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From the Office Of

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June 2, 2001

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: Dkt. No. 01N-0103 – Issues Associated with the Intersection of 180-Day Generic Drug Exclusivity and Pediatric Exclusivity – Comments of Faulding Pharmaceutical Co.

Dear Sir or Madam:

Faulding Pharmaceutical Co. (Faulding) submits these comments in response to the Food and Drug Administration's (FDA's) notice published in the Federal Register of May 21, 2001. 66 Fed. Reg. 27983. The notice invites comment on "whether pediatric exclusivity runs concurrently or consecutively with 180-day generic drug exclusivity when a favorable court decision in a paragraph IV patent challenge lawsuit is issued less than 180 days before the beginning of or during the pediatric exclusivity period."

The comments demonstrate that the intent of Congress was that pediatric exclusivity have no effect on the Hatch-Waxman effective date provisions for abbreviated new drug applications (ANDAs) other than to provide six months of additional protection to NDA applicants as an incentive to conduct pediatric drug studies.

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To carry out this intent, FDA should extend 180-day generic drug exclusivity by an interval sufficient to cancel any effects of pediatric exclusivity, i.e., pediatric exclusivity and 180-day exclusivity should run consecutively.

A. Background

1. Hatch-Waxman Act. The Hatch-Waxman Act amended the Food, Drug, and Cosmetic Act (FDCA) to authorize approval of ANDAs for generic drugs. 21 U.S.C. § 355(j)[1]. ANDAs rely on FDA's finding of safety and effectiveness for a drug approved in a full NDA under §§ 355(b) and (c).

In exchange for granting this right of reliance to generic drug applicants, Congress included two provisions beneficial to NDA applicants.[2] First, ANDAs must contain a certification to any patent that claims the NDA drug on which the ANDA relies. § 355(j)(2)(A)(vii). A paragraph III certification defers the effectiveness of the ANDA approval until patent expiration. A paragraph IV certification that a patent is invalid or will not be infringed permits the ANDA approval to be made effective immediately. However, the ANDA applicant must provide notice to the NDA applicant and patent owner, who can sue the ANDA applicant for infringement and obtain an automatic 30-month deferral of effective ANDA approval. §§ 355(j)(2)(A)(vii)(IV), (j)(2)(B) and

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1 All citations designated "§" are to 21 U.S.C. unless otherwise noted.

2 Congress also provided patent term restoration, as part of the larger compromise that was the basis for the 1984 law. See 35 U.S.C. § 156.

(j)(5)(B)(iii).[3] Second, NDAs can qualify for exclusivity periods (against generic approvals) of 5 years (for new chemical entities (NCEs)) or 3 years (for changes in non-NCEs supported by new and essential clinical investigations). § 355(j)(5)(D)(ii)-(iv).

Congress provided an incentive for a generic drug company to challenge a patent by making a paragraph IV certification. The incentive consists of a 180-day period during which approval of a subsequent ANDA that also contains a paragraph IV certification cannot be made effective. § 355(j)(5)(B)(iv). This 180-day exclusivity period is triggered by the earlier of two events: marketing of the generic drug under the applicant's ANDA, or a court decision that the patent is invalid or not infringed.

2. Pediatric Exclusivity. Beginning in 1992, Congress considered legislation to provide an incentive for drug manufacturers to develop scientific data on the use of drugs in children. See Better Pharmaceuticals for Children Act, S. 3377, 102d Cong. (1992). The 1997 FDA Modernization Act (FDAMA) authorized "market exclusivity" in exchange for the submission of pediatric studies in NDAs. § 355a. The exclusivity consists of a 6-month extension of any existing period of Hatch-Waxman

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[3] If the patent is found to be valid and infringed, the effectiveness of the ANDA approval is deferred until expiration of the patent.

exclusivity or patent associated market protection, and of any period of orphan drug exclusivity. § 355a(c).[4]

Pediatric exclusivity is added to Hatch-Waxman or orphan drug exclusivity by "deeming" the original period to be a 6-month longer period, e.g., the exclusivity for new chemical entities "is deemed to be five years and six months rather than five years." § 355a(c)(1)(A). Pediatric exclusivity is added to patent associated market protection by stating that the protected period "shall be extended by a period of six months." § 355a(c)(2).

B. Generic Drug Exclusivity Must be Harmonized with Pediatric Exclusivity

The 180-day generic drug exclusivity period was intended to be an incentive to generic drug companies to challenge patents that blocked generic drug marketing. A successful patent challenge eliminates a patent barrier, at least for the challenger's formulation, and possibly for all generic versions of the listed NDA drug.

[4] Subsection (c) creates pediatric exclusivity when pediatric studies are submitted to approved NDAs. It is in that situation that pediatric exclusivity has the potential to conflict with 180-day generic drug exclusivity. Pediatric exclusivity is also granted for pediatric studies in NDAs when they are first approved. § 355a(a).

Because of the way the generic drug exclusivity provision is written and has been interpreted, the 180-day exclusivity period may not always be usable by the ANDA applicant entitled to it. Although this outcome is anomalous, it is a product of the Hatch-Waxman provisions as enacted in 1984. The Hatch-Waxman Act was a legislative compromise. Congress may not have foreseen how the specific provisions of the legislation would work in all possible circumstances. However, it is reasonable to assume that, recognizing that compromises are imperfect, Congress intended FDA to give effect to the 1984 law as written, including forfeiture of 180-day generic drug exclusivity in some circumstances by operation of the Hatch-Waxman provisions themselves.

The same cannot be said of forfeiture of 180-day exclusivity that would occur if FDA interpreted the pediatric exclusivity provision enacted in 1997 as further limiting 180-day exclusivity. Unlike the 1984 law, the pediatric exclusivity provision, enacted 13 years after the Hatch-Waxman Act, is not a comprehensive scheme balancing the rights, obligations, and rewards of NDA and generic drug applicants. Congress's sole purpose was to encourage NDA applicants to conduct pediatric studies, not to modify the internal workings of the Hatch-Waxman provisions. Nevertheless, if FDA interpreted generic drug exclusivity as running concurrently with pediatric exclusivity, the 6-month pediatric exclusivity period would do just that. This effect would occur because effective approval of the paragraph IV ANDA entitled to 180-day exclusivity would be deferred, whereas the effective date of ANDAs subject to that exclusivity would not be, thereby

compressing or completely eliminating the advantage Congress intended the priority ANDA to have over later-filed ANDAs.

That outcome would be contrary to Congressional intent. Accordingly, generic drug and pediatric exclusivity must be harmonized by interpreting generic drug and pediatric exclusivity as running consecutively, not concurrently.

FDA is fully authorized by the text of the FDCA to adopt this interpretation. As we show below, failure to harmonize generic drug and pediatric exclusivity would produce results at odds with the intent of Congress and inconsistent with the objectives of both the Hatch-Waxman Act and the pediatric exclusivity provisions of the FDAMA. If they occurred, these results would be attributable to the agency's making "subsequent" paragraph IV ANDA approvals effective under § 355(j)(5)(B)(iv) exactly 180 days after a triggering court decision, rather than deferring effective approval to account for the effects of pediatric exclusivity on the "previous" paragraph IV ANDA. Yet the statute itself does not require FDA to make subsequent ANDAs effective on the 180th day. It requires only that subsequent ANDAs be made effective "not earlier than" 180 days after a triggering court decision. The agency thus has a textual basis for delaying effective approval of later-filed ANDAs to preserve the generic drug exclusivity of the priority ANDA.

An interpretation based on the plain meaning of the words "not earlier than" is consistent with the Chevron test that the validity of an agency interpretation of a statute is determined in the first instance by whether or not "Congress has directly spoken to the precise question at issue." Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984). At least as to FDA's authority to defer the effectiveness of subsequent paragraph IV ANDAs, there is an "unambiguously expressed intent of Congress," id., that FDA has such authority.

Whether FDA's exercise of that authority in a given case, or category of cases, is within its discretion under the FDCA presents, at most, a question of reasonableness. See id. at 844-45. Adopting an interpretation of §§ 355(j)(5)(B) and 355(c) that defers effective approval of later-filed paragraph IV ANDAs by an interval equal to any overlapping pediatric exclusivity affecting the priority ANDA would not only be reasonable on its own terms, but, as we now explain, it would give effect to the intent of Congress by preventing what would obviously be a distortion of the Hatch-Waxman incentive structure that does not serve any discernible objective of the pediatric exclusivity provisions of the FDAMA.

C. Congress Intended Pediatric Exclusivity Not to Alter the Relationship of the Hatch-Waxman Provisions To Each Other

1. The pediatric exclusivity drafting strategy. Pediatric exclusivity originated in the proposed Better Pharmaceuticals for Children Act, introduced in the Senate in 1992 as S. 3337. Under the bill, if an NDA applicant submitted pediatric studies, FDA was to defer effective approval of an ANDA until "the expiration of 6 months from the earliest date on which the approval of such application . . . could otherwise be made effective under the applicable provisions of" the FDCA. S. 3337, § 2 (proposed § 355a(a)). Except to defer its availability, this across-the-board tolling approach would have had no effect on generic drug exclusivity: The effectiveness of both the "previous" and the "subsequent" paragraph IV ANDA would have been deferred by 6 months.

In 1996, in S. 2178 and H.R. 4277, the approach to the pediatric exclusivity incentive was changed to the one incorporated in the FDAMA as enacted in 1997. The modified approach eliminated the freestanding 6-month exclusivity incentive in favor of adding 6 months to existing exclusivity and patent related protection periods. In this approach, Congress specifically identified all existing exclusivity and protection periods, and attached 6 months to each if the applicant for the NDA entitled to such a period submitted pediatric studies.

This change carried out the legislative policy decision to limit the scope of the pediatric study incentive to existing, congressionally-established categories in which

approval of competitive drugs was already subject to deferral. However, within the framework of those categories, the basic nature of the pediatric incentive remained unchanged: the effectiveness of all ANDAs (or NDAs for an orphan drug) was to be tolled for 6 months.

As a strictly mechanical matter, rather than state a tolling rule to further defer the effectiveness of all ANDAs within a category, § 355a individually enlarged each period of deferral. There is no indication that this drafting technique was adopted for any but technical reasons. The Hatch-Waxman and orphan drug provisions of the FDCA are intricate; the chances of inadvertent confusion[5] were reduced by modifying each Hatch-Waxman period.

In adopting this approach, the drafters of § 355a(c) did not incorporate specific language saying that the effective dates of both the previous and the subsequent paragraph IV ANDA were extended by 6 months. The drafters may have believed it was unnecessary to do so, because they assumed that the extensions would occur

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[5] For instance, a general tolling rule further deferring the effective date of all ANDA approvals subject to an existing Hatch-Waxman deferral would have raised an issue of interpretation with respect to the 5-year Hatch-Waxman exclusivity provision for new chemical entities, which is defined in relation to ANDA submission rather than the effectiveness of ANDA approval. See § 355(j)(5)(D)(ii). By restating the 5-year period as 5 1/2 years, § 355a(c)(1)(A)(i), this issue was avoided. Spelling out the mechanics of 6-month pediatric extension for each Hatch-Waxman period eliminated the need for FDA and others to interpret a more general tolling rule for ANDA effectiveness.

automatically as a result of the "shall be extended" language of subsections (c)(2)(A) and (B). If the drafters did not include words that precisely provide for this result, however, their failure to do so is plainly a technical omission that should not be interpreted as undermining the Congressionally mandated terms and conditions for 180-day exclusivity as enacted in the 1984 law.

2. The intent of Congress must be given effect. FDA focused on the wrong statute in reaching its preliminary conclusion that generic drug exclusivity does not run consecutively to pediatric exclusivity. That conclusion was explained in a letter from Melinda Plaisier to Senator Orrin Hatch dated February 22, 2001 ("Plaisier letter"). The letter pointed to court decisions that invalidated agency interpretations of § 355(j)(5)(B) intended, in part, to preserve the value of 180-day exclusivity. According to the letter, FDA concluded that, in light of the court decisions, "the statute, as written, did not guarantee that the 180-day period would be of use to the applicant who received it." Plaisier letter at 4.

But those court decisions related to the Hatch-Waxman Act. As written, that law may not support an interpretation that preserves the value of 180-day exclusivity in the specific ways that were the subject of the court decisions. However, it is not the 1984 Hatch-Waxman Act that is the source of the problem at issue, but the 1997 law adding pediatric exclusivity. In enacting § 355a, Congress clearly intended not to change the

mechanics of the Hatch-Waxman exclusivity and patent protection provisions. Instead, it intended only to add a 6-month incentive for pediatric studies.

This is clear from the legislative history. When the Better Pharmaceuticals for Children Act was first introduced in Congress in 1992, Senator Kassebaum stated:

> Specifically, the Better Pharmaceuticals for Children Act draws on our successful experience with the marketing exclusivity provision of the Federal Food, Drug, and Cosmetic Act to grant 6 months' marketing exclusivity for products for which FDA-approved pediatric studies are conducted.[6]

A House sponsor stated in 1994:

> This bill would establish a 6-month period of market exclusivity for new drugs whose manufacturers conduct pediatric studies at the request of the Secretary of Health and Human Services. Such studies would lead to appropriate labeling of drugs for treating children and take the guesswork out of an important part of medical practice.[7]

In 1994, Senator Kassebaum stated:

> [T]ogether with Senators Dodd, Hatch, and Simon, I am introducing the Better Pharmaceuticals for Children Act. This legislation provides a strong incentive for pharmaceutical companies to conduct pediatric trials for drugs which are developed primarily for adults. It establishes a 6-month market exclusivity for pharmaceuticals for which

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6 138 Cong. Rec. S16999 (daily ed. Oct. 5, 1992) (Statement of Sen. Kassebaum).

7 140 Cong. Red. E935 (daily ed. May 16, 1994) (Statement of Rep. Kriedler).

pediatric studies are conducted at the request of the Secretary of Health and Human Services.[8]

In 1996, she stated:

> The Better Pharmaceuticals for Children Act addresses this need for pediatric use data by providing an incentive to manufacturers to conduct pediatric studies for new and approved drugs. Manufacturers who provide pediatric data for the drugs most urgently needed by our children would receive an extra six months market exclusivity for their product. By taking this type of partnership approach, we can get critically needed information on pediatric uses. Providing the FDA with the extra authority to offer this type of encouragement will help to ensure that companies conduct such studies.[9]

In 1997, Senator Dodd stated:

> I think it is about time, Mr. President, we took the guesswork out of children's medicine. The Better Pharmaceuticals for Children's Act is a simple solution to this problem. It provides a fair and reasonable market incentive for drug companies to make the extra effort needed to test their products for use by children. It grants an additional 6 months of market exclusivity for drugs which have undergone pediatric studies at the request of the Secretary of Health and Human Services.[10]

In 1997, Representative Waxman stated:

> Upon completion of these studies and their acceptance by the Secretary, the manufacturer would be granted an additional 6 months of market exclusivity.[11]

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8 140 Cong. Red. S4165 (daily ed. Apr. 12, 1994) (Statement of Sen. Kassebaum).

9 142 Cong. Rec. S11992 (daily ed. Sept. 30, 1996) (Statement of Sen. Kassebaum).

10 143 Cong. Rec. S4277 (daily ed. May 9, 1997) (Statement of Sen. Dodd).

11 143 Cong. Rec. E1093 (daily ed. June 3, 1997) (Statement of Rep. Waxman).

The Senate report for the FDAMA stated:

> The legislation takes a modest further step toward a better resolution of this problem by providing an additional 6 months of market exclusivity when a drug manufacturer, at the request of the FDA, conducts pediatric studies to support pediatric labeling for a drug, either before the new drug approval application is submitted or later.[12]

These statements of congressional intent over a five year period make clear that the purpose of pediatric exclusivity was to add 6 months to existing Hatch-Waxman and orphan drug exclusivity or patent related protection. The fact that these statements remained the same despite the change in drafting strategy from a general tolling rule for ANDA effectiveness to particularized 6-month enlargements demonstrates that Congress intended not to modify the internal workings of the Hatch-Waxman Act, but only to add 6 months to the effective date of all ANDAs subject to the exclusivity and patent certification provisions of that 1984 law.

The statutory scheme of the Hatch-Waxman Act was carefully crated to balance the rights and obligations of NDA holders and generic drug applicants within an incentive structure that encourages both drug innovation and price competition. See Abbott Labs. v. Young, 920 F.2d 984, 985 (D.C. Cir. 1990). The patent certification provisions for ANDAs were a key element of the 1984 incentive structure. The 180-day exclusivity incentive was a central feature of those provisions.

FDA's preliminary position, as stated in the Plaisier letter, would alter the 180-day exclusivity incentive. When pediatric exclusivity applies, FDA would extend the "previous" paragraph IV ANDA's earliest effective date, but not that of the "subsequent" paragraph IV ANDA. This would be an important change in the relationship between paragraph IV ANDAs. It would significantly diminish the value of 180-day exclusivity to the priority ANDA applicant while providing a windfall advantage to all "subsequent" paragraph IV ANDA applicants. FDA's position would, in short, distort the incentive structure of the 1984 law.

There is no evidence that Congress, in the 1997 pediatric exclusivity provisions of the FDAMA, intended to make such a significant change in the 180-day exclusivity incentive of the 1984 law. If that had been its intent, Congress would presumably have explained the policy basis for altering the generic drug exclusivity part of the 1984 law as part of adding a 6-month incentive for pediatric studies. See, e.g., Amer. Hosp. Assoc. v. NLRB, 499 U.S. 606, 613-14 (1991) ("If this amendment had been intended to place the important limitation on the scope of the Board's rule making powers that petitioner suggests, we would expect to find some expression of that intent in the legislative history."). But the five year legislative history of the pediatric exclusivity provisions is devoid of any such explanation. Instead, there is clear evidence that Congress intended

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[12] S. Rep. No. 105-43, at 52 (1997).

only to defer effective ANDA approval by 6 months, and a technical drafting change to limit the deferral to ANDAs subject to existing exclusivity and patent related protection periods. Thus, Congress plainly intended not to alter the relationship of priority and subsequent paragraph IV ANDAs to each other as established in the Hatch-Waxman Act.

To give effect to this intent, FDA should defer the beginning of 180-day exclusivity – i.e., the earliest effective date of a subsequent paragraph IV ANDA under § 355(j)(5)(B)(iv) – by whatever length of time is necessary to offset the effect, if any, of 6-month pediatric exclusivity on the priority ANDA. This deferral should apply whenever 180-day exclusivity is triggered within a pediatric extension period, including both an extended exclusivity period under § 355(j)(5)(D) and an extended patent related protection period under § 355(j)(5)(B)(iii).

The Plaisier letter points to the text of the statute for the position that this solution cannot be legally defended, given the court decisions striking down the agency's "successful defense" and "court decision" interpretations of the generic drug exclusivity provision. In those cases, the courts held that FDA had impermissibly modified the meaning of the statutory language of the 1984 law. Neither Mova nor Mylan, however, involved the effect of pediatric exclusivity under the 1997 law on the balance struck by Congress in 1984. Instead, they involved FDA interpretations only of the 1984 law itself. In defending those interpretations, FDA did not identify a clearly articulated legislative

intent in the 1984 law to achieve the outcome incorporated in the agency's invalidated interpretations. Here, by contrast, Congress specifically and repeatedly stated that its intent in the 1997 law was to add 6 months of protection for pediatric studies; it said nothing to suggest an intention to change the relationship of the Hatch-Waxman provisions to each other, and indeed the drafting history of the pediatric extension provisions demonstrates the opposite intention.

In this circumstance, FDA cannot, as the Plaisier letter would, mechanically apply §§ 355(j)(5)(B) and 355a(c) to nullify generic drug exclusivity under § 355(j)(5)(B)(iv). See, e.g., Griffin v. Oceanic Contractors, Inc., 458 U.S. 564, 571 (1982) ("in rare cases the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters, and those intentions must be controlling"). Not only would such a result be contrary to the intent of Congress not to alter the internal incentive structure of the 1984 law, it would advance no policy objective of the 1997 law. In general, the 1997 law is meant to encourage pediatric studies by deferring effective ANDA approvals by 6 months. It makes no logical sense, therefore, to interpret the law as deferring effective approval of all ANDAs subject to the Hatch-Waxman exclusivity and patent protection provisions with the single exception of those ANDAs that lack priority paragraph IV status under § 355(j)(5)(B)(iv).

Indeed, from the perspective of the NDA holder, such an interpretation is contrary to the purpose of the 1997 law, because it diminishes the value of the 6-month pediatric extension. NDA holders regard the 180-day deferral of subsequent paragraph IV ANDAs as economically valuable to them, whereas accelerating approval of those ANDAs subjects NDA holders to more intensive generic competition sooner than would otherwise occur. By compressing or eliminating 180-day exclusivity, FDA's preliminary position would actually work against the pediatric exclusivity incentive of the 1997 law. This paradoxical result cannot be defended because, in FDA's view, the words of the statute make it unavoidable, for there is no requirement to adhere to "a statute's literal meaning in cases of gross absurdity and contrary congressional intent." Rod Warner, Inc., v. Commissioner of Internal Revenue, 912 F.2d 325, 326 (9th Cir. 1990).

In sum, Congress clearly intended the 6-month pediatric exclusivity incentive to be neutral as to the Hatch-Waxman provisions themselves. FDA's preliminary position, as stated in the Plaisier letter, would defeat that intent, and should therefore not be adopted. "[E]ven the most basic general principles of statutory construction must yield to clear contrary evidence of legislative intent," Nat'l R.R. Passenger Corp. v. Nat'l Ass'n of R.R. Passengers, 414 U.S. 453, 458 (1974). Instead, FDA should interpret § 355(j)(5)(B)(iv) to make the earliest effective approval date of subsequent paragraph IV ANDAs "not earlier than" 180 days after a triggering court decision plus an interval sufficient to cancel out the effect of pediatric exclusivity on the priority paragraph IV

ANDA. The purpose of this interpretation would not be, as stated in the Plaisier letter, to make the 180-day period "of use to the applicant who received it," i.e., to alter the way in which Congress intended the 1984 law to work. Its purpose would be, rather, the direct the opposite: to prevent pediatric exclusivity from changing the way Congress intended the 1984 law to work, as would occur if pediatric exclusivity were interpreted to modify the relationship of the Hatch-Waxman provisions. Congress made abundantly clear that the pediatric exclusivity provisions of the FDAMA were intended only to encourage pediatric studies, not to change the internal incentive structure of the 1984 law.

The interpretation Faulding believes FDA should adopt would be limited to the narrow situation in which a court decision trigger under § 355(j)(5)(B)(iv)(II) occurs 180 days or less from the beginning of, or during, the pediatric exclusivity period. To the extent that the words of §§ 355(j)(5)(B) and 355a(c) do not explicitly require "consecutive" running of 180-day and pediatric exclusivity, interpreting them to permit that result "deviate[s] no further from the statute than is needed to protect congressional intent." Mova Pharmaceuticals Corp. v. Shalala, 140 F.3d 1060, 1068 (D.C. Cir. 1998). FDA concerns that this interpretation would unavoidably extend to other situations are, therefore, unfounded, because any such extension would have to be based on an underlying necessity to preserve legislative intent as evidenced in other valid sources.

3. The text of the statute supports consecutive 180-day exclusivity where pediatric exclusivity extends a patent protection period. FDA should give effect to Congress's intent that pediatric exclusivity not alter the relationship of the various exclusivity and patent protection provisions of the Hatch-Waxman Act to each other, a relationship that was established by the legislative compromise enacted in 1984. This result is not compelled by any specific text in either law. Rather, it is required because it is what Congress plainly had in mind.

However, the text of the two laws also supports an interpretation that 180-day exclusivity is consecutive to, not concurrent with, pediatric exclusivity in the specific circumstance in which the pediatric exclusivity is added to a Hatch-Waxman patent protection period.

Under the Hatch-Waxman Act, an ANDA must contain a certification to patents that claim the listed NDA drug or a method of using the listed drug (if the ANDA requests approval of the claimed use). The effectiveness of such an ANDA is deferred to the expiration date of any patent for which information was timely submitted pursuant to §§ 355(b)(1) and (c)(2), unless the ANDA contains a paragraph IV certification to the patent. If it does, the ANDA can be made effective without regard to the patent unless the NDA applicant or patent owner sues for infringement. If there is an infringement

suit, the patent expiration date controls the effectiveness of ANDA approval if the court decides that the ANDA infringes the patent.

In all cases where the patent expiration date governs the effectiveness of ANDA approval, pediatric exclusivity requires that the "period" during which ANDA effectiveness is deferred be "extended" by 6 months. § 355a(c)(2)(A) and (B). The "period" referred to is the "period" established in § 355(j)(5)(B), which sets out the rules for ANDA effectiveness when a patent claims the listed drug and an ANDA contains a patent certification. One of the rules in that section is the 180-day generic drug exclusivity rule, which is stated as a requirement that approval of a subsequent paragraph IV ANDA be made effective "not earlier than" 180 days from a triggering event. It is reasonable to interpret the pediatric extension as encompassing the 180-day interval, so that its beginning is "extended by a period of six months after the date the patent expires (including any patent extensions)," as provided in § 355a(c)(2). This interpretation would result in the "consecutive" running of pediatric and 180-day generic drug exclusivity, consistent with the "consecutive" running of the NDA exclusivity and protection periods and pediatric exclusivity, i.e., the adding of 6 months to the ends of those exclusivity and patent protection periods.

This argument is explained in greater detail in the April 5, 2001, letter from William B. Schultz for Barr Laboratories to Michael M. Landa, FDA's Chief Counsel,

which Faulding supports. As explained above, however, Faulding's position is broader than the applicability of the word "extended" in § 355a(c)(2). Faulding believes that Congress intended pediatric exclusivity to have no effect on 180-day exclusivity in any circumstance in which an exclusivity period or patent related protection period is increased by 6 months, irrespective of the specific words used to describe that increment. Effective approval of a subsequent paragraph IV ANDA should therefore be deferred if a priority ANDA is subject to a pediatric extension of either 5- or 3-year exclusivity under § 355(j)(5)(D) or of a patent related protection period under § 355(j)(5)(B).

D. Conclusion

FDA is justifiably alert to the importance of statutory text in determining how the FDCA is to be applied. We believe that in the case of the overlap of generic drug and pediatric exclusivity, however, this concern about statutory text is misplaced. In its preliminary position, FDA focuses on the absence from § 355 of a "guarantee that the 180-day period would be of use to the applicant who received it." Plaisier letter at 4. To the extent that Congress had an intent as to the usefulness of 180-day exclusivity, it was simply part of the larger intent that the Hatch-Waxman provisions be implemented as written in accordance with the 1984 compromise, including its imperfections, even if doing so produced anomalous results in some circumstances.

This congressional intent is limited to the 1984 law. It does not extend to additional anomalous results within the framework of the 1984 law from a completely different statute aimed at a completely different policy objective enacted 13 years later. The pediatric exclusivity section of FDAMA is not the Hatch-Waxman Act, and the authors of the pediatric exclusivity section – all of whom have written the agency to express their disagreement with FDA's preliminary view – clearly intended that the only effect of pediatric exclusivity would be to add 6 months of protected marketing, not to alter the relationship of the Hatch-Waxman exclusivity and patent protection provisions to each other.

Respectfully submitted,

This congressional intent is limited to the 1984 law. It does not extend to additional anomalous results within the framework of the 1984 law from a completely different statute aimed at a completely different policy objective enacted 13 years later. The pediatric exclusivity section of FDAMA is not the Hatch-Waxman Act, and the authors of the pediatric exclusivity section – all of whom have written the agency to express their disagreement with FDA's preliminary view – clearly intended that the only effect of pediatric exclusivity would be to add 6 months of protected marketing, not to alter the relationship of the Hatch-Waxman exclusivity and patent protection provisions to each other.

Respectfully submitted,

Michael J. Nestor
President Chief Operating
Officer Americas

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Harmonized commodity code *if applicable*/Code harmonisé de marchandises *si nécessaire*:

Place vers. VAT/GST No. or EIN/SSN/N° de TPS/TVA ou EIN/NAS du destinataire:

Type of export/Type d'exportation: [x] PERMANENT/PERMANENTE [ ] REPAIR/RETURN/RÉPARATION/RETOUR [ ] TEMPORARY/TEMPORAIRE

Destination duties/Taxes *If left blank receiver pays duties/taxes*
Droits et Taxes à destination *Si vierge le destinataire devra payer les droits et taxes*

- [ ] Receiver/Destinataire
- [x] Sender/Expéditeur
- [ ] Other/Autre *Specify destination agency's account number/Indiquer le numéro de compte destinataire approuvé*

4 Size and weight/Taille et poids

No. of pieces/Nbre de pièces: 1

Weight/Poids: 10 kg

Dimensions *cm L x W x H*
Dimensions *cm L x l x H*

VOLUMETRIC/CHARGED WEIGHT/POIDS VOLUMÉTRIQUE/FACTURÉ: kg

CODES	CHARGES/FRAIS Services/Services
	Special - spéciaux
	Insurance - Assurance
	Other/VAT - Autre/TVA
CURRENCY CODE/CODE DE DEVISE	TOTAL

TRANSPORT COLLECT STICKER No./TRANSPORT PORT DU No.:

PICKED UP BY/RAMASSÉ PAR:

Route/Vol:

Time/Heure:

Date: 6/2011

5 Sender's authorization and signature/Autorisation et signature de l'expéditeur

I/we agree that DHL's standard terms apply to this shipment and limit DHL's liability. The Warsaw Convention may also apply (see reverse).
J'accepte (nous acceptons) que les modalités standard de DHL s'appliquent à cet envoi et limitent la responsabilité de DHL. La convention de Varsovie pourrait s'appliquer (voir au verso).
I/we understand that certain transportation of dangerous goods is not allowed. I/we confirm contents include no DHL prohibited items/Je déclare(nous déclarons) que le contenu ne comprend pas de marchandises interdites par DHL.

Signature: [signature]

Date: 06 20 01

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Destination Copy / Copie de Destination