United States Court of Appeals for the Federal Circuit

2009-1368

WYETH HOLDINGS CORPORATION
and WYETH (now known as Wyeth LLC),

Plaintiffs-Appellants,

v.

Kathleen Sebelius, SECRETARY OF HEALTH AND HUMAN SERVICES,
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Dr. Margaret Hamburg, COMMISSIONER OF FOOD AND DRUGS,
UNITED STATES FOOD AND DRUG ADMINISTRATION,
David Kappos, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY and DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellees.

Randolph D. Moss, Wilmer Cutler Pickering Hale and Dorr LLP, of Washington, DC, argued for plaintiffs-appellants. With him on the brief were Brian M. Boynton and Brian H. Fletcher.

Howard S. Scher, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for defendants-appellees. With him on the brief were Tony West, Assistant Attorney General, Channing D. Phillips, Acting United States Attorney, and Scott R. McIntosh, Attorney. Of counsel on the brief were David S. Cade, Acting General Counsel, Michael M. Landa, Acting Associate General Counsel, Eric M. Blumberg, Deputy Chief Counsel, and James R. Johnson, Associate Chief Counsel, Office of the General Counsel, Food and Drug Division, United States Department of Health and Human Services, of Rockville, Maryland. Of counsel was Drake S. Cutini, Office of Consumer Litigation, United States Department of Justice, of Washington, DC.

Appealed from: United States District Court for the District of Columbia

Judge Henry H. Kennedy, Jr.

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Defendants-Appellees.

Appeal from the United States District Court for the District of Columbia in case no. 08-CV-00981, Judge Henry H. Kennedy, Jr.

DECIDED: May 3, 2010

Before BRYSON and MOORE, Circuit Judges, and FOLSOM, Chief District Judge.[*]

MOORE, Circuit Judge.

Wyeth Holdings Corporation and Wyeth LLC (Wyeth) appeal the judgment, pursuant to summary judgment, of the United States District Court for the District of Columbia rejecting Wyeth's challenge to the United States Food and Drug Administration's (FDA's) determination of the date on which the approval phase of its

[*] The Honorable David Folsom, United States District Court for the Eastern District of Texas, sitting by designation.

phased regulatory review process begins for purposes of calculating patent term extensions. For the reasons discussed below, we affirm.

BACKGROUND

I. Regulatory Background

New animal drugs must receive FDA approval before they can be commercially marketed. Because the regulatory process often spans several years, in 1988 Congress provided for patent term extensions to restore patent life lost during FDA's review of new animal drugs. See Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988). Regulatory review proceeds in two phases: a testing phase followed by an approval phase. The shift from the testing to the approval phase occurs when a sponsor "initially submit[s]" an application for approval of a new animal drug. See 35 U.S.C. § 156(g). A patent holder may obtain an extension equal to half of the duration of the testing phase plus the entire duration of the approval phase, not to exceed five years, exclusive of any regulatory review period occurring before the patent issues. See 35 U.S.C. § 156(c), (g)(6). Thus, the date on which a sponsor initially submits an application marks the beginning of the approval phase and directly affects the length of a patent term extension. At issue on appeal is the proper determination of that date in FDA's phased review process.

The first phase of regulatory review, the testing phase, begins when the sponsor obtains FDA's permission to begin clinical testing of the drug or initiates a major health or environmental effects test, whichever is earlier. See 35 U.S.C. § 156(g)(4)(B)(i); see also 21 C.F.R. § 60.22(d)(1). During the testing phase, the sponsor submits investigational data to FDA, which FDA files in an Investigational New Animal Drug (INAD) file.

The testing phase ends, and the approval phase begins, when the sponsor submits a New Animal Drug Application (NADA) to FDA. See 35 U.S.C. § 156(g)(4)(B)(ii); see also 21 C.F.R. § 60.22(d)(2). The NADA must contain the information required by 21 U.S.C. § 360b(b) and the corresponding FDA regulation, 21 C.F.R. § 514.1(b). Section 360b(b) requires, among other things, full reports of investigations concerning the safety and efficacy of the drug, a description of the methods and facilities used to manufacture the drug, and a description of a method to determine the quantity of the drug that winds up in food. 21 U.S.C. § 360b(b)(1).

In the traditional regulatory review process, determining the date that a sponsor submits a NADA is straightforward: the sponsor gathers all of the information required by § 360b(b) and sends it all to FDA in a single submission, and this is the date that the application is initially submitted. FDA may require additional information from the sponsor in support of the NADA; but minor amendments will not affect the "initially submitted" date or the onset of the approval phase.

In 1989, FDA began offering sponsors the choice of "phased review." In phased review, rather than gathering the information required by § 360b(b) and submitting it to FDA in one package, the sponsor may submit various technical sections directly to the section of FDA's Center for Veterinary Medicine (CVM) responsible for evaluating the technical material. FDA treats technical sections as submissions to the INAD file. As of 1995, FDA recognized six technical sections: (1) Effectiveness, (2) Environmental Safety, (3) Manufacturing Methods and Controls, (4) Public Safety, (5) Residue Chemistry and Regulatory Methods, and (6) Target Animal Safety. Center for Veterinary Medicine Document Submission Information – An Update, 14 (Apr. 1995, as

modified Nov. 1995) (CVM Phased Review Policy). FDA reviews the technical sections on a concurrent as-received basis. In addition, "[w]ith prior agreement, the sponsor may request review of less than one of the [technical sections] listed above." Id. at 14. Thus, sponsors may submit technical sections as they are completed or, by agreement, they may submit "useful pieces of technical sections." Id. at 13. When FDA completes its review of a technical section, it sends the sponsor a "complete letter" for that section. Once the sponsor compiles all of its complete letters, it may submit an administrative NADA. The administrative NADA incorporates by reference all of the complete letters and contains additional administrative information. In phased review, FDA marks the beginning of the approval phase as the date that the sponsor submits the administrative NADA.

FDA described phased review as a more "streamlined" process than traditional review. CVM Phased Review Policy at 2. It summarized the choice between traditional and phased review as follows:

> If the sponsor wants to work interactively with each specialty group within the Office of New Animal Drug Evaluation, then the data should be submitted to the INAD for review. If the sponsor wants to submit all the information at one time and receive a coordinated, comprehensive response on the adequacy of all the data, the sponsor should submit an NADA.

Id. at 1. FDA further explained that in phased review, submissions would not be funneled through a primary reviewer; the sponsor would retain responsibility for ensuring the compatibility of the technical sections. Id. at 2. FDA further explained that "[t]he interrelationships between supporting data should be thoughtfully considered when the sponsor elects to request phased review." Id. at 17. FDA indicated that phased review "should speed the drug development process." Id. at 2.

When a sponsor opts for phased review, it may switch over to traditional review by filing a NADA. As explained by FDA, "[m]ost sponsors find it useful to use the more fluid INAD structure during early development and, as more of the data is acceptable to CVM [Center for Veterinary Medicine], an NADA is filed." Id. at 2. The NADA may incorporate by reference any complete letters that the sponsor has already received. Id.

Once FDA receives a NADA (either traditional or administrative), it evaluates the application and determines whether to approve the drug. Filing an administrative NADA will generally result in a much shorter approval period because FDA has already completed review of the technical sections.

II. Cydectin

Wyeth sought and received FDA approval to market Cydectin for the treatment and control of internal and external parasites in beef and dairy cattle. The regulatory review period for Cydectin spanned nearly eight years. It began on April 5, 1990, when at Wyeth's request, FDA established an INAD file for Cydectin, marking the beginning of the testing phase. Wyeth submitted various investigational information to FDA, including information on drug formulation and protocols for clinical studies. On August 8, 1995, Wyeth opted for phased review and submitted its first technical section, which addressed Residue Chemistry. In 1995 and 1996, Wyeth submitted technical sections concerning Effectiveness, Manufacturing, Public Safety, and Target Animal Safety. By agreement with FDA, Wyeth submitted its final technical section, Environmental Safety, in three modules. Wyeth submitted the first of these modules on August 14, 1996. It is unclear when Wyeth submitted the second and third modules. FDA ultimately approved each section, and by January 13, 1998, Wyeth had received all of its complete letters.

Wyeth submitted an administrative NADA that same day. FDA approved Wyeth's NADA 16 days later on January 28, 1998.

The active ingredient in Cydectin, moxidectin, is claimed in U.S. Patent No. 4,916,154 (the '154 patent), which issued on April 10, 1990.[1] On March 27, 1998, Wyeth sought a patent term extension for the '154 patent based on the regulatory review period for Cydectin. According to Wyeth, this was the first patent term extension request based on a NADA submitted via phased review. Wyeth attached a memorandum to its request setting forth its position that it initially submitted a NADA for Cydectin on August 8, 1995, when it submitted its first technical section (Residue Chemistry). Wyeth argued in the alternative that it initially submitted a NADA no later than August 14, 1996, when it submitted one component of its last technical section (Environmental Safety).

The United States Patent and Trademark Office (PTO) requested FDA's assistance in determining whether Cydectin had been subject to regulatory review within the meaning of 35 U.S.C. § 156(g). FDA informed the PTO that Cydectin had been subject to regulatory review within the meaning of § 156(g).[2] FDA further informed the PTO that Cydectin experienced a regulatory review period of 2,857 days, beginning on April 5, 1990, and ending on January 28, 1998. FDA stated that of this review period, 2,841 days occurred during the testing phase and 16 days occurred during the approval phase. Based on these numbers, the PTO calculated a patent term extension of 1,434 days, representing one half of the testing phase (exclusive of six

[1] The '154 patent is assigned on its face to Wyeth's predecessor, American Cyanamid Company, referred to herein as Wyeth.

days occurring prior to the issuance of the '154 patent) plus the entire approval phase (calculated as (2,841 – 6)/2 + 16).

Wyeth asked FDA to revise its determination of the regulatory review period. Wyeth reiterated its position that it had initially submitted its NADA on August 8, 1995, when it submitted its first technical section (Residue Chemistry). Wyeth reasoned that at that point, FDA had sufficient information to commence its review.

FDA denied Wyeth's request. It set forth its position that "the approval phase for purposes of patent term extension begins when the marketing application is complete, including all technical sections and the CVM complete letters." J.A. 232. It explained that "[a]lthough this approach can result in a very short approval phase, it is most consistent with the idea that alternative drug development and review approaches are intended to permit the applicant to respond to FDA input as the application is developed, making FDA's review more efficient, and shortening the time required for review of the application." Id. FDA further explained that the technical sections are submitted to the INAD file, not to the NADA file, and thus FDA conducts its review of these components as part of the testing phase. FDA therefore concluded that the approval phase in phased review begins with the submission of an administrative NADA. Id.

Wyeth filed a complaint in the United States District Court for the District of Columbia challenging FDA's interpretation of the date that its NADA was initially submitted and seeking injunctive and declaratory relief under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706. FDA moved to dismiss or alternatively for

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[2] The PTO initially requested information from FDA on May 5, 1998. FDA,

summary judgment, and Wyeth cross-moved for summary judgment. The district court granted FDA's motion and entered judgment for FDA. Wyeth appeals that judgment. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review the district court's grant of summary judgment de novo, applying the same standard as the district court. Immunocept, L.L.C. v. Fulbright & Jaworski, L.L.P., 504 F.3d 1281, 1286 (Fed. Cir. 2007). "Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Id.

We review FDA's decisions under the APA. See Mylan Labs., Inc. v. Thomson, 389 F.3d 1272, 1279 (D.C. Cir. 2004). We must uphold FDA's decision unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

This appeal concerns statutory interpretation, a matter of law that we review de novo. See Glaxo Operations UK Ltd. v. Quigg, 894 F.2d. 392, 395 (Fed. Cir. 1990). "Ordinarily we review an agency's interpretation of a statute it is charged with implementing under the familiar and deferential two-part framework of Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 104 S. Ct. 2778, 81 L.Ed.2d 694 (1984)." Mylan, 389 F.3d at 1280.

Under Chevron, we first determine "whether Congress has directly spoken to the precise question at issue." Chevron, 467 U.S. at 842. If the intent of Congress is clear, we must give effect to the unambiguously expressed intent of Congress. Id. at 843.

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however, did not respond. The PTO sent an additional request on September 10, 2003.

However, "[i]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id.

I. Chevron Step 1

We first address whether Congress spoke to the precise issue, specifically, whether the date that a sponsor submits an administrative NADA marks the beginning of the approval phase when the sponsor opts for phased review.

The district court concluded that the date an application is initially submitted for purposes of 35 U.S.C. § 156(g) is ambiguous. The court noted that the parties agreed that the approval phase begins when an application is initially submitted under 21 U.S.C. § 360b(b), but they disagreed over the proper interpretation of when an application is initially submitted. The court explained that the parties emphasized different text in support of their positions, with FDA contending that no "application" exists prior to the submission of an administrative NADA, and Wyeth contending that an application is "initially submitted" upon submission of the first technical section. Wyeth, 607 F. Supp. 2d at 31. The court determined that both parties had advanced plausible interpretations. Id. The court reviewed the text of § 156(g) and determined that it contained "no clear indication of Congressional intent because the statute defines neither 'application' nor 'initially submitted.'" Id. The court looked to the text of 21 U.S.C. § 360b(b) and determined that although it set forth requirements for the parts of an application, "this section does not define 'application' or speak to the issue of when an 'application' is 'initially submitted.'" Id. The court also reviewed the legislative history and noted that it provided little clarity. Id. at 32. The court concluded that in light of its text, context, and legislative history, § 156(g) was ambiguous.

On appeal, Wyeth argues that the statutory text and legislative history demonstrate that an application is initially submitted when a sponsor submits its first technical section. Wyeth contends that the ordinary meaning of the term "initially" makes clear that an application is initially submitted before it is complete, noting that § 156(g) does not require the sponsor to completely or finally submit an application. Wyeth asserts that the legislative history supports its position, citing to a House Report that states: "As long as the application was complete enough so that agency review could be commenced, it would be considered to be 'initially submitted.'" H.R. Rep. 98-457, pt. 1, 44 (1984). Wyeth thus asserts that an application is initially submitted when a sponsor submits its first technical section because at that point, FDA may commence its review. Wyeth argues in the alternative that, at the very latest, an application is initially submitted when the sponsor submits its last technical section because, according to Wyeth, at that point, FDA has received all of the parts of an application required by 21 U.S.C. § 360b(b). Finally, as discussed in the next section, Wyeth argues that even if the text does not unambiguously support one of its interpretations, we should not defer to FDA's interpretation because it is not reasonable.

FDA argues that the statutory text compels FDA's interpretation that an application is initially submitted when the sponsor files an administrative NADA. FDA explains that, contrary to Wyeth's point of view, the date that it may commence review of individual technical sections is irrelevant. According to FDA, for purposes of 35 U.S.C. § 156(g), what matters is the date that FDA may commence review of an application meeting the requirements of 21 U.S.C. § 360b(b). FDA asserts that the administrative NADA is the first document submitted to FDA that contains all of the parts

required by 21 U.S.C. § 360b(b). Thus, it argues that prior to the submission of an administrative NADA, the sponsor has not initially submitted an application for purposes of 35 U.S.C. § 156(g). In the alternative, FDA asserts that even if we conclude that the statutory text is ambiguous, we should defer to its interpretation because it is reasonable.

We agree with the district court that the plain language does not clearly indicate when an application is initially submitted under 35 U.S.C. § 156(g). Section 156(g) defines the regulatory review period as the sum of two periods, which the parties refer to as the testing phase and the approval phase. See 35 U.S.C. § 156(g)(1)(B)(ii). The testing phase covers:

> the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 [21 U.S.C. § 360b] became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512.

Id. at § 156(g)(4)(B). The approval phase covers:

> the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

Id. Section 156(g) does not define the term application, however, it refers to an application initially submitted under 21 U.S.C. § 360b(b). Thus, for purposes of § 156(g), an application must contain the information required by 21 U.S.C. § 360b(b). Section 360b(b) requires that an application for a new animal drug include certain categories of information, such as information on drug safety, efficacy, and manufacturing.

In light of this requirement, we reject Wyeth's argument that § 156(g) unambiguously indicates that an application is initially submitted when a sponsor submits its first technical section. A technical section addresses only one substantive area, such as Residue Chemistry. A technical section does not contain all of the information required by § 360b(b) and therefore it can not constitute "an application" for purposes of 35 U.S.C. § 156(g). This interpretation conflicts with the statutory language.

Although 21 U.S.C. § 360b(b) lists the required parts of an application, it does not indicate whether an application must contain or reference all of the required information in a single document (as asserted by FDA) or whether an application may be an assemblage of technical sections submitted by the sponsor (as asserted by Wyeth). Contrary to Wyeth's assertion, the legislative history by no means renders the statutory language unambiguous. We agree with the district court that both parties advanced plausible interpretations, and we conclude that § 156(g) is ambiguous.[3]

II. Chevron step 2

"If we conclude that 'Congress either had no intent on the matter, or that Congress's purpose and intent is unclear,' then we proceed to step two, in which we ask 'whether the agency's interpretation is based on a permissible construction of the statutory language at issue.'" Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1338 (Fed. Cir. 2008) (citations omitted).

[3] Notably, Congress enacted § 156(g) in 1988, before FDA began offering sponsors the option of phased review. See Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670 (1988) (adding 35 U.S.C. § 156(g) to the statute).

Because the text of § 156(g) is ambiguous with regard to when an application is initially submitted, we must determine whether FDA's interpretation falls within the permissible range of interpretations left open by the statute. As an initial matter, we note that our inquiry is on the permissibility of FDA's interpretation, not Wyeth's. Wyeth's assertion that an application should be deemed initially submitted when the sponsor submits its final technical section may be reasonable if, as Wyeth asserts, FDA has received all of the information required by § 360b(b).[4] However, "a court must defer to an agency's reasonable interpretation of a statute and must not substitute its own judgment for that of the agency even if the court might have preferred another interpretation and even if the agency's interpretation is not the only reasonable one." Wheatland Tube Co. v. United States, 495 F.3d 1355, 1360-61 (Fed. Cir. 2007). We thus limit our analysis to the permissibility of FDA's interpretation.

The district court determined that FDA's "construction runs true to the text and defines 'initially submitted' in a manner 'that is reasonable in light of the legislature's revealed design.'" Wyeth, 607 F. Supp. 2d at 33 (citation omitted). It therefore concluded that FDA's interpretation was not an impermissible construction of the statute. Id.

[4] We note that, at least in the present case, Wyeth's assertion that FDA has all of the information required by 21 U.S.C. § 360b(b) when the sponsor submits its final technical section may not be true. Wyeth states that it submitted its final technical section on August 14, 1996. However, per agreement with FDA, Wyeth submitted its final technical section as three modules. It submitted the first module on August 14, 1996, and it is not clear when it submitted the remaining two modules. Thus, we do not agree that a sponsor necessarily submits all of the information required by § 360b(b) when it submits its final technical section (or more specifically, as here, when it submits the first of three modules of its final technical section).

On appeal, Wyeth argues that FDA's interpretation impermissibly contravenes the purpose of § 156(g). Wyeth notes that Congress sought to provide "[a] year-for-year matching extension . . . for any time the drug approval process that the drug spends awaiting a decision by the FDA." H.R. Rep. 98-457, pt. 2, 4 (1984). Wyeth explains that Congress initially considered providing patentees with a day-for-day extension for the entire regulatory review period, but later struck a balance between the competing interests of pioneer and generic drug manufacturers by dividing the review period into two phases and providing a half-time extension for the testing phase. Wyeth argues that FDA's interpretation shifts time from the approval phase to the testing phase, upsetting the balance.

FDA asserts that this is the trade-off for choosing the more fluid review process. Phased review allows sponsors to "work interactively with each specialty group within the Office of New Animal Drug Evaluation." CVM Review Policy at 1. A sponsor may seek review of individual technical sections or "useful pieces of technical sections," rather than delaying review until all information required by § 360b(b) is ready for submission. Id. at 13. By contrast, in the more regimented traditional review, "all submissions were funneled into the Center through a 'primary' reviewer who coordinated the Center's interaction with, and responses to, the sponsor." Id. at 2. As a result of its more "streamlined" process, phased review provides for potentially faster approval and market entry. However, because the sponsor works directly with individual CVM sections in phased review, FDA's first notice that a sponsor believes it has submitted all of the parts required by § 360b(b) occurs when the sponsor submits an administrative NADA. At that point, according to FDA, it has an application that it

may review for approval. Under FDA's interpretation, the approval phase is quite short—here, 16 days. Treating these days as part of the testing rather than approval phase results in a shorter patent term extension; however, if phased review does result in a faster overall process, there is less delay in the process and quicker market entry. A sponsor weighs these factors and decides whether to pursue phased or traditional review.

FDA further notes that a sponsor may choose to pursue the more fluid phased review during early development and file a traditional NADA later in the process. Id. at 2. A traditional NADA may reference technical sections that FDA has already reviewed in the phased review program.

We conclude that FDA's interpretation is permissible. Section 156(g) created a range of ambiguity by not explicitly defining the term "application," leaving that term open to interpretation. FDA's interpretation tracks the requirements of 21 U.S.C. § 360b(b). As explained by FDA, the administrative NADA is the first document containing or referencing all of the parts required by 21 U.S.C. § 360b(b). Thus, it is permissible to characterize the administrative NADA as the first application submitted for purposes of 35 U.S.C. § 156(g). Because the administrative NADA is the first application submitted, it is reasonable to interpret the date that it is submitted as the "initially submitted" date. Prior to the submission of an administrative NADA, no application has been submitted, initially or otherwise. Thus, FDA's interpretation "reasonably resolves the ambiguity in applying the relevant statutes to a factual situation not fully foreseen or provided for by the Congress when it enacted the statutes or the FDA when it promulgated regulations." Mylan, 389 F.3d at 1284. It is permissible to

interpret § 156(g) to mean that "an application" is "initially submitted" when a sponsor submits an administrative NADA in phased review.

Wyeth's policy considerations regarding the shift in time between the testing phase and the approval phase do not require a different result. Whatever balance may have been struck envisioned traditional review, not phased review. A sponsor may now choose to work more interactively with FDA using the more fluid phased review process and submitting information, including testing data, to FDA on a rolling basis. It follows that with this change in the review process, the respective lengths of the testing phase and the approval phase have also changed.

III. APA Challenge

Wyeth argues that even if FDA's interpretation is permissible, it is arbitrary and capricious because it conflicts with FDA's interpretation of the approval phase for new human drugs in FDA's "fast track" program. The district court determined that FDA's interpretation was not arbitrary and capricious for the same reasons that it concluded FDA's interpretation was permissible under Chevron. Wyeth, 607 F. Supp. 2d at 33. In addition, the court noted that Wyeth's claim that FDA's treatment of animal drugs was inconsistent with its treatment of human drugs had "no merit" because phased review is not available for human drugs. Id. at 33 n.9.

The fast track program differs from the phased review program in many respects. First, fast track sponsors must submit "a schedule for submission of information necessary to make the application complete." 21 U.S.C. § 356(c)(1)(A). If FDA agrees, then the sponsor may submit portions of its application on a rolling basis. Guidance for Industry, Fast Track Drug Development Program – Designation, Development, and Application Review, 13, available at

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079736.pdf (Fast Track Guidance). When the sponsor submits all of the required information, it informs FDA that its application is complete. Id. at 14. FDA marks the beginning of the approval phase when it receives notice that the fast track application is complete. FDA asserts that this is consistent with its interpretation of the approval phase in phased review, which also begins on the date that FDA first receives notice that the application is complete. We perceive no inconsistency between FDA's interpretations. We conclude that the FDA interpretation challenged by Wyeth is not arbitrary and capricious.

CONCLUSION

For reasons stated above, we affirm the judgment of the district court.

AFFIRMED