not followed by a reference to the source of that "require[ment]." The full sentence that contains the exception reads: "Date of approval means the date *on the letter from FDA stating that the new drug application is approved*, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required." 21 C.F.R. § 314.108(a) (emphasis added). It is not plainly erroneous or otherwise inconsistent with the regulation's text to read the phrase "expressly required" to refer back to the phrase "letter from FDA stating that the new drug application is approved," which appears in the very same sentence.

Although the regulation's text could have been clearer, the FDA's interpretation is a plausible one, and Eisai's "alternative" construction is not "compelled by the regulation's plain language." *Thomas Jefferson Univ.*, 512 U.S. at 512.

2. *The Agency's Intent Behind the Regulation*

Eisai also argues that the FDA's interpretation of its regulation is inconsistent with the agency's intent at the time it proposed the regulation. The company points to the preamble to the Federal Register notice that proposed 21 C.F.R. § 314.108, which stated, in relevant part:

> The "date of approval" of the application as used in these provisions means the date on the approval letter sent by FDA to the applicant. A requirement in the approval letter for submission (but not for approval) of final printed labeling or other material that might delay the actual initiation of marketing of the product is not relevant to a determination of the date of approval, so long as the product could be legally marketed.

54 Fed. Reg. 28872, 28898 (July 10, 1989). Eisai asks the Court to make an inference from this explanation: If a requirement for submission of final printed labeling is "not relevant" to the date of approval "so long as the product could be legally marketed," then it stands to reason, the company suggests, that the date on the approval letter should *not* be the official "date of approval" if the product *cannot be* legally marketed at that time. This argument is not without merit. But there are several reasons why the preamble is ultimately insufficient to compel the Court to cast aside the high level of deference that *Auer* otherwise requires.

First, the preamble sheds little light on the issue that is central to Eisai's case, which is where or how the FDA must "expressly require" approval of labeling materials to trigger the exception in 21 C.F.R. § 314.108(b)(2). As explained above, the FDA's interpretation of the regulation as reaching only "express require[ments]" for future approval of labeling materials in the NDA approval letter is itself consistent with the plain text of the regulation, *see* Part III.B.1, and neither approval letter at issue here contained such an express requirement, *see* Part III.A. The preamble speaks principally to when labeling changes required in NDA approval letters should be deemed more than ministerial (*i.e.*, when they prevent the product from being legally

marketed), but it is of less help in settling whether such requirements found outside of approval letters should alter the official date of approval.

Second, both the preamble and the regulation might raise potential concerns about how the FDA approval process and DEA's scheduling process interact, but they are not the concerns at issue in this litigation. A company may only avail itself of the exception in 21 C.F.R. § 314.108 when the FDA expressly requires that the company obtain approval for labeling changes before taking the drug to market. The preamble is fully consistent with the regulation's text, suggesting that the date on the NDA approval letter should be the final date of approval unless the FDA delays when the applicant could legally market the drug by requiring some additional FDA approval of labeling. But the approval of the drugs' labeling was not the source of the delay for either Belviq or Fycompa. Instead, as explained above, the FDA is in the habit of exercising its discretion to waive under 21 C.F.R. § 314.90 any requirement that it approve ministerial changes to labeling that reflect DEA scheduling. *See* AR 13 & n.71. Eisai recognized during its administrative appeal that the FDA "routinely" grants these waivers, and Eisai received waivers for both Belviq and Fycompa. *See id.*; *see also* Arg. Tr. at 6:24-7:5. Thus, at the time Eisai received its NDA approval letter from the FDA for both drugs, the company understood that there was only one actual impediment to taking the drugs to market. That barrier was DEA finalizing the drugs' scheduling, not FDA approval of any subsequent labeling changes. Both the regulation and the preamble, however, address only the latter and say nothing about the former when defining "date of approval."

Once again, Eisai raises a fair point, but it is one that is insufficient to overcome the FDA's interpretation of its own regulation. The preamble to the regulation may support Eisai's broader policy argument that a drug should not be deemed "approved" for exclusivity purposes

until it can legally go to market. But, the preamble is not sufficiently clear or definite—or, for that matter, binding on the agency—to demonstrate that the FDA's interpretation of its otherwise ambiguous regulation is "plainly erroneous or inconsistent with the regulation." *Auer*, 519 U.S. at 461.

3. *The Statutory Purpose*

Eisai also contends that there is tension between the FDA's interpretation of § 314.108 and Congress's intent to provide an effective incentive to producers of new drugs through the provision of a five-year period of market exclusivity. The company asserts that beginning the five-year exclusivity period before a drug could be legally marketed would impermissibly "change the incentive structure adopted by Congress" and reflect the agency's "arrogat[ion] for itself the power to deprive a NCE sponsor of its earned exclusivity." Dkt. 14-1 at 12 n.5 (quotation marks and alterations omitted). This argument is more atmospheric than formal in Eisai's briefing, and Eisai has explicitly disclaimed any attack on § 314.108 itself as inconsistent with the governing statute, 21 U.S.C. § 355. *See* Arg. Tr. at 31:17-22 (noting that *Chevron* deference does not apply because "nobody is challenging the regulation"). The Court takes Eisai to be suggesting that the statutory purpose is so clearly contrary to the FDA's interpretation of its regulation that the interpretation does not even satisfy the highly deferential standard in *Auer*.

Eisai cites two cases that are relevant to this question: *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 121-22 (D.C. Cir. 2006) and *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1316 (D.C. Cir. 2010). Both concerned an agency regulation that affected the operation of 21 U.S.C. § 355(j)(2)(A)(vii), which provides that in certain circumstances, the first generic drug manufacturer to challenge successfully a patent held by the developer of a new drug is entitled to a 180-day period of limited exclusivity during which the FDA may not approve any other generic drug manufacturer's version of the drug. The FDA's policy under attack in both cases,

however, allowed drug developers to exploit a loophole that prevented generic manufacturers from obtaining 180-day exclusivity: After an application for approval of a generic version was filed, the drug's patent holder could request that the FDA "delist" the challenged patent from the developer's new drug application, and the agency would grant the request as long as the developer had not already filed a lawsuit to protect its patent. *Ranbaxy Labs.*, 469 F.3d at 122-23. Because the manufacturer no longer claimed patent protection, the first generic manufacturer whose application was approved would not receive 180-day exclusivity. In both cases, the D.C. Circuit struck down the FDA's policy because it was "inconsistent with the structure of the statute" by "diminish[ing] the incentive for a manufacturer of generic drugs to challenge a [listed patent." *Ranbaxy Labs.*, 469 F.3d at 125-26; *see also Teva*, 595 F.3d 1318.

Eisai would analogize this case to *Ranbaxy Labs.* and *Teva*. In its view, the FDA's policy of beginning the five-year exclusivity period for drugs before the drugs can be legally marketed interferes with the incentive Congress intended to create for developers of new drugs. This is a substantial argument. There are, however, important ways in which this case is unlike *Ranbaxy Labs.* and *Teva*. For one thing, the FDA policies in those cases allowed drug manufacturers to manipulate the exclusivity system in direct conflict with Congress's purpose, *see Teva*, 595 F.3d at 1317 ("[G]iven the incentives for the brand manufacturer, [strategic delisting] will be used only where its impact on Congress's scheme is most destructive." (emphasis omitted)). There does not appear to be a similar concern here. Although bureaucratic delay within the FDA or the DEA or other innocent factors might hamper a drug manufacturer's use of its full five-year exclusivity period, Eisai has not suggested that the FDA's policy opens the door to intentional and strategic manipulation by private third-party competitors.

More significantly, the Court must consider the actual impediment that Eisai faced in marketing Belviq and Fycompa after the approval letters were issued. One possible impediment was FDA Form 356h, which required Eisai to commit that it would refrain from marketing the drugs before the DEA made its scheduling determination. *See* U.S. Food and Drug Administration, FDA Form 356h, *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM082348.pdf (last visited Sept. 28, 2015). Eisai, however, has not separately challenged the lawfulness of that requirement—nor does it argue that Form 356h has anything to do with the FDA's "date of approval" regulation, which creates an exception only for "such labeling or other materials" where FDA approval is "expressly required," 21 C.F.R. § 314.108(a). FDA Form 356h might be an obstacle to Eisai (and other similarly situated companies) receiving a full five-year window of exclusivity, but that obstacle has little to do with whether the agency's interpretation of its "date of approval" regulation is "plainly erroneous or inconsistent with the regulation."

To the extent Eisai challenges the underlying impediment resulting from the *DEA*'s delay in scheduling the drugs, moreover, that policy concern goes well beyond the type of concern at issue in *Ranbaxy Labs.* and *Teva*. Unlike the challenges to the FDA's actions in *Ranbaxy Labs.* and *Teva*, consideration of the DEA's delay is difficult to reconcile with the statutory text, which simply provides that the exclusivity period runs for "five years from the date of the approval of the [new drug] application." 21 U.S.C. § 355(c)(3)(E)(ii). If Congress had intended for the FDA to take into account reasons that marketing of a drug might be delayed that are beyond the FDA's control, it is unlikely that it would have focused on the date of the FDA's approval of the NDA, rather than the date on which the drug was permitted to be marketed or the date on which all regulatory requirements were satisfied. Indeed, before the Hatch-Waxman Amendments were

adopted, the FDA had "specified" by regulation "that the applicant shall be notified in writing that the application is approved and *the application shall be approved on the date of the notification*," and the D.C. Circuit has "found absolutely no reason to believe that Congress intended the term 'approved' in the Hatch-Waxman Amendments to mean anything other than what the FDA understood it to mean." *Mead Johnson Pharm. Grp. v. Bowen*, 838 F.2d 1332, 1336 (D.C. Cir. 1988). Put simply, the FDA has always looked to the NDA approval letter when determining a new drug's approval date, and the D.C. Circuit has endorsed that approach as consistent with Congress's intent. That the FDA also tethers the exception in § 314.108(a) to the approval letter appears perfectly consistent with Congress's intent.

The only other impediment that Eisai might have faced was the requirement that it include the DEA scheduling designation in its final label. Eisai might rely, for example, on the fact that approval of a drug's labeling is a part of the FDA's approval process. *See* 21 U.S.C. § 355(b)(1) (requiring new drug applicants to submit "specimens of the labeling proposed to be used for such drug"); 21 C.F.R. § 314.105(c) ("FDA will approve an application after it determines that the drug meets the statutory standards for . . . labeling"). If approval requires a determination that the drug's labeling is adequate, then it is reasonable to argue that the FDA has not granted "approval" until it makes that determination. And for controlled substances like Belviq and Fycompa, the FDA does not approve the *final* labeling until after the DEA makes its scheduling decision. *See* 21 C.F.R. §§ 201.57(a)(2), 314.70(b)(2)(v)(C).

The FDA, however, has drawn a distinction between minor labeling changes (such as the addition of a Controlled Substances Act schedule designation) and more significant ones in this regard. Its regulations explicitly contemplate that the agency may "approve an application and issue the applicant an approval letter on the basis of draft labeling" as long as the "only

deficiencies" are "editorial or other similar deficiencies in the draft labeling." 21 C.F.R. 314.105(b). That FDA's position is both understandable and reasonable. Where the agency requires that an applicant make only minor, mechanical changes to its labeling, the agency has concluded its approval of the application. The fact that the FDA may be required to perform the ministerial function of reviewing minor changes to draft labeling after it formally approves the drug—and, with a waiver, *see* 21 C.F.R. § 314.90, after the drug has already been marketed—does not render the formal approval in any way illusory. Moreover, as explained above, the FDA has reasonably explained that it routinely grants waivers—as it did for Belviq and Fycompa—of any pre-approval requirement for label changes required after the DEA makes a scheduling designation. *See* AR 13 & n.71; AR 107.

Ultimately, then, to the extent any *FDA* action impeded Eisai from taking advantage of the full five years of market exclusivity, it was the use of Form 356h—which was not a labeling rule, which did not require any post-approval FDA action, and which is not separately challenged in this action. The existence of that impediment has no relevance to the Court's interpretation of the FDA's entirely separate "date of approval" regulation, and, in particular, its exception for "labeling or other materials" where further FDA approval is "expressly required."

Moreover, although Eisai correctly characterizes the policy considerations that underlie the Hatch-Waxman Amendments, its position is difficult to reconcile with the statutory text. Most significantly, as the FDA noted, adopting Eisai's interpretation of § 314.108 would have the anomalous effect of creating different "approval" dates for different purposes under the Hatch-Waxman Amendments. For example, as Eisai acknowledges, the FDA does and will continue to determine which of two competing drugs was first approved—and therefore entitled to five-year exclusivity in the first place—by reference to the date of the approval letter. Arg. Tr.

at 28:18-23; *see also* 21 U.S.C. § 355(c)(3)(E)(i) (providing five-year exclusivity for any drug "no active ingredient . . . of which *has been approved* in any other application") (emphasis added). It is unlikely that Congress intended to refer to different triggering events when it used the phrase "has been approved" early in the first sentence of § 355(c)(3)(E)(i) and the phrase "date of approval" later in that same sentence. But, in any event, the FDA hardly exceeded the scope of its interpretive authority when it concluded that the phrase should be given a consistent meaning.

Despite the ambiguity noted above with respect to the "expressly required" language, § 314.108 speaks with relative clarity about the criteria for determining the "date of approval" for a new drug. The date on which the drug may be legally marketed is not one of those criteria. Instead, the regulation focuses on when the FDA has taken the last action it must take that constitutes "approval." *See* 21 C.F.R. § 314.108(a) ("Date of approval means the date on the letter from the FDA stating that the new drug application is *approved* . . . ." (emphasis added)); *see also id.* (providing no exception where "final printed labeling or other materials must yet be submitted as long as *approval* of such labeling or materials is not expressly required" (emphasis added)). This case illustrates that the date on which the FDA "approv[es]" a drug is not always the date on which the drug may be marketed. Although this disparity may reflect a flaw either in the FDA's regulation or in the statute, it does not reflect any deficiency in the agency's interpretation of its regulation. [3] Because § 314.108(a) does not, by its terms, admit of an interpretation that triggers five-year exclusivity at the time a drug may be legally marketed,

[3] The Court notes that legislation has been introduced in Congress that would explicitly define the "date of approval" of a drug subject to scheduling as a controlled substance as "the date of issuance of the interim final rule controlling the drug." H.R. 639, Improving Regulatory Transparency for New Medical Therapies Act. The bill was passed by the House of Representatives on March 16, 2015, and is awaiting action in the Senate.

rather than when the FDA takes an action that constitutes "approval" of the drug, the Court cannot plausibly interpret the regulation to avoid the fundamental statutory concerns Eisai has raised. And because Eisai has limited its challenge to an attack on the FDA's interpretation of its regulation, the Court need not resolve the question whether § 314.108, as reasonably interpreted by the FDA, is inconsistent with 21 U.S.C. § 355.

* * *

Although the extent to which the current regulatory scheme comports with the incentive structure that the Hatch-Waxman Amendments put in place raises difficult issues, the question presented here is a narrow one: Is the FDA's interpretation of the exception to its "date of approval" regulation "plainly erroneous or inconsistent with the regulation." The answer to that question is relatively straightforward. The FDA has reasonably construed the exception to mean that the requirement for further FDA approval must appear in the letter itself.

This leads to one final interpretive question: What rational basis might plausibly exist to confer different effective periods of exclusivity on new drugs based on whether a requirement for further FDA approval of labeling or other materials is expressly mentioned in the approval letter itself or simply mandated by statute or regulation. As explained above, the answer is that the approval letters signify completion of the FDA's process for reviewing and approving a manufacturer's NDA. The letters do, after all, bear the caption "NDA APPROVAL." Some requirements that may remain after the FDA sends such a letter are ministerial and do not affect the finality of that approval. In those circumstances—including when the manufacturer will have to finalize a label to reflect DEA scheduling—the FDA does not need to consider further any aspect of the NDA and so it treats its "approval" as final. In other cases, however, the requirements that remain are substantial and will require further substantive review and approval.

In those cases, the agency expressly requires further action *in its approval letter* as a signal that the FDA has concluded that its process is not yet completed. Although not the only method that the FDA might use to differentiate applications that require no further substantive review from those that still demand some significant approval, the approach the FDA has adopted is a reasonable one. The operative statute makes it necessary for the FDA uniformly to define the "date of approval," and the agency drew that line in a reasonable place. The Court, accordingly, concludes that the FDA's interpretation of 21 C.F.R. § 314.108(a) is not "plainly erroneous or inconsistent with the regulation," *Auer*, 519 U.S. at 461, and it thus defers to that interpretation.

C. Razadyne and the FDA's Prior Practice

Eisai also argues that the FDA's interpretation of its "date of approval" regulation constitutes an "'unexplained reversal'" that constitutes "'the height of arbitrary and capricious decision making.'" Dkt. 14-1 at 21 (quoting *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 884 (D.C. Cir. 2004)). As Eisai acknowledges, "agency action is arbitrary and capricious if it departs from agency precedent without explanation." *Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003). Here, Eisai's argument turns on the FDA's previous treatment of Razadyne ER ("Razadyne"), a drug used to treat Alzheimer's disease.

The record establishes that Razadyne was approved in an FDA letter dated December 22, 2004. Dkt. 1-1. Unlike Belviq and Fycompa, however, Razadyne was approved "without a tradename." *Id.* at 3. Instead, "because of recent medication errors associated with" the drug under its former appellation and a similarly-named drug, the producer had agreed to "adopt a new name for the [drug] prior to its marketing," and, critically, "to submit the new proposed proprietary names to the Agency for [its] review prior to implementation." *Id.* Following the general rule articulated in § 314.108, the FDA initially determined that Razadyne's exclusivity

period began on December 22, 2004—the date of the letter approving the drug. *See* Dkt. 1-6. The producer, however, requested that the the FDA "revise the approval date" to April 1, 2005. Dkt. 1-4. Its request was "based upon the fact that it was not until the later date that FDA and [the producer] agreed upon the new trade name . . . for the product." *Id.* The FDA granted the request, stating it was "reasonable to conclude that Razadyne . . . was not approved until April 1, 2005, when the Agency completed its review of the proposed trade name, found it acceptable, and conveyed this information to" the drug's producer. *Id.* Although the FDA's letter approving the request does not cite § 314.108, the parties appear to agree that the agency's decision to change the approval date for Razadyne reflected a determination that the drug qualified for the exception to the approval-date rule in that section. *See* Dkt. 15 at 16; Dkt. 17 at 9.

Eisai contends that the FDA's decision to change the approval date for Razadyne is inconsistent with the narrow construction of § 314.108 the agency now offers. It reasons that "[t]here was no explicit statement [in the FDA's initial approval letter] to the effect that" the sponsor of Razadyne "must obtain FDA approval of a trade name for its product before marketing could begin," so Razadyne's approval date could not have been changed under the standard the agency now asserts. Dkt. 17 at 9 (internal quotation marks omitted).

The Razadyne letter stated that Razadyne had made a "commitment to adopt a new name for [Razadyne] prior to its marketing, and to submit the new proposed proprietary names to the [FDA] for [its] review prior to implementation." Dkt. 1-1 at 3. Eisai makes something of the fact that this was a "voluntary" commitment—rather than being "expressly required" to do anything, the manufacturer simply received the FDA's recitation of voluntary commitments it had made during the approval process. Dkt. 14-1 at 20 n.7. But the question of whether a

voluntary commitment of this type gives rise to a "require[ment]" for purposes of the "date of approval" regulation has nothing to do with the issue presented in this case.

Instead, the relevant distinction the FDA draws for present purposes is between its statement that Eisai must "make appropriate revisions" to certain labeling components—which does not refer at all to FDA review or approval—and its statement to the manufacturer of Razadyne that that company had committed to "submit the new proposed proprietary names to the [FDA] *for [its] review prior to implementation*." Dkt. 1-1 at 3 (emphasis added). Eisai argues that this language does not expressly require "approval." Dkt. 17 at 5. True, the Razadyne letter does not explicitly say that the FDA must approve Razadyne's new trade name before the drug is marketed; it says only that the producer must "submit" the name for "review prior to implementation." But by expressly requiring "review prior to implementation," the Razadyne letter comes closer to expressly requiring "approval" of the subsequent submission than did the Belviq or Fycompa letters, which did not expressly require any further agency review. And it seems reasonable for the FDA to have concluded that requiring the manufacturer of Razadyne to submit the new name for agency "review prior to implementation" carried with it an understanding that FDA approval was necessary, particularly since the FDA had *rejected* the prior name as confusing and as posing potential health concerns.

The Razadyne letter thus reveals where the FDA draws the line for the § 314.108 exception. Its interpretation is strict enough that merely mentioning regulatory obligations that, in turn, give rise to a requirement to obtain approval of a label change is insufficient to trigger the exception. But it is accommodating enough that language expressly referring to an obligation to submit labeling-related materials for "review" qualifies for the exception. The agency did not need to draw the line in this place—it could have adopted an interpretation of the

exception under which both Eisai and the sponsor of Razadyne qualified, and it likely could have adopted an interpretation under which neither qualified. The conclusion it actually reached, however, reasonably relies on a real—even if modest—textual difference in the letters the FDA issued, and it warrants deference. *See Rollins Envtl. Servs. (NJ) Inc. v. EPA*, 937 F.2d 649, 652 (D.C. Cir. 1991) ("[I]n a competition between possible meanings of a regulation, the agency's choice receives substantial deference."); *cf. Universal City Studios LLLP v. Peters*, 402 F.3d 1238, 1243 (D.C. Cir. 2005) ("An agency's strict construction of a general rule in the face of waiver requests is insufficient evidence of an abuse of discretion." (internal quotation marks omitted)).

More relevant to the FDA's consistency is the fact that it has always treated drugs awaiting DEA scheduling in the same way it treated Belviq and Fycompa here. The record reveals 11 drugs approved since 2005 that were subject to DEA scheduling determinations. *See* AR 157. In none of those cases did the FDA delay the beginning of the exclusivity period until after the drug had been scheduled. *Id.* And the FDA has offered a reasonable explanation for its decision to apply the § 314.108(a) exception to Razadyne, which is not a scheduled drug. The evidence thus suggests that the FDA is actually consistent in how it treats drugs referred for scheduling and that Razadyne was a unique case that received an exception in light of the agency's reasonable understanding that its Razadyne approval letter called for further FDA action. Such a reasoned explanation backed by relevant evidence is not arbitrary and capricious. *See Emily's List*, 581 F.3d at 22 n.20.

D. Eisai's Other Arguments

In addition to its contention that the FDA misinterpreted its own regulation, Eisai argues that the agency arbitrarily treated its drugs differently from (1) drugs that do not require scheduling under the Controlled Substances Act and (2) other drugs that do require such

scheduling. The APA, Eisai notes, mandates that "an agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so." *Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996).

The first of these arguments has it backwards. The FDA, as noted above, treated Belviq and Fycompa precisely the same way it treats drugs not subject to controlled substance scheduling—it began their five-year exclusivity periods on the date of the FDA's letters approving the drugs. Eisai asks the agency to treat its drugs *differently* from drugs that need not await scheduling before they can be marketed. But the agency's refusal to do so is manifestly not a failure to "treat similar cases in a similar manner." *Babbitt*, 92 F.3d at 1258. And although Eisai argues that the FDA has "entirely failed to consider an important aspect of the problem" in this case by refusing to tie the beginning of the exclusivity period to the date on which a drug may be marketed, *State Farm*, 463 U.S. at 43, that argument is directed at the validity of § 314.108 itself. It is the language of the regulation—not the FDA's interpretation of it—that omits any reference to the date on which a drug may be legally marketed.

The second argument fares no better. It is true that the FDA's interpretation of § 314.108 gives the agency significant discretion regarding the start date for five-year exclusivity of scheduled drugs. By simply including a detailed statement of the particular labeling requirements facing a drug manufacturer, including the requirement to obtain subsequent FDA approval of updated labels reflecting scheduling information, the FDA can create a letter that qualifies for the exception and confers a substantial benefit on the recipient company. This discretion could be abused, but there is no evidence the FDA has done so here. Instead, as noted above, the FDA has not delayed the approval date until after DEA scheduling for any of the 11 drugs the agency has considered since 2005 that required DEA scheduling. *See* AR 157.

To the extent Eisai suggests, moreover, that the FDA treats similarly situated drugs differently because different companies end up with different exclusivity windows based on the time it takes DEA to schedule the drugs (and the time it takes FDA to refer the drugs for scheduling), Dkt. 14-1 at 18-19, Eisai might in theory have a claim against either agency on that ground. But Eisai is not suing to obtain a prompt scheduling determination—it is suing to change the effect that delays in scheduling determinations have on drug manufacturers' exclusivity periods. As explained above, however, all scheduled drugs are treated alike in this respect: None of them obtain deferred approval dates pending completion of the DEA the scheduling process.

Finally, Eisai notes in two sentences at the end of its brief that the FDA's response to the company's petition is "devoid of any consideration of FDA's disparate treatment of NCEs that require [Controlled Substances Act] scheduling." Dkt. 14-1 at 25. This argument sounds in the oft-repeated rule that agencies, not courts, should decide issues in the first instance, for courts "cannot exercise their duty of review unless they are advised of the considerations underlying [agency] action." *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943). Eisai has a point here. The FDA's response to this argument, which Eisai raised below, *see* AR 38-39, is minimal at best. Nevertheless, the Court concludes that the agency's explanation is just barely enough to satisfy the requirement of *Chenery*.

The FDA's decision survives because of the final footnote of its response to Eisai's petition. There, the agency explained that it "underst[ood] the equitable arguments" that Eisai raised and was "actively considering whether it should change its approach going forward, perhaps to an approach of issuing complete response letters to drugs subject to scheduling rather than approval letters in appropriate circumstances." AR 18 n.96. The sentence in the text

accompanying that footnote explained that "under the existing statutory framework, there is only a single date of approval, and an exclusivity period begins on that date." AR 18. And two paragraphs earlier, the FDA explained that "by arguing that the approval letter that [it] received is not really an approval of [its] NDAs," Eisai was in reality "asserting that [it] . . . should have received a form of 'complete response letter'" that would reject the application "'in its present form'" and "explain[] what additional information must be submitted before approval can be granted." *Id*. (quoting 21 C.F.R. § 314.110). But, the agency noted, Eisai "did not seek such a response." *Id*.

This explanation responds, albeit obliquely, to Eisai's complaints about unequal treatment. The agency recognized that there were "equitable" concerns with the process that cost Eisai some of its exclusivity period for both Belviq and Fycompa. It also recognized that there might be an existing solution to this equitable concern under a separate regulatory provision—the "complete response letter." But, the FDA explained, Eisai had not asked for a complete response letter. The company instead went through the standard NDA process and received an approval. And like all other companies that receive an NDA approval letter, Eisai's five-year exclusivity window was triggered on the date that letter was issued. Because the company chose to pursue that course, and because the "existing statutory framework" allowed for "only a single date of approval," the agency was unwilling to entertain Eisai's argument. That explanation, although far from the clear response agencies should strive to provide, sufficiently addressed the company's argument that it was receiving unequal treatment.

IV. CONCLUSION

For the foregoing reasons, Eisai's motion for summary judgment is **DENIED** and the FDA's motion for summary judgment is **GRANTED**. An appropriate Order accompanies this Memorandum Opinion.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: September 30, 2015