IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH HOLDINGS CORPORATION, ET AL., Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL., Defendants.	Civil Action No. 08-00981 (HHK) **ORAL ARGUMENT REQUESTED**

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Fed. R. Civ. P. 56 and LCvR 56.1, Plaintiffs Wyeth Holdings Corporation, formerly known as American Cyanamid Company, and Wyeth (collectively and individually referred to as "Wyeth" or "Plaintiffs"), by and through their attorneys, hereby move for summary judgment in the above-captioned action on the grounds that no genuine issue of material fact exists and that Plaintiffs are entitled to judgment as a matter of law.

In support of this motion, Plaintiffs rely on the Administrative Record ("A.R.") filed in this action by the Defendants, together with Plaintiffs' Memorandum in Support of Plaintiffs' Motion for Summary Judgment and in Opposition to Defendants' Motion to Dismiss, Plaintiffs' Statement of Material Facts As To Which There Is No Genuine Issue in Support of Plaintiffs' Motion for Summary Judgment, and the Declaration of Peter. S. Choi, also filed this date.

Wherefore, Plaintiffs respectfully request that their motion be granted and summary judgment be entered in their favor.

REQUEST FOR ORAL HEARING

Plaintiffs respectfully request an oral hearing on this Motion.

Dated: September 8, 2008

/s/ Gary Veron

Jeffrey P. Kushan (D.C. Bar # 461155)
Gary Veron (D.C. Bar # 445450)
Peter S. Choi (D.C. Bar # 496780)
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000
Facsimile: (202) 736-8711

Counsel for Plaintiffs

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PLAINTIFFS' MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS

Plaintiffs Wyeth Holdings Corporation, formerly known as American Cyanamid Company, and Wyeth (collectively and individually referred to as "Wyeth" or "Plaintiffs"), through undersigned counsel, have moved for summary judgment in the above-captioned action under Fed. R. Civ. P. 56. As explained below, Plaintiffs' motion should be granted because there are no genuine issues of material fact and Plaintiffs are entitled to judgment as a matter of law. In addition, Defendants Motion to Dismiss (D.I. 22) should be denied. Plaintiffs have sufficiently pled a claim for relief and have put Defendants on fair and sufficient notice of the basis for that relief.

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INTRODUCTION

In this civil action, Plaintiffs seek to set aside the final determination of the Food and Drug Administration ("FDA" or the "Agency") of the regulatory review period for Plaintiffs' animal drug product CYDECTIN® (moxidectin) Pour-On ("Cydectin"), from which the patent term extension for U.S. Patent No. 4,916,154 ("the '154 patent") is derived, as erroneous, arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law.

Under the statutory scheme of the Generic Animal Drug and Patent Term Restoration Act of 1988 ("GAD/PTR Act"), an eligible patent may have its term restored by a period corresponding to the period of regulatory review by the FDA of the animal drug product, subject to certain limitations. 35 U.S.C. § 156(g)(4)(A), (B). The statute defines two phases of the regulatory review period; namely, a testing phase and an approval phase. Under the scheme established in the statute, the length of the regulatory review period is the sum of (i) one-half of the period of the testing phase, plus (ii) the entire period of the approval phase. *Id*. at § 156(c)(2).

The dispute in this case centers on FDA's determination of the regulatory review period for Cydectin, and, in particular, the manner in which the Agency determined the length of the "approval phase" for Cydectin pursuant to 35 U.S.C. §156(g)(4)(B). Unambiguously, the statute specifies that the approval phase commences when an applicant "initially submits" an application to the FDA for review, and ends when the FDA approves the application. 35 U.S.C. § 156(g)(4)(B)(ii). As explained in the legislative history, Congress intentionally used the phrase "initially submitted" -- rather than simply "submitted" or "filed" -- because Congress recognized that the Agency begins its substantive review of a New Animal Drug Application ("NADA") well before the date that the application is considered to be "complete" by the Agency and in

condition to be approved. H.R. Rep. No. 98-857, pt. 1, at 44 (1984) (regarding similar patent term restoration language for human drug products). As Congress clearly stated, "[a]s long as the application was *complete enough* so that agency action could be commenced, it would be considered to be '*initially submitted*.'" *Id.* (emphasis added). The legislative history also makes it clear that Congress elected to provide day for day credit for the period during which the FDA is conducting its substantive review of the technical content of the application, rather than the short periods of time associated with the Agency's review of formalities of the application. *Id.*; *see also* H.R. Rep. No. 100-972, pt. 1, at 3 (1988).

In this case, Plaintiffs' application for Cydectin was "initially submitted" on August 8, 1995, when the first technical section of the application, *i.e.*, the Residue Chemistry section, was submitted to the FDA for substantive review. The FDA commenced its substantive review of this section of the application shortly after it was submitted. The remaining five technical sections of the Cydectin application were submitted over the course of the next year. By August 14, 1996, Plaintiffs had provided the FDA with each of the technical sections of the Cydectin application required by the Agency's regulations. During this period, and continuing on until January of 1998, the FDA conducted its substantive review of these technical sections of the application.

Despite this clear record showing when the Agency began its substantive review of the Cydectin application, the FDA determined that the approval phase of the Cydectin application began only when Plaintiffs submitted something the Agency has termed an "Administrative NADA" on January 13, 1998. In other words, the FDA concluded that the Cydectin application was "initially submitted" only after the Agency had completely finished its substantive review of each of the individual technical sections of the Cydectin application. To reach this extraordinary

conclusion, the FDA determined -- despite the statutory language and clear legislative history to the contrary -- that "the approval phase begins when the marketing application *is complete*." Determination of Regulatory Review Period for Purposes of Patent Term Extension; CYDECTIN, 71 Fed. Reg. 54993, 54994 (Sept. 20, 2006) (emphasis added).

The Agency's determination is directly at odds with the statutory provisions and legislative history of the GAD/PTR Act. As Congress made clear when enacting the GAD/PTR Act, the approval phase begins when the marketing application is "initially submitted" -- not when it is "complete." 35 U.S.C. § 156(g)(4)(B)(ii); *see also* H.R. Rep. No. 98-857, pt. 1, at 44. In other words, the FDA adopted the precise construction Congress expressly ruled out. The FDA's approach also conflicts with, and is unreasonable in light of, the legislative purpose of the patent term restoration provisions of the GAD/PTR Act, which are designed to compensate patent owners fully (*i.e.*, on a day for day basis) for the entire period during which the Agency is conducting its substantive review of an application.

The FDA's incorrect determination of when the approval phase for Cydectin began has led the Agency to conclude that the "approval" phase of Cydectin lasted a mere 16 days. This result is illogical given the actual record of agency conduct in this case. FDA's erroneous and unreasonable determination will operate to deprive Plaintiffs of more than 10 months of patent term to which it is entitled under the statute.

As explained below, Defendants' Motion to Dismiss should be denied because the Complaint provides Defendants with fair notice of what Plaintiffs' claim is and the grounds upon which it rests. However, because the material facts in this case are not in dispute and because the question before the Court is purely legal, Plaintiffs hereby move for summary judgment pursuant to Fed. R. Civ. P. 56. Plaintiffs' Motion for Summary Judgment should be granted because the

FDA's interpretation of the term "initially submitted" conflicts with the clear and unambiguous terms of the statute and is directly contrary to the legislative history and purpose of the GAD/PTR Act. Therefore, the final agency action should be set aside. For these reasons, Plaintiffs are entitled to judgment as a matter of law.

BACKGROUND

I. Statutory And Regulatory Background

A. The Legislative Foundation Of The GAD/PTR Act Is The Drug Price Competition And Patent Term Restoration Act, Which Was Designed To Compensate Drug Manufacturers For Patent Term Lost During Regulatory Review

The Hatch-Waxman Amendments were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984. Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282) ("DPC/PTR Act"). In the DPC/PTR Act, Congress struck a balance between two competing policy interests: (1) encouraging pioneering research and development of new drugs, and (2) enabling competitors to bring low-cost, generic copies of those drugs to market. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002); *see also Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting).

To achieve those ends, the DPC/PTR Act created a new type of application, called an Abbreviated New Drug Application, or "ANDA," to speed approval of generic drugs. The ANDA "permits generic drug applications to piggy-back on clinical findings that FDA has already embraced" by its approval of a new drug application ("NDA"). *In re Barr Labs., Inc.*, 930 F.2d 72, 73 (D.C. Cir. 1991). It does this by authorizing reliance on the safety and efficacy studies previously submitted as part of the NDA, and evidence showing the generic drug is bioequivalent to the previously approved new drug product. *See* 21 U.S.C. § 355(j)(2)(A).

Congress also recognized that innovative drug manufacturers lose a significant amount of the "effective" patent term as a consequence of the regulatory review process.[1] H.R. Rep. 98-857, part 1, at 17. To ensure adequate incentives for future drug research and development, Congress created a mechanism for restoring at least a portion of the period of lost effective patent term due to the regulatory review process. *Id.* Thus, the DPC/PTR Act authorizes restoration of patent term corresponding to the period of regulatory review, subject to certain limits. *Id*.; *see generally* 35 U.S.C. § 156.

B. The Purpose Of The GAD/PTR Act Is To Restore Patent Term Lost During Regulatory Review Of An Animal Drug Product Under The Identical Statutory Scheme Of The DPC/PTR Act

The DPC/PTR Act addressed human drugs, but did not address animal drugs. The GAD/PTR Act was enacted in 1988 and reflects Congress' intent to provide animal drug innovators with patent incentives to develop new animal drugs pursuant to the statutory framework Congress had previously established for human drugs through the DPC/PTR Act. H.R. Rep. No. 100-972, pt. 1, at 2 (observing that the purpose of the GAD/PTR Act was "to create in the animal drug industry *similar conditions* for generic drugs and patent term restoration as Congress did in the human drug industry in 1984") (emphasis added); *see also id*. at 8 (GAD/PTR Act "simply makes the additions to [the DPC/PTR Act] necessary to include animal drugs . . . .").

As with pioneering human drug products, Congress recognized that:

> [A]nimal drug innovators *typically lose years* of patent protection because of FDA's scientific testing requirements and regulatory review. While this FDA process is essential to confirming the safety and effectiveness of animal drugs, it can have the effect of reducing

[1] The "effective" patent term is the period remaining in the life of the patent following approval of the new drug by the FDA. It is termed the "effective" patent term because, prior to approval, neither the patent owner nor any other party can market the new drug in the United States.

> incentives to develop new animal drugs. *Patent term restoration will assure these important incentives*.

H.R. Rep. No. 100-972, pt. 1, at 3 (emphases added). Thus, Congress enacted the GAD/PTR Act to stimulate research and development of new animal drugs by restoring patent term lost during the lengthy *testing* and *review* periods during the regulatory review of a new animal drug, thereby allowing developers of new animal drugs to recover at least a portion of the period of regulatory review of a new animal drug. *Id*.; *see also* 134 Cong. Rec. 30272 (1988) (statement of Sen. Hatch); 134 Cong. Rec. 30560 (1988) (statement of Rep. Waxman).

C. The Procedure for Obtaining a Patent Term Restoration Involves a Determination of the "Regulatory Review Period" By FDA

The GAD/PTR Act authorizes the restoration of up to 5 years of patent term if, before marketing, the animal drug product covered by the patent was subject to regulatory review by FDA. 35 U.S.C. § 156(g)(4)(A); *id*. at § 156(a). To obtain a patent term restoration, the patent owner must apply to the Director of the United States Patent and Trademark Office ("PTO") within 60 days of receiving marketing approval for the drug product covered by the patent. 35 U.S.C. § 156(d)(1). The PTO must then send a copy of the patent term restoration application to FDA. No later than 30 days after receiving the application, the FDA must determine the applicable "regulatory review period" for the drug product covered by the patent for which restoration is sought and must publish a notice of its determination in the Federal Register. 35 U.S.C. § 156(d)(2)(A)(ii). If the Director of the PTO determines that the patent term is eligible for a restoration, the Director issues a certificate extending the term of the patent for an amount equal to the period of regulatory review. 35 U.S.C. § 156(e)(1).

As is the case for human drug products, the "regulatory review period" for an animal drug product has two phases; namely, the "testing phase" of the drug *and* the "approval phase." 35 U.S.C. § 156(g)(4)(B)(i), (ii); *see also* 21 C.F.R.§ 60.22(d); H.R. Rep. 98-857, part 1, at 40

("*[a]ll* regulatory review periods are divided into a testing phase and an agency approval phase") (emphasis added); *see also id.* at 44 ("*in all cases* [the regulatory review period] is considered to have a testing phase and an agency approval phase.") (emphasis added).

Congress clearly defined how the FDA is to determine the periods of time corresponding to these two phases of regulatory review. The testing phase begins on the date "an [investigational new animal drug (INAD)] exemption under subsection (j) of section 512 [of the Food, Drug, and Cosmetic Act] became effective for the new animal drug product," and ends "on the date an application was *initially submitted* for such animal drug product under section 512." 35 U.S.C. § 156(g)(4)(B)(i) (emphasis added); *see also* 21 C.F.R. § 60.22(d)(1) ("The testing phase begins on the date . . . on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug [*i.e.*, the INAD file] . . . and ends on the date a marketing application under section 512 of the Act is initially submitted to FDA.").

The approval phase is the period during which the FDA conducts its substantive review of the application and ends when the Agency approves the application. As defined in the statute, this period begins "on the date the application was *initially submitted* for the approved animal drug product under subsection (b) of section 512" and ends "on the date such application was approved under such section." 35 U.S.C. § 156(g)(4)(B)(ii) (emphasis added); *see also* 21 C.F.R.§ 60.22(d)(2) ("The approval phase begins on the date a marketing application under section 512 of the Act is initially submitted to FDA and ends on the date the application is approved.").

In deciding how to define the start of the approval phase, Congress recognized the dynamic and interactive nature of the drug application process. Rejecting a "form over function" approach, Congress determined that the approval phase should begin on the date FDA has

enough information to begin reviewing the application, rather than on the date that FDA considers the application to be complete, or "filed":

> [The term "initially submitted"] is used instead of the term 'filed,' because an application is often not considered to be filed, *even though agency review has begun*, until the agency has determined that no other information is needed and a decision on the application can be made. For purposes of determining the regulatory review period and its components periods, an application for agency review is considered to be 'initially submitted' if the applicant has made a deliberate effort to submit an application containing all information necessary for agency review to begin. The Committee recognizes that the agency receiving the application might decide it needs additional information or other changes in the application. *As long as the application was complete enough so that agency action could be commenced, it would be considered to be 'initially submitted*'.

H.R. Rep. No. 98-857, pt. 1, at 44 (emphases added). Thus, Congress clearly ruled out a formalistic view of when the approval phase of regulatory review begins by specifically rejecting the idea that it can only begin after an applicant has filed a "complete" application that complies with all of the Agency's formalities. *Id*. Consistent with this legislative history and the language of the statute, FDA's own regulations provide that a marketing application "is *initially submitted* on the date it contains sufficient information to allow FDA to commence review of the application." 21 C.F.R. § 60.22(f) (emphasis in original).

Under the statutory scheme established by Congress, the term of a patent may be restored by a period equal to the sum of (i) one-half of the time an animal drug was in the testing phase; and (ii) as many days as the animal drug was under review by FDA before approval during the approval phase. 35 U.S.C. § 156(c). The potential period of term restoration due to regulatory review, however, is not limitless. Indeed, Congress balanced numerous competing public policy interests in the course of designing the patent term restoration scheme. In particular, Congress recognized the need to balance the interests of patent owners in receiving sufficient effective

patent terms for their animal drug inventions, and the interests of the public in obtaining timely access to generic versions of these drugs. *See Andrx Pharms.*, 276 F.3d at 1371. Congress implemented three explicit statutory provisions concerning the length of animal drug patent term restorations to reflect its conclusions on the appropriate balance of these competing public policy considerations.

First, if the sponsor did not act with due diligence during the regulatory review period, the period of patent term restoration must be reduced by the amount of time the sponsor caused undue delay. 35 U.S.C. § 156(c)(1). This prevents time from being credited for periods during which "the degree of attention, continuous directed effort, and timeliness" did not comport with what was reasonable and ordinary for a new drug applicant. *Id.* § 156(d)(3). Second, the period of time remaining in the patent term, after marketing approval of the animal drug and including the patent term restoration, may not exceed 14 years. 35 U.S.C. § 156(c)(3). Finally, no period of patent term restoration may exceed 5 years, even if the regulatory approval period is longer than 5 years. 35 U.S.C. § 156(g)(6)(A). Thus, Congress expressly considered the need for, and then implemented, statutory limitations on the potential period for patent term restoration, regardless of the actual time consumed in the regulatory review period of a new drug. Notwithstanding these limitations, Congress believed that "research intensive companies will have the necessary incentive to increase their research and development activities." H.R. Rep. No. 98-857, pt. 1, at 41.

D. A Marketing Application For An Animal Drug Product May Be Submitted On A Phased, Rolling Basis

Before a new animal drug can be marketed, it must be shown to be safe and effective for its intended use. Under subsection (b) of section 512, a new animal drug applicant must submit "as part of the" marketing application information that includes, among other things, full reports

demonstrating safety and efficacy, a description of the articles used as components and the composition of the animal drug, a description of the methods used in, and the facilities used for, the manufacture, processing, and packing of the drug, samples of the drug, labeling information, and a description of analytical methods for determining the quantity of the drug in food. 21 U.S.C. § 360b(b). The detailed information supporting an application is organized into several parts called "technical sections," which, in 1995, included (1) public safety, (2) target animal safety, (3) environmental safety, (4) effectiveness, (5) residue chemistry and regulatory methods, and (6) manufacturing, methods and controls. *See* Center for Veterinary Medicine Document and Submission Information – An Update (April 1995) ("CVM Update 1995"), FDA000017.

To streamline and expedite the review of applications, the FDA implemented a policy that permits sponsors of new animal drugs to submit the technical sections of an application for review on a "phased," or rolling basis. Indeed, the FDA "encourages" sponsors to submit the various technical sections of the application for review on a phased basis, "outside the strict NADA review process" to facilitate an interactive approach to the collection and review of the information necessary to fulfill the requirements of subsection (b) of section 512. CVM Update 1995, FDA000016; *see also id.* FDA000004 (FDA "remains extremely committed to the concept of reviewing data at the most appropriate and productive times in the drug development process and . . . will continue to accept data for evaluation outside the strict structure of 'all in, all out' of the conventional NADA."). The fluidity and interactive nature of the phased review process is mutually beneficial to the FDA and the sponsor of the new animal drug product marketing application because of the greater efficiencies it creates in the approval of new animal drugs. Guidance for Industry – The Administrative New Animal Drug Application Process #132,

November 6, 2002 ("Draft Guidance 2002"), FDA 000108 ("Phased review . . . create[s] greater efficiencies that facilitate the approval of new animal drugs.").

Importantly, there is no difference in the substantive requirements imposed on an applicant, or in the review by the FDA of the information provided by an applicant, under the phased review or rolling process as compared to the traditional NADA process. In other words, the substantive information that must be provided under either procedure is exactly the same regardless of how it is provided to the Agency, and it is reviewed under the same technical standards by the Agency. *See* CVM Update 1995, at FDA 000024 ("NADAs are organized by technical sections . . . ."); *see also id.* at FDA 000016 ("Under the Phased Review Policy, [technical sections] of NADA-supporting data may be submitted and evaluated to aid in the drug development process."). And, while the Agency has specified that technical sections of an NADA submitted pursuant to the phase or rolling process are, as an administrative matter, to be made to the drug INAD file, the FDA's own regulations specify that these submissions "will be considered as part of, an application on the basis of specific reference to such information." 21 § C.F.R. 514.1(a).

Pursuant to the Agency's regulations and guidelines, the FDA will not commence its substantive review of safety and effectiveness data associated with a new animal drug unless the applicant provides information of sufficient quality and substance to permit the FDA to commence this review. If a sponsor presents information insufficient to permit FDA to begin its substantive review of that section, the sponsor is notified that review will be deferred until the deficiency is cured. CVM Update 1995, FDA00004 ("the sponsor will be notified that review will be deferred until additional information is submitted"); *see also id.* at FDA000019 (FDA will issue a "Refuse to Review Letter" without review of the submission "[i]f the submission is

less than a package that [FDA] finds useful to review"). The FDA indicates that it has completed its substantive review of a technical section of an application provided under the phased review process by issuing a technical section "complete letter." Draft Guidance 2002, FDA0000112.

The phased review process culminates with the sponsor's filing of a document which the FDA has termed the "Administrative NADA." Draft Guidance 2002, FDA000109-112. A sponsor may submit an "Administrative NADA" only after the sponsor has received technical section "complete" letters for each of the technical sections required under subsection (b) of section 512 (*i.e.*, indicating that the Agency has received and completed its substantive review of all of the technical sections of the NADA). *Id.* Because all of the supporting data has already been submitted and substantively reviewed by the FDA by this point in the phased review process, the Administrative NADA is a simple, administrative document consisting of a cover letter, a table of contents, a summary, a copy of each technical section "complete letter," and other administrative information. *Id.* The thousands of pages of information typically found in an NADA corresponding to the technical sections of the NADA have already been provided by the applicant to the FDA by this point, and are not submitted again. *Id.* As FDA has explained, "[i]f an application meets the definition of an Administrative NADA, the review should take fewer than 180 days because the review of the individual sections of the application has *already been completed*." Draft Guidance 2002, FDA000113 (emphasis added).

II. Concise Statement of Facts[2]

Cydectin is an animal drug product labeled for use in beef and dairy cattle for the treatment and control of internal and external parasites. SOF ¶ 9. The Fort Dodge Animal

[2] Unless otherwise noted, the following facts are take from Plaintiffs' Statement of Material Facts As To Which There Is No Genuine Issue ("SOF") filed herewith in support of Plaintiffs' Motion for Summary Judgment.

Health Division of Wyeth holds the NADA for Cydectin, which was approved by the FDA on January 28, 1998. *Id.* at ¶¶ 10, 56.

On or about April 9, 1990, the FDA notified Plaintiffs that the INAD file for moxidectin had been established. SOF ¶ 12. Between April of 1990 and August of 1995, Plaintiffs concentrated their efforts on collecting test data in support of the safety and efficacy of moxidectin. *See, e.g.*, Administrative Record ("A.R."), at FDA000085-94. The first technical section supporting the NADA for Cydectin was submitted to the FDA on August 8, 1995 pursuant to the Agency's phased review process. SOF at ¶¶ 15-16. This section, the Residue Chemistry technical section, contained four sets of information, covering the subjects of total metabolism in target animal, comparative metabolism in rodents, tissue residue depletion studies, as well as analytical methods and method validations, *id.*, and contained 4,790 pages of information. *Id.* On March 26, 1996, the FDA issued a letter stating that it had "proceeded with [its] review." *Id.* at ¶ 17. On December 10, 1997 -- 28 months after this section was first filed -- the FDA issued a "complete letter" for the Residue Chemistry technical section. *Id.* at ¶ 20.

While the FDA was still reviewing the Residue Chemistry technical section, on December 15, 1995, Plaintiffs submitted the Target Animal Safety technical section. SOF ¶ 21. The FDA issued a "complete letter" for this component on July 22, 1996. *Id.* Additional technical sections corresponding to Manufacturing Chemistry ("CMC"), Effectiveness, and Public Safety were made on December 21, 1995, January 16, 1996, and June 7, 1996, respectively. *Id.* at ¶¶ 22-23. The FDA issued "complete letters" for these sections on September 17, 1996, November 4, 1997, and January 13, 1998, respectively. *Id.*

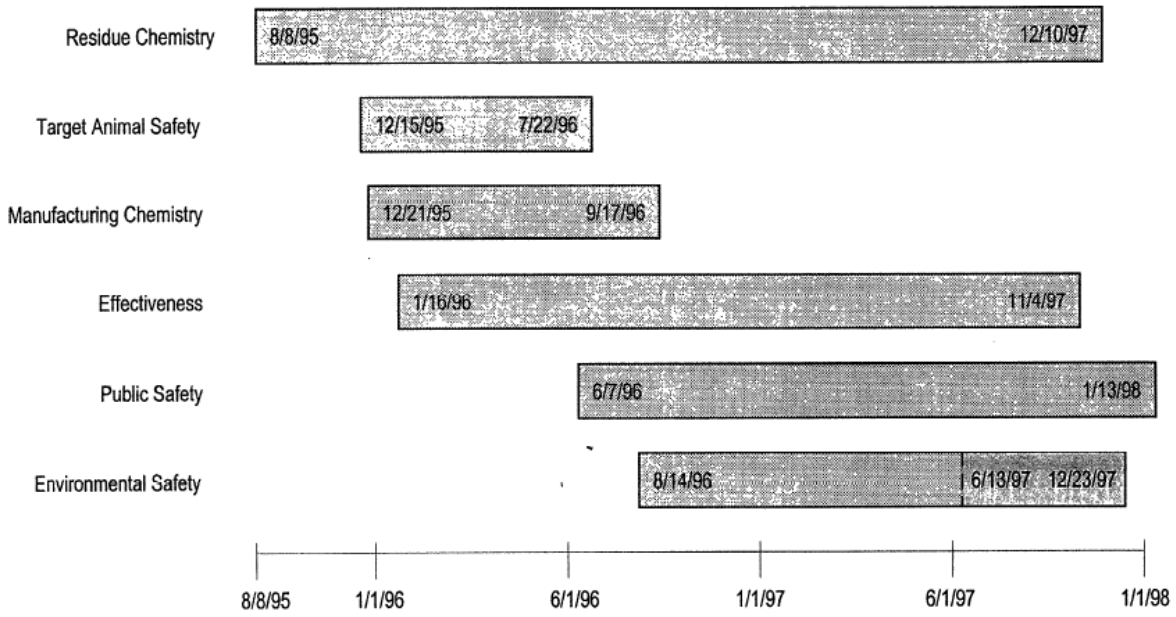
A summary of the various technical sections, the date each section was submitted to the FDA, and the date on which the FDA issued a technical section complete letter for the various sections is shown in the following table.

Technical Section	Date Filed	Date of FDA's Technical Section Complete Letter
Residue Chemistry	August 8, 1995	December 10, 1997
Target Animal Safety	December 15, 1995	July 22, 1996
CMC	December 21, 1995	September 17, 1996
Effectiveness	January 16, 1996	November 4, 1997
Public Safety	June 7, 1996	January 13, 1998
Environmental Safety	August 14, 1996	December 23, 1997

On August 14, 1996, Plaintiffs made their final technical section submission to the FDA relating to Environmental Safety. SOF ¶ 23. Once Plaintiffs submitted the Environmental Safety technical section, all of the technical sections necessary for a complete NADA had been submitted to the Agency for review and approval. *Id*. FDA issued a "complete letter" for the Environmental Safety technical submission on December 23, 1997. *Id*. at ¶ 24.

As shown in the following figure, taken from the administrative record filed by the Defendants, there was no period of time between the filing of the first technical section and the issuance of the last technical section complete letter that the FDA did not have before it a technical section undergoing substantive review.

Figure 1



See FDA000084.

On January 13, 1998, upon receipt of the "complete letter" for the Public Safety section, Plaintiffs submitted the Administrative NADA for Cydectin. SOF ¶¶ 29-30. That letter cited all the "complete letters" FDA had previously issued for all of the components of the application. *Id*. On or about January 14, 1998, the Agency issued an acknowledgement letter for the Administrative NADA and issued an NADA number for the application. *Id.* at ¶ 31. Two weeks later, on or about January 28, 1998, FDA issued the marketing approval letter for Cydectin. *Id.* at ¶ 32.

On March 27, 1998, within the 60-day period for submission, *see* 37 C.F.R. 1.720(f), Plaintiffs filed with the PTO a Request for Extension of Patent Term Under 35 U.S.C. § 156.

SOF ¶ 33. The patent for which extension was sought was the '154 patent,[3] which originally had an expiration date of April 10, 2007. *Id.* at ¶ 34. The Request for Extension of Patent Term indicated that the testing exemption under subsection (j) of section 512 (of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360b(j)) became effective for the new animal drug product on August 9, 1990, the date FDA assigned the INAD file number for the active ingredient in Cydectin, moxidectin. *Id.* at ¶ 40.

The Request for Extension of Patent Term indicated that the approval phase began when the marketing application was "initially submitted" on August 8, 1995, the date on which the Residue Chemistry technical section was first submitted to FDA, allowing FDA to begin its review. The Request for Extension of Patent Term indicated that the date the application was approved was January 28, 1998. SOF ¶¶ 41-42.

Based on Plaintiffs' calculation of one-half of the "testing phase" (after the grant of the patent) from April 10, 1990 to August 8, 1995 (973.5 days); and a calculation of all the time corresponding to the "approval phase" from August 8, 1995 to January 28, 1998 (904 days), Plaintiffs determined that the regulatory review period for the approved product is 1877.5 days. SOF ¶ 43. Given that under 35 U.S.C. § 156(c)(3), the period remaining in the term of the patent after the date of approval when added to the review period cannot exceed 14 years, Plaintiffs determined that the '154 patent is eligible for an extension of a period of 1,754 days. *Id.* at ¶ 44. Thus, the new expiration date of the '154 patent based on an approval phase that began on

[3] The '154 patent covers the active ingredient in Cydectin, moxidectin, methods of using the approved product, and compositions containing the approved product. SOF ¶ 39. Wyeth Holdings Corporation is the current assignee of the '154 patent, and owns all rights, title, and interests in and to the '154 patent. *Id*. at ¶ 36.

August 8, 1995, the date when substantive review of the application could (and did) begin, would be January 28, 2012.[4] *Id.* at ¶ 45.

On September 20, 2006, more than 8 years after Plaintiffs filed for their Request for Extension of Patent Term Under 35 U.S.C. § 156, FDA published its determination of the regulatory review period for purposes of patent term restoration for Cydectin in the Federal Register.[5] SOF ¶ 49. FDA determined that the applicable regulatory review period for Cydectin is 2,857 days. *Id.* at ¶ 50. Importantly, no deduction was made for any lack of due diligence. *Id.* at ¶ 51. Of this time, FDA determined that 2,841 days occurred during the testing phase, while *only 16 days* occurred during the approval phase. *Id.* at ¶ 52. The beginning of the testing phase was derived from a determination that April 5, 1990 is the effective date for the INAD. *Id.* at ¶ 53. The approval phase was based on FDA's determination that the Cydectin marketing application was initially submitted on January 13, 1998, the date on which Wyeth submitted its Administrative NADA. *Id.* at ¶ 54.

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[4] Because Plaintiffs were aware that this was, to their knowledge, the first patent term extension request for a phased animal drug submission, the Request for Extension of Patent Term indicated, as an alternative calculation/determination, that the approval phase began on August 14, 1996, when the final technical section of the marketing application -- *i.e.*, the Environmental Safety technical section -- was "initially submitted" to the FDA. SOF ¶ 46. Based on Plaintiffs' calculation of one-half of the "testing phase" (after the grant of the patent) from April 10, 1990 to August 14, 1996 (1159 days), and a calculation of all the time corresponding to the "approval phase" from August 14, 1996 to January 28, 1998 (532 days), under this alternative, Plaintiffs determined that the appropriate regulatory review period for the approved product would be 1,691 days. *Id.* at ¶ 47. Under this alternative, the new expiration date of the '154 patent based on an approval phase that began on August 14, 1996, would be November 26, 2011. *Id.* at ¶ 48.

[5] Although the statute requires that FDA make its determination of the regulatory review period within 30 days upon receipt of notice from the PTO, 35 U.S.C. § 156(d)(2)(A), it took the FDA ***over 8 years*** to publish its determination of the regulatory review period. Not only does this evidence FDA's willingness to ignore the statutory scheme, but this undue and unexplained delay also prejudices Wyeth because it requires Wyeth to pursue judicial review of the agency action on an expedited basis so that a final judicial determination may be completed prior to the expiration date of the patent under FDA's erroneous determination.

FDA's reasoning for its determination of the event that triggered approval phase was that "the approval phase begins when the marketing application *is complete*." 71 Fed. Reg. at 54994 (emphasis added).[6] *Id.* at ¶ 55. FDA also determined that the date the marketing application was approved was January 28, 1998. *Id.* at ¶ 56. Based on FDA's determination of the regulatory review period for Cydectin, the PTO issued a notice of final determination on June 13, 2007 indicating that the period of patent term extension had been determined to be 1,434 days. *Id.* at ¶ 57. Under FDA's interpretation, the '154 patent would expire on March 14, 2011, more than 10 months earlier than it would expire under Plaintiffs' calculation. *Id.* at ¶ 58.

Plaintiffs timely filed a Request for Revision of Regulatory Review Period with the FDA on November 20, 2006. SOF ¶ 59. It asked that the "date the application was initially submitted with respect to the animal drug product under section 512(b) of the act" be corrected from January 13, 1998, the date in the Federal Register notice, to *August 8, 1995*, the date Plaintiffs submitted to FDA the first technical section of the NADA application. *Id.* at ¶¶ 60-61. Plaintiffs also requested that the Agency recalculate the "regulatory review period" accordingly. *Id.* On May 7, 2008, FDA denied Plaintiffs' Request for Revision of Regulatory Review Period. *Id.* at ¶ 62.

FDA's May 7, 2008 response constitutes the Agency's final action on the regulatory review period determination for purposes of the patent term extension for the '154 patent. *Id.* at ¶¶ 63-64; *see* 21 C.F.R. § 60.26(b)(2). On June 6, 2008, Plaintiffs filed this civil action in this Court seeking judicial review of the Agency's decision. D.I. 1 ("Compl.").

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[6] The Federal Register notice states that "A review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141-099 was January 13, 1998, which is considered to be the initially submitted date for NADA 141-099." 71 Fed. Reg. at 54994. The date of FDA's official acknowledgement letter is actually January 14, 1998. FDA000102. January 13, 1998 is the date on which Wyeth submitted the Cydectin Administrative NADA to the FDA. *Id.*; *see also* SOF ¶ 29.

ARGUMENT

As explained below, Plaintiffs' Motion for Summary Judgment should be granted because there are no genuine issues of material fact and Plaintiffs are entitled to judgment as a matter of law. Fed. R. Civ. P. 56. In addition, Defendants Motion to Dismiss should be denied because Plaintiffs have properly pled a claim for relief. *See Radack v. Dept. of Justice*, 402 F. Supp. 2d 99, 103 n.2 (D.D.C. 2005) (Kennedy, J.).

I. Plaintiffs' Motion For Summary Judgment Should Be Granted Because The Undisputed Facts Show That The FDA's Determination Of The Regulatory Review Period For Cydectin Was Erroneous, Arbitrary, Capricious, An Abuse of Discretion, And Not In Accordance With The Law

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Ass'n of Flight Attendants v. USAir*, 24 F.3d 1432, 1436 (D.C. Cir. 1994). The undisputed facts demonstrate that FDA's interpretation of 35 U.S.C. § 156 was erroneous arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law. Thus, Plaintiffs are entitled to judgment as a matter of law.

The familiar two-step analysis of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) ("*Chevron*") governs the Court's review of FDA's construction of the statute. Under *Chevron*, the Court must first consider "whether Congress has directly spoken to the precise question at issue." 467 U.S. at 842-43. If the intent of Congress is clear, that is the end of the matter. If, however, "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.* at 843. If the agency's reading "fills a gap or defines

a term in a way that is reasonable in light of the legislature's revealed design, [the court gives] the administrator's judgment 'controlling weight.'" *NationsBank of N.C. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 257 (1995) (quoting *Chevron*, 467 U.S. at 844). In addition, the court may disregard the administrator's interpretation where it is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); *see also Kent County v. EPA*, 963 F.2d 391, 393 (D.C. Cir. 1992); *GHS Health Maintenance Org., Inc. v. United States*, No. 2007-5143, 2008 U.S. App. LEXIS 17160, at *19 (Fed. Cir. Aug. 13, 2008).

As explained below, Congress has spoken directly (and clearly) to the question of how the FDA must determine the length of the approval phase of regulatory review. Even if the Court concludes that there is some ambiguity remaining, it must find that the FDA's interpretation cannot be sustained, as it does not comport with any reasonable interpretation of the underlying statutory authority.

A. Congress Clearly Intended That the Approval Phase Begin When The Application Is "Initially Submitted" And FDA Can Commence Its Review

Under the first step of *Chevron*, the traditional tools of statutory construction must be employed to determine whether Congress has directly spoken to the precise question at issue. The traditional tools include examination of the statute's text, legislative history, structure, and purpose. *See Delverde, SrL v. United States*, 202 F.3d 1360, 1363 (Fed. Cir. 2000); *Timex V.I. v. United States*, 157 F.3d 879, 882 (Fed. Cir. 1998). Using these tools, it is clear that Congress intended that the approval phase correspond to the period of time that the FDA actually spends performing its substantive review of an application, and not just the trivial amount of time (*e.g.*, 16 days with respect to Cydectin) it takes to review an "Administrative NADA," an

administrative record submitted only after FDA has indicated that it has completed its substantive review of all the individual technical sections of a NADA.

The statutory language at issue is straightforward and clear:

> The regulatory review period for a new animal drug product is the sum of --
>
> (i) 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 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, and
>
> (ii) 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.

35 U.S.C. § 156(g)(4)(B) (emphasis added). As specified in the statute, the regulatory review period plainly consists of two phases; namely, the "testing phase" (defined in § 156(g)(4)(B)(i)), and the "approval phase" (defined in § 156(g)(4)(B)(ii)).

Congress has specifically addressed the issue in dispute in this case, namely when the "approval phase" begins. The approval phase unambiguously begins when the marketing application under subsection (b) of section 512 is "*initially* submitted." 35 U.S.C. § 156(g)(4)(B)(ii) (emphasis added). Congress has further explained that an application is "initially submitted" on the date that a sponsor submits information sufficient to enable the Agency to commence its substantive review of data generated during the testing phase of a new animal drug. As Congress explained:

> [The term "initially submitted"] is used instead of the term 'filed,' because an application is often not considered to be filed, even though agency review has begun, until the agency has determined that no other information is needed and a decision on the application can be made. For purposes of determining the

> regulatory review period and its components periods, an application for agency review is considered to be 'initially submitted' if the applicant has made a deliberate effort to submit an application containing all information necessary for agency review to begin. The Committee recognizes that the agency receiving the application might decide it needs additional information or other changes in the application. As long as the application was *complete enough* so that agency action could be *commenced*, it would be considered to be 'initially submitted'.

H.R. Rep. No. 98-857, pt. 1, at 44 (emphasis added).

Consistent with this statutory language and legislative history, FDA's own regulations provide that a marketing application "is initially submitted on the date it contains sufficient information to allow FDA to *commence review* of the application." 21 C.F.R. § 60.22(f) (emphasis in original). Thus, Congress expressly recognized that the Agency has started its review of an application *even if* the FDA later decides that "additional information or other changes in the application" are necessary. *Id*.

Indeed, Congress thus plainly rejected the idea that the approval phase could begin only after the sponsor has submitted *all* the information necessary for an application to be approved. In this case, the Agency's interpretation of when the approval phase begins adopts the view that the approval phase begins only *after* the FDA has actually *completed* its substantive review of all of the individual technical sections of a new drug application and has found those sections sufficient to meet the substantive requirements of subsection (b) of section 512. 71 Fed. Reg. at 54994. This interpretation of when the approval phase starts thus adopts the meaning Congress clearly ruled out. H.R. Rep. No. 98-867, pt. 1, at 44.

In defining the statute in this manner, Congress specifically recognized that the drug approval process is an interactive process, with ongoing communications between the Agency and the drug sponsor concerning the safety and effectiveness of the new animal drug product. It

relied on this appreciation of the nature of the approval process to conclude that the Agency's substantive review begins long before an application is administratively "complete." H.R. Rep. No. 98-857, pt. 1, at 44. Indeed, Congress pointed out that the "approval phase" could be rendered meaningless if it was found to begin only after the date on which the FDA had determined that all the requirements under subsection (b) of section 512 had been met. *Id*. By providing that the approval phase begins on the date in which the application is "initially submitted," *i.e.*, when enough information has been provided to FDA to commence review of the application, Congress determined that period of time to be credited under the "approval phase" be meaningful and correspond to the period of actual *substantive review* of the application by FDA, rather than the very short period that corresponds to a formalistic review of the application record. By defining the approval phase to correspond to the entire period during which the Agency is conducting its substantive review of the information generated during the testing phase, the design and purpose of the statute meets the Congressional objective of providing drug sponsors meaningful patent term restorations reflecting the true effects on delaying approval of *both* the testing phase and the approval phase. *See* H.R. Rep. 98-857, part 1, at 40, 44.

Under the plain meaning of the statute, Wyeth "initially submitted" the Cydectin application on August 8, 1995. It was on that date that Wyeth submitted the first technical section of the application, *i.e.*, the Residue Chemistry section comprising 4,790 pages of information, which allowed FDA to commence its review of the safety and efficacy of the drug. SOF ¶ 16. This section was not "virtually any piece of information," *see* Defs' Mem. at 20, but a substantive and -- under the Agency's interpretation of subsection (b) of section 512 -- *necessary* part of the marketing application for Cydectin. Indeed, as the Agency stated upon receipt of this section, "[y]ou have submitted an extensive amount of data that is intended to fulfill our residue

chemistry requirements." SOF ¶ 17. FDA also informed Plaintiffs that it had "proceeded with [its] review" of the section. *Id*. Thus, it was at this point -- in the words of the Agency itself -- that Plaintiffs had submitted enough information for FDA to "commence review" of the application. Under the clear and unambiguous language of the statute and the clear intent of Congress, this shows that the approval phase of Cydectin began on August 8, 1995 with the submission of the Residue Chemistry technical section. FDA's arguments to the contrary do not withstand scrutiny.

Under its interpretation, the FDA does not consider an application "initially submitted" until the application is "complete" and contains "all information necessary for approval." Def. Mem. at 3; *see also* 71 Fed. Reg. at 54994 ("the approval phase begins when the marketing application *is complete*.") (emphasis added). FDA's interpretation of the statute improperly ignores and contradicts its plain and unambiguous terms. In particular, by concluding that the approval phase commenced only when the Administrative NADA was submitted on January 13, 1998, the Agency not only improperly ignores the fact that it received and began its substantive review of the Cydectin application on August 8, 1995 when Wyeth submitted the Residue Chemistry technical section, it ignores the fact that by August 14, 1996 (the date the last technical section was filed by Wyeth), it had received *all* of the technical sections required under subsection (b) of section 512 for the Cydectin application. The Agency's position also ignores the fact that FDA acknowledged that it had completed its substantive review of all those sections by January 13, 1998. In so doing, the Agency, contrary to the unambiguous statutory language and clear legislative history, argues that Wyeth did not "initially submit" the Cydectin application until Wyeth had submitted a "complete" NADA that was ready for approval (*i.e.*,

what it calls the "Administrative NADA"). Thus, FDA has adopted the very interpretation of the statute that Congress expressly ruled out. *See* H.R. Rep. No. 98-857, pt. 1, at 44.

FDA's interpretation effectively reads the term "initially" out of the statute. "It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (internal quotations omitted); *see also New York Life Ins. Co. v. United States*, 190 F.3d, 1372, 1382 (Fed. Cir. 1999) ("A statute is to be read in its entirety . . . so as to give effect to all of its parts."). Therefore, FDA's interpretation must be set aside.

In support of the Agency's interpretation, Defendants argue that Wyeth did not "file an application" under subsection (b) of section 512 until Wyeth submitted the Administrative NADA. According to FDA, individual technical sections are not "'an application.'" Defs' Mem. at 20. FDA's formalistic emphasis on administrative completeness of an application is plainly contrary to the clear intent of Congress.

The technical sections of a NADA are the substantive portions of the application that comprise all of the essential data and information required under the statute to approve a new animal drug as safe and effective. *See* CVM Update 1995, at FDA 000024. For applications submitted under phased review, that approval phase begins with the submission of the individual technical sections because with any one of these substantive sections, FDA has enough information to commence review of the safety and efficacy merits of the new drug. It is this time that the FDA takes to review the technical sections that Congress intended to provide "day for day" credit for patent term restoration. By the time an Administrative NADA has been filed, the

individual technical sections of the application have not simply been received, they have been *substantively reviewed and approved* by the Agency.

Moreover, pursuant to the Agency's own regulations, the technical sections submitted by an applicant pursuant to the phased or rolling review process *are part of the application*. Specifically, FDA's regulations state that technical sections submitted to the INAD file "will be considered as part of, an application on the basis of specific reference to such information." 21 C.F.R. § 514.1(a). As the Agency has explained, it reviews the technical sections as they are submitted, and once the Agency finds each section sufficient, a technical section complete letter is sent to the applicant. These technical sections are not submitted again with the "Administrative NADA" nor does the Agency perform any additional review of these individual sections of the application after the "Administrative NADA" has been submitted.

Defendants also argue that there is significance in the procedural requirement that the individual technical sections be submitted to the drug INAD file. Defs' Mem. at 20. Under the statutory scheme of 35 U.S.C. § 156, however, this fact is irrelevant. The procedural formality of how the FDA manages the submission and its review of the technical sections of an NADA (*i.e.*, including them in the INAD file, as opposed to assigning the technical sections an application number) does not change the fact that during this process, the Agency is reviewing the substantive information of the application.

The very names "Administrative NADA" and "phased review" betray FDA's formalistic arguments concerning the term "application." As its name implies, the "Administrative NADA" is an administrative document that collates the technical sections of an application. The term "Administrative" NADA is found nowhere in the statute. As the FDA acknowledges, an Administrative NADA simply collects the elements of an NADA that have not only been

received by the FDA, but of which the substantive review has been completed. Similarly, the term "phased review" refers to the phased *review* of an *application*. Thus, FDA is clearly *reviewing* "the application" when it reviews the individual technical sections of the application that are submitted under the phased review procedure. For FDA to now argue that no "application" is filed, and that it is not conducting a substantive review of that application until an Administrative NADA is submitted elevates form over substance to frustrate the clear intent of Congress.

FDA asserts that its position on when the "approval phase" begins is necessary to prevent inadequate technical submissions from prematurely or improperly triggering the start of the approval phase. According to FDA, under Plaintiffs' standard, "the submission of virtually any piece of information to an INAD file is sufficient to trigger the approval phase." Def. Mem. at 20. This argument ignores two independent mechanisms that foreclose the risk that the FDA identifies (*i.e.*, that an applicant will be able to unfairly extend the duration of the approval phase by filing a non-substantive submission and thereby obtain a longer patent term restoration period). First, under its phased review process, the FDA will *not accept* a technically insufficient submission for review, nor will it start its review of that information under the phased or rolling review process. To the extent a sponsor makes a substandard submission, FDA, under its stated procedures, will notify the sponsor that review will be deferred until the deficiency is cured. CVM Update 1995, FDA00004; *see also id*. at FDA000019 (FDA will issue a "Refuse to Review Letter" without review of the submission "[i]f the submission is less than a package that [FDA] finds useful to review"). Second, under the statutory scheme of 35 U.S.C. § 156, periods where an applicant is not acting with reasonable diligence to obtain approval of its drug, or which operate to delay the overall period of regulatory review, are subtracted from the

patent term restoration period. In other words, if an applicant were to take the types of actions suggested by the FDA, not only would the FDA not begin its substantive review of what had been submitted, under the statutory design of 35 U.S.C. § 156, the delays the applicant caused in the approval phase resulting from those actions will be subtracted from the overall period of patent term restoration.

FDA's concerns about the potential for abuse of the phased review process are squarely addressed by policies already in place within the Agency for policing the substance of each technical submission, and in the statutory design of the patent term restoration authority for new animal drugs. And, importantly, in this case the FDA has made no allegation that Wyeth took actions to manipulate or otherwise delay the regulatory review process to receive an inappropriate patent term restoration period. To the contrary, as demonstrated in the figure provided above in the Concise Statement of Facts, Wyeth aggressively and diligently pursued approval of its Cydectin application under the procedures established by the FDA. Under these procedures, the Cydectin application was "initially submitted" when Wyeth submitted the first technical section, which prompted the FDA to observe that Wyeth had submitted an "an extensive amount of data" and that the FDA had "proceeded with [its] review." SOF ¶ 17. Thus, when Plaintiffs submitted their 4,790 page technical section of the Cydectin application on August 8, 1995, they provided the FDA with enough information for the FDA to commence its review of the Cydectin application and thereby triggered the beginning of the approval phase.

For these reasons, FDA's determination that the marketing application for Cydectin was initially submitted on the date a complete Administrative NADA was submitted should be set aside as inconsistent with Congress' clear intent as manifested in the plain meaning of the statute. Thus, *Chevron* step one begins, and ends, the analysis. *New York Life*, 190 F.3d at 1379-80.

B. Even If Congress Has Not Directly Spoken On the Issue, FDA's Interpretation Of The Statute Is Unreasonable And Should Not Be Accorded Deference

If the Court finds the language of 35 U.S.C. § 156(g)(4)(B) ambiguous in delineating when the approval phase begins, it should find that the FDA's interpretation is plainly inconsistent with the language, structure, and purpose of the statute, is not supported by the legislative history, is unreasonable, and, therefore, should not be accorded any deference by the Court.

According to FDA, the approval phase begins "when the marketing application is complete." 71 Fed. Reg. at 54994. FDA has determined that the day on which the Administrative NADA -- an administrative filing with the FDA after all the technical sections that compose the NADA have been substantively reviewed and approved -- marks this date. The FDA's interpretation of when the approval phase starts for an application submitted for phased review operates to eliminate the majority of the period of the approval phase under § 156(g)(4)(B), thereby frustrating the clear intent of Congress to provide day-for-day restoration of patent terms for this period of time.

The phased or rolling review procedure dictates when and how an applicant must present the various technical sections of an application for FDA review. This procedure is an administrative convenience for the Agency and helps make the overall review process of an application more efficient. Under this procedure, the Agency clearly receives sufficient information to commence its review of an application and actually starts that review, long before an applicant files an "Administrative NADA" signifying that an application is complete and ready for approval.

Indeed, as the Agency acknowledges, for marketing applications submitted under phased review, "review of the individual sections of the application *has already been completed*" by the

time the administrative NADA has been filed. Draft Guidance 2002, FDA000113. Despite this, the Agency asserts that, for purposes of the patent term restoration law, the "approval phase" of an application does not begin until the date the "Administrative NADA" is submitted.

FDA's interpretation is unreasonable. The definition of the start of the approval phase in 35 U.S.C. § 156(g)(4)(B) refers to the Agency's conduct. In this respect, it is inconsistent and unreasonable for the FDA, on one hand, to acknowledge that it is actually engaging in the substantive review of the technical sections of an application during the phased application process, while on the other hand, denying that it has received information sufficient for the Agency to commence its review of the application. The Agency's interpretation thus conflicts with the clear terms of the statute, which provides that the approval phase begins when the marketing application is "initially submitted." Congress determined that an application is "initially submitted" when it is "complete enough" for review by FDA to "commence" even if "additional information or other changes in the application" are necessary. H.R. Rep. No. 98-857, pt. 1, at 44. FDA may not construe the statute in a way that "completely nullifies textually applicable provisions" meant to effectuate the intent of Congress. *Whitman v. American Trucking Ass'n*, 531 U.S. 457, 484 (2001); *see also GHS Health*, 2008 U.S. App. LEXIS 17160, at *13 (agency action "that contradict and undermine Congress' statutory schemes must be invalidated").

The FDA's interpretation is also unreasonable because it operates to carve out of the approval phase virtually the entirety of the period during which the FDA is *actually conducting* its substantive review of an application. FDA's actions undermine the design and purpose of the patent term restoration scheme and vitiate the clear Congressional intent to credit the full period during which the Agency is conducting its review of an application toward restoration. FDA's

interpretation will lead (and has led) to approval phase determinations that do not correspond to the actual periods during which FDA is conducting its substantive review of applications. In the case of Cydectin, the FDA concluded that the approval phase lasted *16 days* on the basis of a record which shows that it was conducting its substantive review of this application for more than 28 months (*i.e.*, the time between the submission of the Residue Chemistry section and FDA's issuance of the "complete letter" for the final technical section). SOF ¶ 52. In other applications which underwent phased review, FDA's interpretation has resulted in approval phases lasting a mere *17 days*. Defs' Mem. at 24.

Clearly, these periods do not reflect the actual periods of time during which the Agency is actually conducting its review of these applications. Applications under traditional review typically are found to have approval phases lasting "years." H.R. Rep. No. 100-972, pt. 1, at 3. Thus, FDA's interpretation of the statute should not be entitled to deference because it defeats the purpose of 35 U.S.C. § 156(g)(4)(B)(ii) by effectively nullifying the "approval phase" of the regulatory review period. The Agency's interpretation will thus vitiate the clear intent of Congress to provide day for day credit to the portion of the regulatory review period during which the Agency is conducting its review of the application. *Western Union Telegraph Co. v. Federal Communications Commission*, 729 F.2d 811, 817 (D.C. Cir. 1984) ("the FCC's interpretation vitiates the exemption mandated by Congress. Such a result surely should be avoided . . . .").

The unreasonableness of FDA's position is also shown by its selective reading of the key portions of the legislative history that inform the meaning of the statute. For example, the FDA states that "the legislative history specifies that the application must contain 'all information necessary' for agency review." Def. Mem. at 22. The FDA, however, ignores the most

important part of this portion of the legislative history, which states clearly that the approval phase starts when the Agency receives "all information necessary for agency review ***to begin.***" H.R. Rep. No. 98-857, pt. 1, at 44 (emphasis added). The Agency's interpretation also is flatly inconsistent with the Agency's own acknowledgement that by time an Administrative NADA has been submitted, the Agency has not only received enough information to start the review, but that it has actually completed that review. A.R. at FDA000113. Thus, the FDA's assertions are inconsistent with Congressional intent holding that the approval phase starts when an application is "complete enough so that agency action could be commenced." *Id.*

The FDA also attempts to draw unjustified distinctions between the phased review and the traditional review procedures. FDA notes that Wyeth chose to seek approval of Cydectin through phased review and that it was "free to use whichever review process it deemed appropriate."[7] Defs' Mem. at 23. Importantly, the Agency does not point out that the nature of the Agency's review of the technical sections of an application do not differ in any respect depending on how these sections are submitted for review (*i.e.*, via a "traditional" NADA or under the phased review procedure). In reality, there is no difference. More directly, the statute makes no distinctions about the manner by which an applicant presents elements of an application for review. Instead, it simply defines the approval period as the period during which

[7] The Agency asserts that it provided guidance to the industry that the time to approve an application filed under phased review "usually will be shorter that the time it takes to approve a traditional NADA," and that "a new animal drug that was the subject of an Administrative NADA is likely, in most cases, to receive a shorter patent term extension than it would have received had it been the subject of a traditional NADA." Defs' Mem. at 22-23. This guidance was provided in 2002, more than 7 years after Plaintiffs began to make their technical section submissions, and more nearly 4 years after the filing of Plaintiffs' Administrative NADA. In addition, it states nothing more than the uncontroverted fact that a shorter regulatory review period will result in a shorter patent term extension, just as the statute contemplates.

In addition, Defendants argue that "For the purposes of new animal drugs, FDA has consistently interpreted the term application . . . to mean a complete application (NADA)." Defs' Mem. at 3, 24. This is exactly the construction that Congress considered *and rejected*.

the Agency is conducting its substantive review of the application. And, under both pathways, the amount of time the FDA takes to conduct this review is significant, with the effect that in both pathways, applicants are unable to commence marketing of their new animal drugs for substantial periods of time while the agency review is occurring.

Despite the substantive equivalence of the two procedures, the FDA has determined that the approval phase for "phased" applications will usually amount to a matter of days or weeks, while the approval phase for "regular" applications ordinarily will last several years. Such a varied result for the same underlying administrative activities (*i.e.*, substantive review of a new animal drug product) thwarts Congressional intent and is unreasonable on its face. For these reasons, if the Court finds that the statute is ambiguous and unclear, the FDA should not be entitled to any deference in its interpretation of the statute.

C. FDA's Interpretation Of The Statute Is Arbitrary And Capricious Because It Relies on Improper Factors to Undermine the Statutory Scheme and Treats Similarly Situated Drug Products Differently Contrary To The Explicit Intent Of Congress

FDA's determination of the point at which marketing applications for animal drug products are "initially submitted" under phased review is also arbitrary and capricious because it relies on improper policy considerations that undermine the statutory scheme and is inconsistent with its treatment of human drug products submitted under phased review. This provides another, independent, basis for the Court to set aside the Agency's action. *See GHS Health*, 2008 U.S. App. LEXIS 17160, at *19-20 (finding that the arbitrary and capricious nature of an agency regulation provides "an independent basis for invalidating the regulation"); *compare Shay v. Federal Election Commission*, 414 F.3d 76, 96 (D.C. Cir. 2005) (noting an overlap between the *Chevron* step two analysis and the arbitrary and capricious standard).

Specifically, FDA argues that its interpretation is entitled to deference because "FDA reasonably balanced the complex policy considerations of patent term restoration and phased review." Defs' Mem. at 22. According to Defendants:

> The purpose of the phased review process is to create greater efficiencies that facilitate the approval of new animal drugs. A more efficient and shorter regulatory review period . . . will generally result in that drug entering the market faster. The purpose of the patent term extension provisions of the Hatch-Waxman Amendments and the GAD/PTR Act is to allow for a patent term extension[] when the patent life of a new animal drug is lost during a period of regulatory review. Therefore, in blending these policy goals, it follows that, if the patent life lost during a period of regulatory review is decreased because of the phased review process, the length of the patent term extension should be limited accordingly.

Id. This newly articulated policy concern rings hollow.[8] To the extent phased review of an application is efficient and allows an applicant to get to market quickly, the efficiencies would automatically be reflected in shorter patent term restoration periods granted (*i.e.*, because the overall regulatory review period will be shorter). However, instead of finding a shorter approval phase, the FDA's interpretation effectively eliminates the approval phase from the patent term restoration calculation. Given that Congress intended that in "all cases" the regulatory review period consist of a testing phase *and* an approval phase, H.R. Rep. 98-857, part 1, at 40, 44, this result cannot meet the policy objective of the patent term restoration statute. And, contrary to Defendants' allegations, Plaintiffs are not trying to have it both ways by having a short approval phase and a long patent term restoration period. Defs' Mem. at 3. Plaintiffs simply are seeking

[8] FDA's policy rationale was not articulated in the Federal Register notice where FDA justified its determination of the regulatory review period. To the extent it represents a post hoc rationalization to defend the policy in this litigation, it "will not create a statutory interpretation deserving of deference." *Parker v. Office of Personnel Management*, 974 F.2d 164, 166 (Fed. Cir. 1992).

to have patent term restored in a meaningful manner for both the testing and approval phases, as they are rightfully entitled according to the statutory scheme created by Congress.

More importantly, the policy considerations advanced by Defendants have already been addressed by Congress within the legislative scheme. Congress has already placed limits on patent term restoration periods. Under 35 U.S.C. § 156(c)(3) and 156(g)(6)(A), the period of extension cannot exceed 5 years, and the period remaining in the term of the patent after the date of approval when added to the review period cannot exceed 14 years. The statute also reduces the patent term restoration period by the amount of time that the applicant did not act with due diligence. 35 U.S.C. § 156(c)(1). Due diligence is defined by the statute as "the degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period." 35 § 156(d)(3). Thus, any concern that an applicant may attempt to "game" or abuse the phased review submission policy is already addressed by the statute. FDA's interpretation of the statute seeks to place additional limits at odds with the "complex policy choices" that have already been made by Congress and that have already been incorporated into the statutory scheme.

In determining when the approval phase began for Cydectin, the FDA should have looked to the amount of time it spent reviewing the application and when that review began rather than taking into consideration abstract policy issues in which it has no particular expertise. Accordingly, FDA's determination is arbitrary and capricious. *FDA v. Brown & Williamson Tobacco Co.*¸ 529 U.S. 120, 125 (2000) ("Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law.") (internal quotations omitted); *see also Motor Vehicle Mfrs. of the U.S., Inc. v. State Farm Mut. Auto. Ins.*

Co., 463 U.S. 29, 43, (1983) (interpreting the APA to require that agencies "articulate a satisfactory explanation for [their] action including 'a rational connection between the *facts found* and the choice made.'") (emphasis added).

Additionally, FDA's treatment of animal drugs is inconsistent with the Agency's treatment of human drugs. As discussed, the express purpose of the GAD/PTR Act was "to create in the animal drug industry similar conditions for generic drugs and patent term restoration as Congress did in the human drug industry in 1984" with the DPC/PTR Act. H.R. Rep. No. 100-972, pt. 1, at 2; *see also id*. at 8 (GAD/PTR Act "simply makes the additions to [the DPC/PTR Act] necessary to include animal drugs . . . ."). Despite Congress' attempts to afford new animal drugs the same patent term restoration period as new human drugs, FDA's treatment of Wyeth's request for a patent term extension for Cydectin stands in stark contrast with its policy for calculating patent term extensions for human drugs that are submitted and reviewed on a phased basis.

On the same day FDA published its determination of the regulatory review period for Cydectin, FDA also published its determination of the regulatory review period for the human drug product, FUZEON® ("Fuzeon"), marketed by Roche. SOF ¶ 65. Similar to Cydectin, the marketing application for Fuzeon underwent a phased review. *Id*. at ¶ 66. Specifically, Fuzeon utilized the rolling NDA procedure authorized by statute for drugs intended to treat serious or life-threatening conditions, or address unmet medical needs. *See* 21 U.S.C. § 356.

FDA determined that the Fuzeon application was "initially submitted" on the day the "final module of the marketing application was submitted" to FDA. Determination of Regulatory Review Period for Purposes of Patent Term Extension; FUZEON, 71 Fed. Reg. 54993, 54997 (Sept. 20, 2006); *see also* SOF ¶ 67. In contrast, FDA did not determine that the

Cydectin application was initially submitted when the final Cydectin technical section was submitted on August 14, 1996 -- *i.e*. the alternate initial submission date proposed by Plaintiffs in their Request for Extension of Patent Term Under 35 U.S.C. § 156. SOF ¶¶ 46-48. Rather, FDA determined that the Cydectin application was initially submitted after FDA had already completed its review of all of the technical sections and the Administrative NADA was submitted. In light of the different standards used for animal and human drugs, Fuzeon had an approval phase that lasted several months instead of several days like Cydectin.

FDA, however, claims that its treatment of Fuzeon was consistent with Cydectin. According to FDA, FDA used the date that the application was "complete" for both Fuzeon and Cydectin. Defs' Mem. at 25. However, FDA provides no explanation as to why the Fuzeon application, but not the Cydectin application, was considered complete with the submission of the final module. In light of the stated Congressional intent to provide animal drugs with the same patent term restoration period as human drugs, FDA's actions are arbitrary and capricious. *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20 (D.D.C. 1997) (holding that the disparate treatment of similarly situated products is arbitrary and capricious).

D. The Marketing Application For Cydectin Was "Initially Submitted" On August 8, 1995

The Court should set aside FDA's determination that the marketing application for Cydectin was initially submitted on the date in which Plaintiffs filed the Administrative NADA form for the completed application. The Court should find that the marketing application for Cydectin was initially submitted on August 8, 1995, the date on which the first technical section (*i.e.*, the Residue Chemistry) was submitted to the FDA.

Based on Plaintiffs' calculation of one-half of the "testing phase" (after the grant of the patent) from April 10, 1990 to August 8, 1995 (973.5 days); and a calculation of all the time

corresponding to the "approval phase" from August 8, 1995 to January 28, 1998 (904 days), Plaintiffs have determined that the regulatory review period for the approved product is 1877.5 days. Given that under 35 U.S.C. § 156(c)(3), the period remaining in the term of the patent after the date of approval when added to the review period cannot exceed 14 years, Plaintiffs have determined that the '154 patent is eligible for an extension of a period of 1,754 days. Thus, the new expiration date of the '154 patent based on an approval phase that began on August 8, 1995, the date when substantive review of the application could (and did) begin, should be January 28, 2012. Defendants have not disputed this calculation.

For at least these reasons, Plaintiffs Motion for Summary Judgment should be granted.

II. Defendants' Motion To Dismiss Should Be Denied Because The Complaint Sufficiently Puts Defendants On Notice As To Plaintiffs' Claim For Relief

Defendants have styled their motion as a "Motion to Dismiss" under Fed. R. Civ. P. 12(b)(6). Defendants' motion should be denied. In order to survive a motion to dismiss for failure to state a claim, a plaintiff need only provide a statement "that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). The plaintiff need not demonstrate that it will prevail on the merits. *Chandamuri v. Georgetown University*, 274 F. Supp.2d 71, 76 (D.D.C. 2003) ("A motion to dismiss under Rule (12)(b)(6) tests not whether the plaintiff will prevail on the merits, but whether the plaintiff has properly stated a claim.").

Defendants' Motion to Dismiss should be denied because Plaintiffs have adequately pled factual allegations giving rise to a legally cognizable claim for relief. The Complaint asserts that FDA has engaged in final agency action in its determination of the regulatory review period for Plaintiffs' drug product, Cydectin, and that Plaintiffs have exhausted all of their available administrative remedies. *See, e.g.*, Compl. ¶¶ 81-90, 99-100. The Complaint also asserts that

FDA's action was erroneous, arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. *Id*. at ¶ 111. Under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 704-706, Plaintiffs are entitled to judicial review of this final agency action. These basic facts, all of which are alleged in the Complaint, suffice to put Defendants on fair notice of the grounds on which Plaintiffs' claim rests. *Radack*, 402 F. Supp. 2d at 103 n.2.

Rather than addressing the sufficiency of the Complaint, Defendants arguments for dismissal are, in reality, directed to the *merits* of Plaintiffs' claim for relief. Specifically, Defendants argue in their motion that, under *Chevron*, FDA has "complied with the clear terms of the statute" and that FDA's "determination was reasonable and fully in accord with the language, structure, and purpose of the statute. . . ." Defs' Mem. at 3. As this Court has previously held, these are arguments for dismissal that "miss[] the mark because [they] address[] the merits of [Plaintiffs'] APA claim, not the principles that govern whether a claim has been properly stated." *Radack*, 402 F. Supp. 2d at 103. For these reasons, Defendants' Motion to Dismiss should be denied. Should the Court, however, find it appropriate to reach the merits of Plaintiffs' claim under Fed. R. Civ. 12(b)(6), Defendants' Motion to Dismiss should be denied for the reasons Plaintiffs provide herein in support of Plaintiffs' Motion for Summary Judgment.

Alternatively, Defendants' Motion to Dismiss should be converted to a Motion for Summary Judgment. *See* Fed. R. Civ. Proc. 12(c) ("if, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56.") (emphasis added); *see also Marshall County Health Care Authority v. Shalala*, 988 F.2d 1221, 1226 n.5 (D.C. Cir. 1992) (When the district court consults the

administrative record in a challenge to an agency action, "it is probably the better practice for a district court always to convert to summary judgment . . ."); *but see Radack*, 402 F. Supp. 2d at 103 n.2 (refusing to convert motion to dismiss that challenged the merits into a motion for summary judgment for failure to comply with the local rules). In the event the Court converts defendants' motion into a Motion for Summary Judgment, the converted motion should be denied for the reasons Plaintiffs provide herein in support of Plaintiffs' Motion for Summary Judgment.

CONCLUSION

For the forgoing reasons, summary judgment should be granted in favor of Plaintiffs and against the Defendants. In addition, Defendants' Motion to Dismiss should be denied.

Dated: September 8, 2008

/s/ Gary Veron

Jeffrey P. Kushan (D.C. Bar # 461155)
Gary Veron (D.C. Bar # 445450)
Peter S. Choi (D.C. Bar # 496780)
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000
Facsimile: (202) 736-8711

Counsel for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH HOLDINGS CORPORATION, ET AL., Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL., Defendants.	Civil Action No. 08-00981 (HHK) **ORAL ARGUMENT REQUESTED**

PLAINTIFFS' STATEMENT OF MATERIAL FACTS
AS TO WHICH THERE IS NO GENUINE ISSUE IN SUPPORT OF PLAINTIFFS'
MOTION FOR SUMMARY JUDGMENT

Plaintiffs Wyeth Holdings Corporation, formerly known as American Cyanamid Company, and Wyeth (collectively and individually referred to as "Wyeth" or "Plaintiffs") by and through undersigned counsel, hereby submit this Statement Of Material Facts As To Which There Is No Genuine Issue pursuant to LCvR 56.1 in support of Plaintiffs' Motion for Summary Judgment.

I. The Parties

1. Plaintiff Wyeth Holdings Corporation is a Maine corporation, formerly known as American Cyanamid Company, which has its principal office at 5 Giralda Farms, Madison, NJ 07940. Complaint ("Compl.") at ¶ 10; *see also* Administrative Record ("A.R.") at FDA000126, FDA000179.

2. Plaintiff Wyeth is a Delaware corporation, which has its principal office at 5 Giralda Farms, Madison, NJ 07940. Compl. at ¶ 11.

3. Defendant U.S. Department of Health and Human Services, which has its principal office at 200 Independence Avenue, S.W., Washington, D.C. 20201, is a federal agency headquartered in the District of Columbia that has authority over the Food and Drug Administration ("FDA" or the "Agency"). Compl. at ¶ 12; *see also* A.R. at FDA000107-114, FDA000119-123.

4. Defendant Michael O. Leavitt is sued in his official capacity as Secretary of Health and Human Services. As Secretary, Mr. Leavitt has the ultimate responsibility for the activities of the Department of Health and Human Services. Mr. Leavitt maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201. Compl. at ¶ 13; *see also* A.R. at FDA000047.

5. Defendant FDA, which has its principal office at 5600 Fishers Lane, Rockville, MD 20857, is a federal agency headquartered in Maryland. FDA reviews and approves new animal drug applications. FDA also makes determinations regarding the regulatory review period for new animal drug applications for the purposes of patent term restoration under authority delegated by Congress and the Secretary of the U.S. Department of Health and Human Services. Compl. at ¶ 14; 35 U.S.C. § 156; *see also* A.R. at FDA000107-114, FDA000119-123, FDA000126-136.

6. Defendant Andrew C. von Eschenbach, M.D. is sued in his official capacity as Commissioner of the FDA. As Commissioner, Dr. von Eschenbach has the ultimate responsibility for the activities of the FDA. Dr. von Eschenbach maintains an office at 5600 Fishers Lane, Rockville, MD 20857. Compl. at ¶ 15; *see also* A.R. at FDA000126-136.

7. Defendant United States Patent and Trademark Office ("PTO"), which has its principal office at Madison Building East, Room 10B20, 600 Dulany Street, Alexandria, VA 22314, is a federal agency headquartered in Virginia. The PTO determines the eligibility of patents for which patent term extension is sought and issues a certificate of patent term extension for eligible patents. Compl. at ¶ 16; 35 U.S.C. § 156; *see also* A.R. at FDA000037-106.

8. Defendant Jon W. Dudas is sued in his official capacity as Director of the PTO. As Director, Mr. Dudas has the ultimate responsibility for the activities of the PTO. Mr. Dudas maintains an office at Madison Building East, Room 10B20, 600 Dulany Street, Alexandria, VA 22314. Compl. at ¶ 17; *see also* A.R. at FDA000179.

II. The Cydectin New Animal Drug Application ("NADA")

9. Cydectin is an animal drug product labeled for use in beef and dairy cattle for the treatment and control of internal and external parasites. A.R. at FDA000120, FDA000136.

10. The Fort Dodge Animal Health Division of Wyeth holds the NADA for Cydectin, which was approved by the FDA on January 28, 1998 as NADA 141-099. A.R. at FDA000117, FDA000126-27; *see also* FDA000102, FDA000137.

11. In March of 1990, Wyeth Holdings Corporation, known as American Cyanamid Company at the time, formally requested that the FDA establish an Investigational New Animal Drug ("INAD") file for moxidectin. A.R. at FDA000085.

12. On or about April 9, 1990, the FDA notified Plaintiffs that the INAD file for moxidectin had been established. A.R. at FDA000121.

13. New animal drug applications ("NADAs") are organized by technical sections. Each technical section supports a condition of approval required by the FDA. A.R. at FDA000024.

14. Under FDA's phased review policy, an applicant may submit the technical sections of the NADA on a phased or rolling basis. FDA begins review of the submitted technical sections even if the other sections have not yet been submitted. FDA then notifies the applicant in writing of its conclusions regarding the information submitted. A.R. at FDA000016-20; *see also* FDA000132-133, FDA000143-148.

15. Plaintiffs submitted the first technical section supporting the NADA for Cydectin, *i.e.*, the Residue Chemistry technical section, on August 8, 1995 pursuant to the Agency's phased review process. A.R. at FDA000137-138; *see also* FDA000094.

16. The Residue Chemistry technical section contained four sets of information covering the subjects of total metabolism in target animal, comparative metabolism in rodents, tissue residue depletion studies, as well as analytical methods and method validations, and contained 4,790 pages of information. A.R. at FDA000137-138.

17. On March 26, 1996, the FDA issued a letter stating that it had "proceeded with [its] review" of the Residue Chemistry technical section. A.R. at FDA000139. FDA also stated in the letter that "[y]ou have submitted an extensive amount of data that is intended to fulfill our residue chemistry requirements. We concluded that you did an excellent job of reporting the claimed pivotal studies." A.R. at FDA000139.

18. In May of 1996, the name of the sponsor of Cydectin was changed from American Cyanamid Corporation to the Fort Dodge Animal Health Division of Wyeth. A.R. at FDA000094; *see also* FDA000137.

19. If FDA is satisfied that an individual technical section has complied with the requirements of 21 U.S.C. § 360b, FDA issues a "technical section complete" letter for that section. A.R. at FDA000112.

20. On December 10, 1997, the FDA issued a "complete letter" for the Residue Chemistry technical section. A.R. at FDA000137; *see also* FDA000101.

21. While the FDA was still reviewing the Residue Chemistry technical section, on December 15, 1995, Plaintiffs submitted the Target Animal Safety technical section. A.R. at FDA000137; *see also* FDA000094. The FDA issued a "complete letter" for this component on July 22, 1996. A.R. at FDA000095.

22. Additional technical sections corresponding to Manufacturing Chemistry ("CMC"), Effectiveness, and Public Safety were made by Plaintiffs on December 21, 1995, January 16, 1996, and June 7, 1996, respectively. A.R. at FDA000137. The FDA issued "complete letters" for these sections on September 17, 1996, November 4, 1997, and January 13, 1998, respectively. A.R. at FDA000137.

23. On August 14, 1996, Plaintiffs made their final technical section submission to the FDA relating to Environmental Safety. A.R. at FDA000137; *see also* FDA000096. With the submission of the Environmental Safety technical section, all of the technical sections necessary for a complete NADA had been submitted to the Agency for review and approval. A.R. at FDA000078-79; Compl. at ¶ 66.

24. FDA issued a "complete letter" for the Environmental Safety technical submission on December 23, 1997. A.R. at FDA000137.

25. There was no period of time between the filing of the first technical section and the issuance of the "complete letter" for the last technical section that FDA did not have before it a technical section supporting the safety and efficacy of Cydectin undergoing substantive review. A.R. at FDA000084; *see also* FDA000085 *et seq*.

26. When a new drug applicant has received technical section complete letters for each of the technical sections submitted to support approval of a new animal drug, the applicant may submit an "Administrative NADA." A.R. at FDA000112.

27. The Administrative NADA includes a cover letter, FDA Form 356V, a table of contents, a summary, a copy of each technical section complete letter, complete facsimile labeling, and a "FOI summary." A.R. at FDA000112.

28. By the time a drug sponsor submits an Administrative NADA, FDA has completed its review of all the individual technical sections that support the NADA. A.R. at FDA000113.

29. On January 13, 1998, upon receipt of the "complete letter" for the Public Safety technical section from the FDA, Wyeth submitted the Administrative NADA for Cydectin. A.R. at FDA000137-138; *see also* FDA000102.

30. The Administrative NADA for Cydectin cited all the "complete letters" FDA had previously issued for all of the components of the application. A.R. at FDA000138.

31. On or about January 14, 1998, the Agency issued an acknowledgement letter for the Administrative NADA and issued an NADA number for the Cydectin application. A.R. at FDA000138; *see also* FDA000102.

32. On or about January 28, 1998, FDA issued the marketing approval letter for Cydectin. A.R. at FDA000138; *see also* FDA000102.

III. Wyeth's Request for Extension of Patent Term Under 35 U.S.C. § 156

33. On March 27, 1998, within the 60-day period for submission, *see* 37 C.F.R. § 1.720(f), Plaintiffs filed with the PTO a Request for Extension of Patent Term Under 35 U.S.C. § 156. A.R. at FDA000037-106; *see also* FDA000117.

34. The patent for which extension was sought was U.S. Patent No. 4,916,154 ("the '154 patent"). A.R. at FDA000041; *see also* FDA000117.

35. The PTO has determined that the '154 patent is eligible for patent term restoration. A.R. at FDA000040; *see also* FDA000103, FDA000118.

36. Wyeth Holdings Corporation is the current assignee of the '154 patent, and owns all rights, title, and interests in and to the '154 patent. A.R. at FDA000179; Compl. at ¶ 48.

37. The '154 patent issued on April 10, 1990. A.R. at FDA000051.

38. The original expiration date of the '154 patent is April 10, 2007. A.R. at FDA000041.

39. The '154 patent covers the active ingredient in Cydectin, moxidectin, methods of using the approved product, and compositions containing the approved product. A.R. at FDA000040-46, FDA000051-64.

40. Wyeth's Request for Extension of Patent Term indicated that the testing exemption under subsection (j) of section 512 (of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360b(j)) became effective for the new animal drug product on April 9, 1990, the date FDA assigned the INAD file number for the active ingredient in Cydectin, moxidectin. A.R. at FDA000047; *see also* FDA000085.

41. The Request for Extension of Patent Term indicated that the approval phase began when the marketing application was "initially submitted" on August 8, 1995, the date on which the Residue Chemistry technical section was first submitted to FDA. A.R. at FDA000047; *see also* FDA000094.

42. The Request for Extension of Patent Term indicated that the date the application was approved was January 28, 1998. A.R. at FDA000047; *see also* FDA000102.

43. Based on Plaintiffs' calculation of one-half of the "testing phase" (after the grant of the patent) from April 10, 1990 to August 8, 1995 (973.5 days); and a calculation of all the time corresponding to the "approval phase" from August 8, 1995 to January 28, 1998 (904 days), Wyeth determined that the regulatory review period for the approved product is 1877.5 days. A.R. at FDA000049.

44. Given that under 35 U.S.C. § 156(c)(3), the period remaining in the term of the patent after the date of approval when added to the review period cannot exceed 14 years, Wyeth determined that the '154 patent is eligible for an extension of a period of 1,754 days. A.R. at FDA000049.

45. Thus, the new expiration date of the '154 patent based on an approval phase that began on August 8, 1995, the date the Residue Chemistry technical section was submitted, would be January 28, 2012. A.R. at FDA000049.

46. Plaintiffs' Request for Extension of Patent Term also indicated, as an alternative calculation/determination, that the approval phase began on August 14, 1996, when the final technical section of the marketing application -- *i.e.*, the Environmental Safety technical section -- was "initially submitted" to the FDA. A.R. at FDA000083; *see also* FDA000096.

47. Based on Plaintiffs' calculation of one-half of the "testing phase" (after the grant of the patent) from April 10, 1990 to August 14, 1996 (1159 days), and a calculation of all the time corresponding to the "approval phase" from August 14, 1996 to January 28, 1998 (532 days), under this alternative, Plaintiffs determined that the appropriate regulatory review period for the approved product would be 1,691 days. A.R. at FDA000083.

48. Under this alternative calculation/determination, the new expiration date of the '154 patent based on an approval phase that began on August 14, 1996, would be November 26, 2011. A.R. at FDA000083.

49. On September 20, 2006, the FDA published its determination of the regulatory review period for purposes of patent term extension for Cydectin in the Federal Register. 71 Fed. Reg. 54993 (Sept. 20, 2006); *see also* A.R. at FDA000180.

50. The Federal Register indicated that the FDA determined that the applicable regulatory review period for Cydectin is 2,857 days. A.R. at FDA000121.

51. No reduction under 35 U.S.C. § 156(c)(1) in the applicable regulatory review period was made for any lack of due diligence on the part of Plaintiffs. A.R. at FDA000121.

52. FDA determined that 2,841 days occurred during the testing phase, while only 16 days occurred during the approval phase. A.R. at FDA000121.

53. These periods of time were derived from a determination that April 5, 1990, is the effective date for the INAD, which began the testing phase. A.R. at FDA000121.

54. The approval phase was based on FDA's determination that the Cydectin marketing application was initially submitted on January 13, 1998, the date on which Wyeth submitted its Cydectin Administrative NADA to the FDA. A.R. at FDA000121-22.

55. FDA's reasoning for this determination was that "the approval phase begins when the marketing application is complete." 71 Fed. Reg. 54993, 54994 (Sept. 20, 2006); A.R. at FDA000121-22.

56. FDA also determined that the date the marketing application was approved was January 28, 1998. A.R. at FDA000122.

57. Based on FDA's determination of the regulatory review period for Cydectin, the PTO issued a notice of final determination on June 13, 2007 indicating that the period of patent term extension had been determined to be 1,434 days (3.9 years). Compl. ¶ 88; Declaration of Peter S. Choi ("Choi Decl."), Ex. 1, p. 1.

58. Under FDA's interpretation, the '154 patent would expire on March 14, 2011. Compl. at ¶ 89; Choi Decl., Ex. 1, p. 2.

59. Plaintiffs timely filed a Request for Revision of Regulatory Review Period with the FDA on November 20, 2006. A.R. at FDA000126-77.

60. Plaintiffs' Request for Revision of Regulatory Period asked that the "date the application was initially submitted with respect to the animal drug product under section 512(b) of the act" be corrected from January 13, 1998, the date in the Federal Register notice, to August 8, 1995, the date Plaintiffs submitted to FDA the first technical section of the NADA application. A.R. at FDA000126; *see also* FDA0000138.

61. Plaintiffs also requested that the Agency recalculate the "regulatory review period" accordingly. A.R. at FDA000126.

62. On May 7, 2008, FDA denied Plaintiffs' Request for Revision of Regulatory Review Period. A.R. at FDA000181-85.

63. FDA's May 7, 2008 response to Plaintiffs' Request for Revision of Regulatory Review Period constitutes the Agency's final action of the regulatory review period determination for the purposes of patent term restoration for the '154 patent. 21 C.F.R. § 60.26(b)(2).

64. Plaintiffs have exhausted all of their available administrative remedies. Compl. at ¶ 100.

IV. FDA's Determination Of The Regulatory Review Period For The Human Drug Fuzeon

65. On the same day that FDA published its determination of the regulatory review period for Cydectin, FDA also published its determination of the regulatory review period for the purposes of patent term extension for a human drug product marketed by Roche, FUZEON® ("Fuzeon"). 71 Fed. Reg. 54993, 54997 (Sept. 20, 2006).

66. The marketing application for Fuzeon was submitted in several units as part of a rolling or phased new drug application ("NDA") submission procedure authorized by statute for human drugs intended to treat serious or life-threatening conditions, or address unmet medical needs. *See* 21 U.S.C. § 356; Compl. at ¶ 92.

67. FDA determined that the NDA for Fuzeon was initially submitted on the day the "final module of the marketing application was submitted" to FDA. 71 Fed. Reg. 54993, 54997 (Sept. 20, 2006).

Dated: September 8, 2008

/s/ Gary Veron

Jeffrey P. Kushan (D.C. Bar # 461155)
Gary Veron (D.C. Bar # 445450)
Peter S. Choi (D.C. Bar # 496780)
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000
Facsimile: (202) 736-8711

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on September 8, 2008, I caused a true and correct copy of the foregoing Plaintiffs' Motion for Summary Judgment, and supporting documents, to be served by express courier next day delivery upon the following, and to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send a notification to the following:

Drake S. Cutini
DEPARTMENT OF JUSTICE
Office of Consumer Litigation
P.O. 386
Washington, DC 20044
drake.cutini@usdoj.gov

Lead Attorney for Defendants

/s/ Gary Veron
Gary Veron