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May 13, 2003

VIA HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Submission of Citizen Petition by Ranbaxy Laboratories Limited

Dear Sir or Madam:

Please accept the attached citizen petition (in four copies) submitted on behalf of Ranbaxy Laboratories Limited pursuant to 21 C.F.R. § 10.35.

Sincerely,

David G. Adams

May 13, 2003

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: *CITIZEN PETITION*

Dear Sir or Madam:

Ranbaxy Laboratories Limited ("Ranbaxy") submits this petition pursuant to 21 C.F.R. § 10.35.

A. ACTION REQUESTED

Ranbaxy requests the Commissioner of Food and Drugs to confirm the following:

(1) That, the concept of shared exclusivity for multiple ANDAs submitted on the same day, as set forth in the agency's proposed rulemaking of August 6, 1999, is required by law and is being implemented by FDA, and

(2) That Ranbaxy's ANDA No. 76-595 for modafinil 100 mg and 200 mg tablets will be entitled to shared 180-day exclusivity upon the triggering of such exclusivity under 21 U.S.C. 355(j)(5)(A)(4).

B. STATEMENT OF GROUNDS

1. Background

(a) FDA's Interpretation of the "Previous Application" Requirement for 180-Day Exclusivity

The 180-day exclusivity provisions of the Federal Food Drug and Cosmetic Act (the Act) are an integral part of the statutory scheme that allows ANDA applicants to challenge patents listed by the holder of the NDA for the reference listed drug. An ANDA applicant seeking to challenge a listed patent must file a paragraph IV certification[1] with FDA and provide a notification to the NDA (and patent) holder that can result in an infringement suit.[2] The 180-day exclusivity is a statutory delay in the approval of ANDA's containing paragraph IV certifications

[1] This is a certification under section 505(j)(2)(A)(vii)(IV) that the patent is invalid or will not be infringed by the filing of the ANDA.

[2] *See* section 505(j)(2)(B)(i).

that were submitted subsequent to a "previous application" containing a paragraph IV certification for the same drug. The statute provides as follows:

> If the application contains a [paragraph IV certification] and is for a drug for which a *previous application* has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—
>
> > (i) the date the Secretary receives notice from the applicant under the *previous application* of the first commercial marketing of the drug under the previous application, or (ii) the date of a decision of a court in an action described in clause holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.[3]

Congress did not explain in the statute or legislative history how this 180-day delay would operate where there was more than one "previous application." This posed the possibility of a new 180-day exclusivity each time an ANDA was filed for the same drug, a concept known as "rolling exclusivity. FDA determined early on that, although every ANDA other than the last-filed ANDA could be deemed a "previous application," there should be only one 180-day exclusivity period for each drug with regard to each patent. FDA thus informed the industry by letter in 1988 that 180-day exclusivity would go only to the "first applicant" to file a complete ANDA with a paragraph IV certification.[4] The agency successfully litigated the issue in 1989,[5] and incorporated the concept into its proposed regulation published the same year.[6]

The proposed regulation made clear that 180-day exclusivity would go only to "the *first of the previous applicants* to submit a substantially complete abbreviated new drug application."[7] The proposed regulation also made clear that applications submitted on the same day would not be deemed previous or subsequent to each other. The proposed regulation stated:

> For purposes of paragraph [314.107(c)(1)(i)], an abbreviated new drug application will be considered to have been "previously submitted" with respect to another application for the same listed drug if the *date* on which the first application was both substantially complete and contained a certification that the patent was invalid or not infringed is earlier than the

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3 21 U S C. § 355(j)(5)(B)(iv) (emphasis added).

4 Letter to all NDA and ANDA Holders and Applicants from Carl Peck, M.D., FDA, at 1-2 (July 29, 1988).

5 *Mylan Pharmaceuticals. Inc., v. Sullivan*, Civ. No. 89-0036-C(K) (N.D. W.Va. 1999).

6 54 Fed. Reg. 28872, 28,929 (1989) (proposed section 314.107(c)(i)).

7 *Id.*

date on which the second application was both substantially complete and contained the same certification.[8]

Unfortunately, when the agency promulgated its final regulation, it removed entirely the definition of "previously submitted," and left no guidance as to whether an ANDA could be deemed "previously submitted" with regard to another ANDA submitted on the same day. The agency's current regulation simply states that "subsequent" ANDAs will be delayed based on successful litigation or first commercial marketing by "the applicant submitting the first application." The regulation provides in relevant part as follows:

> *Subsequent abbreviated new drug application submission.* (1) If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable or would not be infringed, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180-days from whichever of the following dates is earlier:
>
> (i) the date the *applicant submitting the first application* first commences commercial marketing of its drug product; or
> (ii) the date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.[9]

While the removal of the definition of "previously submitted" left the regulation silent regarding multiple ANDAs submitted on the same day, it is clear that the change was not intended to reflect new and different interpretation of "previously submitted.[10] Unfortunately, however, the agency ultimately implemented the statute in a different manner, deeming ANDAs to be "subsequent" based solely on their ANDA number, and without regard to whether they were submitted on the same day, or even at the same time.

(b) FDA's Attempt to Designate a Single ANDA Filer as a "First" Applicant Among Multiple Same-Day Filers

FDA's decision to designate a single ANDA as the "first" ANDA based solely on its ANDA number created obvious problems for the agency. Applications arrive at the agency by different means, sometimes in a bundle of mail, and the agency has no public standard and no system in place for determining which application should be deemed "first" among multiple applications submitted on the same day. In a 1999 proposed rulemaking, the agency acknowledged that its system for initial processing of new ANDAs does not permit FDA to

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[8] *Id.* (proposed section 314.107(c)(2)) (emphasis added).

[9] 21 C.F.R. § 314.107(c) (emphasis added).

[10] The agency made clear in the preamble to the final regulation that this modification of section 314.197(c)(2) was intended to "clarify" the regulations. 59 Fed. Reg. at 50,338, 50,354 (1994).

identify the order in which ANDAs are received on a given date.[11] As the clerk wielding the ANDA stamp may have no way to determine whether an application was the first or seventh or last ANDA received by FDA on a given date, the lowest ANDA number stamped on the application is deemed "first." In the 1999 proposed rulemaking, FDA admitted that the process was arbitrary and unworkable:

> Another option is for the agency to attempt to determine which application is received first on the same day, an inquiry that is impractical and may result in an arbitrary ordering of applications. It may not be possible for the agency to determine which application was received first. If, for example, the agency received more than one eligible application in the same mail delivery on a particular day, it would be impossible to determine which application was received first. If applications were received by various means throughout the day, when the applications in the pile were retrieved to date and time stamp, the application that the agency received first might be stamped last. Although theoretically this particular problem could be avoided by stamping each document at the time of receipt, this solution is impractical given agency workload and resource constraints.[12]

(c) FDA's Proposal for Shared Exclusivity for Multiple Same-Day Filers

The agency proposed in the 1999 proposed rulemaking a more reasonable approach in which any first-day filing would be deemed to be a "first application" under the regulation, sharing in any 180-day exclusivity. The agency stated:

> All applicants for ANDA's containing paragraph IV certifications for a particular drug product that are received on the same day will be eligible for exclusivity if no other ANDA with a paragraph IV certification has been previously filed. *All such applicants would be considered first applicants.*[13]

FDA noted that the statutory language of 21 U.S.C. § 355(j)(5)(B)(iv) supports treating all same-day filers as first applicants. In the agency's view, such an approach would protect the incentive created by Congress for ANDA applicants to challenge patents.[14]

FDA received 22 comments on its Proposed Rule. Of these, only five addressed the shared exclusivity proposal. All five comments were in agreement with FDA's view that the process described in the proposed rulemaking should be abandoned. The comments disagreed,

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11 64 Fed. Reg. 42,873, 42,877 (Aug. 6, 1999).

12 *Id*

13 *Id.* at 42,876 (emphasis added).

14 *Id.* at 42,877.

however, on the best alternative approach. Purepac Pharmaceutical Co. favored the shared exclusivity proposal, because, in the company's view, FDA had no other viable alternative.[15] The company noted that, although several applicants might share exclusivity, only the most diligent applicant, e.g., the one with an approved ANDA and no remaining litigation issues, would reap the actual benefit when the event triggering the 180-days of exclusivity occurred.[16] Barr Laboratories, Inc., and the Generic Pharmaceutical Industry Association (GPIA) opposed shared exclusivity and urged FDA to implement a new process for selecting a single ANDA for entitlement to 180-day exclusivity that would block other ANDAs submitted on the same day.[17] The Private Label Manufacturers Association and Perrigo Company suggested that there should be no 180-day exclusivity in the event of multiple same-day filings.[18]

(d) The Zenith Goldline Petition

On August 8, 2000, while FDA's proposed rulemaking was pending, Zenith Goldline Pharmaceuticals ("Zenith Goldline") filed a citizen petition requesting that FDA award shared 180-day exclusivity to all paragraph IV ANDAs submitted on the same day for Alendronate Sodium Tablets (Zenith Petition).[19] Zenith Goldline argued in its petition that FDA's system of designating "first" submissions among multiple submissions is "legally arbitrary"[20] and that ANDAs filed on the same day cannot legally be deemed to be "previous" to one another.[21] FDA has not yet provided a substantive response to the petition.

(e) FDA's Withdrawal of the Proposed Rulemaking

On November 1, 2002, FDA withdrew its proposed rule.[22] The withdrawal was based on court decisions affecting certain provisions of the proposed rule that were unrelated to shared

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15 Letter from Richard F. Moldin, President and CEO, Purepac Pharmaceuticals, to Dockets Management Branch, FDA, at 10-11 (Nov. 9, 1999) (Purepac Letter)

16 *Id.*

17 Letter from Alice Till, Ph.D., President, GPIA, to Dockets Management Branch, FDA, at 5 (Nov. 4, 1999); letter from James Hurst, Winston & Strawn on behalf of Barr Laboratories to Dockets Management Branch, at 11-12 (Nov. 4, 1999) (Barr Letter).

18 Letter from Paul M. Hyman, Private Label Manufacturers Association to Dockets Management Branch, FDA, at 8 (Nov. 4, 1999); Letter from Brian Schuster, Perrigo Company to Dockets Management Branch, FDA, at 1 (Nov. 3, 1999).

19 Docket No. 00P-1445. The Zenith Petition was filed in the docket for comments on the Proposed Rule. Zenith also filed a petition for a stay of action against granting effective approval of any ANDA for Alendronate Sodium Tablets, 5 mg, 10 mg and 40 mg prior to the approval of Zenith's ANDA. Docket No. 00P-1443 (Aug. 8, 2000).

20 Zenith Petition at 23.

21 *Id.* at 31-32.

22 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 67 Fed. Reg. 66,593 (withdrawal of proposed rule Nov. 1, 2002).

exclusivity for multiple first-filers. The agency did not abandon its proposal for shared exclusivity, but rather stated that it would "...continue to regulate directly from the statute and applicable FDA regulations to make 180-day exclusivity decisions on an issue-by-issue basis."[23]

(f) FDA's Confirmation of Shared Exclusivity for Blocking First Filers

In 2001, FDA confirmed that the statute and regulations should be interpreted to provide shared exclusivity for multiple first filers where the first filers are entitled to blocking exclusivities on separate patents.[24] In the case of Omeprazole Delayed-Release Capsules, the agency confronted a situation in which different ANDA applicants were first to file on different patents, which would have resulted in mutually blocking exclusivities in the absence of shared exclusivity. The agency determined that, under its regulation, each of the blocking ANDAs should be considered to be "the first application" for purposes of triggering exclusivity and enjoying its benefits.

In reaching its decision, FDA noted that "the choice appears to be between rewarding all applicants who filed a first paragraph IV ANDA by giving them the chance to market during the exclusivity period, or rewarding the *very first* applicant to challenge any patent by giving that applicant the entire exclusivity period to itself."[25] The agency determined each first applicant should share exclusivity even though "this approach may deprive any one applicant of the chance to be the sole competitor to the NDA holder."[26] The agency found it significant that that there would be a "clear benefit to consumers if FDA were to approve more than one ANDA: with multiple ANDAs approved, it is more likely that the exclusivity period will be triggered and at least one of the generic drugs will reach the market during the exclusivity period."[27]

(g) Ranbaxy's ANDA

On December 24, 2002, Ranbaxy and three other applicants filed ANDAs for modafinil 100 mg and 200 mg tablets containing a paragraph IV certifications.[28] One of three other applicant's ANDA was stamped by FDA mailroom staff as No. 76-594; Ranbaxy's ANDA was stamped No. 76-595. If FDA selects a single "first" applicant based on ANDA number, the other applicant will receive 180-day exclusivity and Ranbaxy's ANDA will be blocked for 180 days. This outcome would be unfair and inherently arbitrary. FDA has not explained how it assigned these ANDA numbers and has not justified its use of ANDA numbers to determine rights to 180-day exclusivity.

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23 *Id.* at 66,594.

24 Letter to Andrx Pharmaceuticals, Inc., from Gary Buehler, FDA (November 16, 2001) (Buehler Letter).

25 *Id* at 5.

26 *Id.* at 6.

27 *Id.*

28 This was the first date upon which ANDAs could be submitted for modafinil because it has 5-year New Chemical Entity exclusivity under Section 505(j)(5)(D)(ii) of the Act.

2. FDA Should Confirm Its "Shared Exclusivity" Interpretation of the Act for Multiple Same-Day Filers.

(a) FDA Correctly Determined that the Statute Should Be Interpreted to Provide Shared Exclusivity to Multiple Same-Day Filers.

In its 1999 proposed rulemaking, FDA discussed several possible interpretations of the statutory mandate that a "previous" ANDA with paragraph IV certification delay a subsequent ANDA with paragraph IV certification. The agency correctly determined that shared exclusivity represented the best interpretation of the statute:

> The agency believes the statutory language supports [shared exclusivity], which would protect the incentive created by Congress for ANDA applicants to challenge patents. Further, this approach is preferable to alternative approaches. . . . Another option is for the agency to attempt to determine which application it received first on the same day, an inquiry that is impractical and may result in an arbitrary ordering of applications. . . .[29]

In fact, it makes no sense to deem one ANDA to be a "previous application" with regard to another ANDA submitted on the same day. The filing of multiple ANDAs on the same day is invariably the result of the expiration of a blocking patent or exclusivity. In this circumstance, there is no purpose to be served by rewarding one applicant and penalizing another. A reward based solely on the ANDA number assigned to the application would not be based on greater "willingness to challenge unenforceable and invalid innovator patents, or design noninfringing drug products," as Congress intended.[30] It rather would be based on an inherently arbitrary process governed by the order in which multiple ANDAs are stamped and assigned numbers. ANDAs submitted on the same day would be delayed for 180 days, or more, for no reason that can be gleaned from the statute or from the intent of Congress. It would, in fact, be contrary to "the legislative purpose of section 505(j)(5)(B)(iv) . . . to provide an incentive for challenging a listed patent, while at the same time *preventing prolonged or indefinite delays in the availability of generic drug products.*"[31]

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[29] 64 Fed. Reg. at 42,877.

[30] *Id.* at 42882. *See also Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp.2d 30, 33 (D.D.C. 2000).

[31] *Id.* at 42,874 (emphasis added). Although Barr Laboratories and GPHA submitted comments to the agency arguing that shared exclusivity would negate the incentive intended by Congress, Ranbaxy believes that shared exclusivity will help to retain the incentive to challenge patents and bring new generic drugs to the market. Where ANDA applicants may be blocked by 180-day exclusivity regardless whether they file their ANDAs and challenge patents at the earliest possible date, they may feel less incentive to mount a quick challenge to the patent and may simply wait out the patent action. Purepac, in its comments, agreed that shared exclusivity would provide the appropriate incentive because "the most diligent applicant (*i.e.*, the one with an ANDA approval and no remaining litigation issues) will reap the actual benefit when the trigger occurs." Purepac Letter at 6. Similarly, Zenith Goldline stated in its petition that shared exclusivity would not deter first filers but would rather encourage first submissions. Zenith Petition at 30-31. Moreover, Barr acknowledged in its letter that each of the first-filers would have an incentive to be prepared to market at the earliest possible because any one of the first-filers could trigger their exclusivity. Barr Letter at 12.

Shared exclusivity would also be more consistent with the intent of Congress "to increase competition in the drug industry by facilitating the approval of generic copies drugs."[32] Shared exclusivity would provide a "clear benefit to consumers" because, "with multiple ANDAs approved, it is more likely that the exclusivity period will be triggered and at least one of the generic drugs will reach the market during the exclusivity period."[33]

(b) FDA Has Acknowledged that Its Attempt to Designate a Single First Applicant Is Arbitrary and Inconsistent with Congress' Intent.

FDA stated clearly in its proposed rulemaking that the statute cannot be implemented appropriately by attempting to designate a "previous application" among multiple applications that are submitted on the same day.

> [F]or the agency to attempt to determine which application is received first on the same day . . . is impractical and may result in an arbitrary ordering of applications. It may not be possible for the agency to determine which application was received first. If, for example, the agency received more than one eligible application in the same mail delivery on a particular day, it would be impossible to determine which application was received first. If applications were received by various means throughout the day, when the applications in the pile were retrieved to date and time stamp, the application that the agency received first might be stamped last.[34]

This is a clear description of an arbitrary and capricious means of resolving an issue of great importance -- importance in terms of incentives to challenge patents, access to lower-priced generic drugs, and financial consequences to the companies involved. Administrative due process requires a reasonable standard for determining when one ANDA is deemed to be "previous" to another, as well as a reasonable and workable process for making that determination. The standards would have to be made public, the process would have to be transparent, and all applicants filing on the same day would have to have an equal opportunity to deemed "previous" to the other applicants. The standards and process would also have to be consistent with the intent of Congress "to provide an incentive for challenging a listed patent, while at the same time *preventing prolonged or indefinite delays in the availability of generic drug products.*"[35] FDA conceded in its proposed rulemaking that the implementation of the180-day exclusivity provisions of the Act based on ANDA numbering rather than on date of submission cannot meet these criteria.

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32 *Mead Johnson Pharmaceutical Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988).

33 Buehler letter at 6.

34 *Id.*

35 *Id.* at 42,874 (emphasis added).

(c) The Agency Is Not Required to Amend Its Regulation.

Although the 1999 proposed rulemaking included a provision to clarify that multiple ANDAs submitted on the same day are entitled to shared exclusivity, such an amendment is not required for 180-day exclusivity. The proposed clarification regarding shared exclusivity was part of an omnibus proposal driven primarily by adverse court decisions on other 180-day exclusivity issues. The clarification consisted of a single sentence stating that "[t]he first applicant includes all applicants filing substantially complete ANDA's with paragraph IV certifications for the same drug product on the first day that the agency receives applications with a paragraph IV certification for the drug product."[36] This statement was simply to clarify the agency's interpretation of its regulation – that "[a]ll such applicants [submitting ANDAs on the same day] would be considered first applicants."[37]

While helpful, this clarifying language is not required. It merely expresses a reasonable interpretation of the regulation – that all applicants submitting ANDAs on the same day should be "considered first applicants."[38] Indeed, this would be consistent with the interpretation of "previously submitted" in the agency's 1989 proposed regulation, which clarified that ANDAs submitted on the same day were not considered to be previous to each other.[39]

Moreover, the agency has recently made clear, without amending its regulation, that multiple applicants can each be considered to be the "first applicant" for purposes of triggering exclusivity. As discussed above, the agency stated in its 2001 letter to Andrx Pharmaceuticals regarding omeprazole that, where two applicants have blocking exclusivities, both applicants are deemed to be "the applicant submitting the first application" for purposes of triggering 180-day exclusivity. While the agency expressed this interpretation only in the context of blocking exclusivities, the fundamental point is that the agency interprets the regulation to mean that more than one applicant can qualify as "first."

While the agency appears never to have issued an authoritative statement regarding 180-day exclusivity in the context of multiple same-day filers, it is clear that the agency has in practice designated a single "first" applicant based on the ANDA number assigned to the application. Thus, the agency's implementation of a shared-exclusivity approach may be deemed a change in practice or policy. Such a change would not require the agency to amend its regulation because, as FDA has already determined, the wording of the regulation permits more than one applicant to be deemed "the applicant submitting the first application."[40] FDA has

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36 *Id.* at 42,885 (proposed section 314.107(a)(2)

37 *Id.* at 42,876.

38 *Id.* at 42,876.

39 54 Fed. Reg. at 28,929 (1989) (proposed section 314.107(c)(i)).

40 *See Chief Probation Officers of California v. Shalala*, 118 F.3d 1327, 1334, 1337 (9th Cir. 1997) (agency "free to change" its interpretation of statute where agency's prior policy merely represented the agency's interpretation and the policy had not gone through formal rulemaking procedures).

often announced changes in practice and policy in letters to all affected ANDA applicants and in guidance to industry.[41]

(d) FDA's Designation of a Single First Applicant Will Likely Be Overturned in Court.

Should the agency continue to designate single "first" applicants in the context of multiple same-day applications, the agency's position will likely be challenged in court by Ranbaxy and/or by some other applicant in a similar situation. The agency will likely lose this challenge because it has already determined that (1) the shared-exclusivity interpretation best satisfies the legislative intent and (2) the designation of a single first applicant is arbitrary and inconsistent with legislative intent.

The courts will deem an agency action to be arbitrary and capricious under the Administrative Procedure Act, 5 U.S.C. § 706(a), where it is not supported by reasoned decisionmaking. Here, the agency has created a record in a proposed rulemaking demonstrating that the 180-day exclusivity provisions of the Act cannot be applied in a proper and reasonable manner where the agency must designate a single "first" applicant among multiple same-day filers. There is no evidence in the record supporting such an approach. The record now imposes a significant burden on the agency, which the agency has not met. As one court noted, an agency's "duty to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives" is "especially important when the agency admits its own choice is substantially flawed."[42] Moreover, as discussed above, the agency has not satisfied the basic elements of administrative due process by providing a reasonable standard

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[41] *See, e.g.*, Letter from Gary Buehler, Director, Office of Generic Drugs, Center for Drug Evaluation and Research to Dear ANDA Applicant for Gabapentin (Jan. 28, 2003); Guidance for Industry, Court Decisions, ANDA Approvals and 180-day Exclusivity under the Hatch-Waxman Amendments to the U.S. Department of Health and Human Services FDA, CDER (Procedural) (Mar. 2000); Guidance for Industry, 180-day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (Procedural Guidances), FDA, CDER (June 1998).

[42] *Farmers Union Central Exchange, Inc v. Federal Energy Regulatory Commission*, 734 F.2d 1486, 1511 (D.C. Cir. 1984). Other courts have held similar agency conduct to be arbitrary and capricious. *See, e.g., Fox Television Stations, Inc. v Federal Communications Commission*, 280 F.3d 1027 (D.C. Cir. 2002) (FCC decision to recommend retaining its National Television Station Ownership ("NTSO") rule without addressing a prior FCC report that the NTSO rule should be repealed); *Motor Vehicles Manufacturers Association v State Farm Mutual Automobile Insurance Companies*, 463 U.S. 29 (1983) (National Highway Transportation Association's rescission of the passive occupant restraint system requirement in Modified Standard 208 to protect the safety of occupants in a collision held arbitrary and capricious where the agency failed to present an adequate basis and explanation for rescinding the requirements, including all relevant factors); *U.S.V. F/V Alice Amanda*, 987 F.2d 1078 (4th Cir. 1993) (where the agency knew scallops harvested under a new technology would fail sampling tests created by its regulations for scallops harvested under the old technology due to obvious weight differences between chilled and defrosted scallops, the agency acted arbitrarily and capriciously when it did not change them, but instead issued an enforcement memo requiring sampling tests of defrosted scallops under the old regulations and, when they inevitably failed them, demanded forfeiture of the catch); *Farmers Union Central Exchange, Inc v Federal Energy Regulatory Commission*, 734 F.2d 1486, 1511 (D.C. Cir. 1984) (FERC's decision making process was characterized as "arbitrary and capricious" by the court when it "decided to adhere to the rate base formula it inherited from the [Interstate Commerce Commission]," and "gave no rational justification for doing so," did not consider reasonable alternatives, and did not give a reasoned explanation for rejecting those alternatives).

for determining whether an applicant is "first," a transparent process for making the determination, and an equal and fair opportunity for each applicant to satisfy the standard.

The agency's practice of designating a single "first" applicant among multiple same-day filers is also reversible under section 706(a) because it is contrary to law. Where Congress has expressed its intent in either the wording of the statute or in legislative history, the agency is bound by that intent.[43] It is clear, as discussed above, that a reward of 180-day exclusivity based solely on the ANDA number assigned to the application would not be based on greater "willingness to challenge unenforceable and invalid innovator patents, or design noninfringing drug products," as FDA agrees that Congress intended.[44] It would, in fact, be contrary to "the legislative purpose of section 505(j)(5)(B)(iv) . . . to provide an incentive for challenging a listed patent, while at the same time *preventing prolonged or indefinite delays in the availability of generic drug products*."[45]

(e) FDA Should Confirm that Ranbaxy's ANDA Is Eligible for Shared Exclusivity as Quickly as Possible.

The agency's determination of 180-day exclusivity can have dramatic consequences for an ANDA applicant. This is particularly the case with regard to Ranbaxy's ANDA for modafinil. If FDA awards exclusivity only one of the first-to-file applicants based on its ANDA number and that applicant is allowed to launch in January 2006 and to delay the effective approval of Ranbaxy's product, Ranbaxy stands to lose $25,000,000 to $30,000,000 in sales over the years 2006, 2007, and 2008.[46] This is significant for a company the size of Ranbaxy, whose 2002 sales volume in the U.S. was $296 million. These lost sales are a result of three well-characterized marketplace dynamics. The first of these dynamics is the lost sales that are incurred by not being in the market for the first six months of sales. The second dynamic is the long term reduction in market share resulting from not being among the first to enter the market, i.e., the loss of first mover advantage. The third dynamic is the price erosion that occurs when companies, in addition to the three excluded first filers, enter the market at the end of the marketing exclusivity. Five to six generic companies are predicted to enter the modafinil market. Thus, in the absence of shared exclusivity, when Ranbaxy enters the market it will be competing against four or five other companies rather than two other companies.

In addition to the lost sales, Ranbaxy will suffer because of the extension of the payback period of the investment used to develop the modafinil tablets. By lengthening the payback period, the investment funds necessary for Ranbaxy to develop generic drugs are less readily

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[43] *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984).

[44] 64 Fed. Reg. at 42882. *See also Mylan Pharmaceuticals, Inc., v. Shalala*, 81 F. Supp.2d 30, 33 (D.D.C. 2000).

[45] *Id.* at 42,874 (emphasis added).

[46] Our economic analysis does not extend beyond 2008 because the market is mature after 2-3 years and there will not be significant changes in price and sales.

available. This will impede Ranbaxy's ability to bring additional, low cost generic drugs to the U.S. market.

In addition to the potential harm to Ranbaxy related to its modafinil ANDA, there are broader harms associated with the agency's determination of 180-day exclusivity based on ANDA numbers. Because the assignment of ANDA numbers is arbitrary and unpredictable, investors and shareholders are at greater risk. This unpredictability is harmful not only to the investors and shareholders but also to the companies such as Ranbaxy in which they invest.

C. ENVIRONMENTAL IMPACT

As provided in 21 C.F.R. § 15.30 neither an environmental assessment nor an environmental impact statement is required.

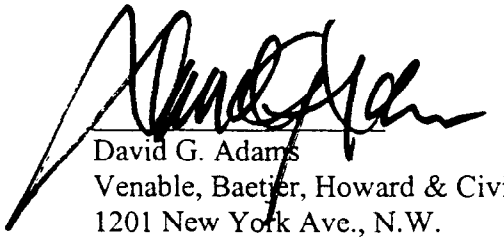
D. CERTIFICATION

As provided in 21 C.F.R. § 10.30(b) economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

E. ECONOMIC IMPACT

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



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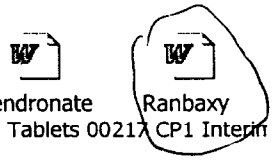
Counsel for Ranbaxy

Tseng, Elaine

From: Dickinson, Elizabeth
Sent: Wednesday, July 23, 2003 9:10 PM
To: Beakes, Virginia G; Parise, Cecelia M
Cc: Tseng, Elaine; Schifter, Karen; Dettelbach, Kim
Subject: RE: camping CP responses

Here are my suggestions.
Cec - does this work with OGD's practice on making public exclusivity decisions?



-----Original Message-----
From: Beakes, Virginia G
Sent: Tuesday, July 22, 2003 9:17 AM
To: Parise, Cecelia M
Cc: Dickinson, Elizabeth; Tseng, Elaine
Subject: FW: camping CP responses

Cec - Can you take a look at these? Are the petitioners factually correct about their respective entitlements to shared exclusivity? Thanks, Ginny

-----Original Message-----
From: Beakes, Virginia G
Sent: Monday, July 21, 2003 5:07 PM
To: Dickinson, Elizabeth
Subject: camping CP responses

Liz - what do you think about these? Ginny

<< File: Alendronate Sodium Tablets 00P-1443 PSA1 00P-1445 CP1 Response.doc >> << File: Ranbaxy 03P-0217 CP1 Interim.doc >>

Mr. David G. Adams
Venable, Baetjer, Howard & Civiletti, LLP
1201 New York Avenue, N.W., Suite 1000
Washington, D.C. 20005-3917

Re: Docket No. 03P-0217/CP1

Dear Mr. Adams,

This letter responds to your citizen petition dated May 13, 2003, requesting the Food and Drug Administration (FDA) to confirm (1) that the concept of shared exclusivity for multiple ANDAs submitted on the same day is required by law and is being implemented by FDA and (2) that Ranbaxy's ANDA No. 76-595 for modafinil 100-mg and 200-mg tablets will be entitled to shared 180-day exclusivity upon the triggering of such exclusivity under 21 U.S.C. 355(j)(5)(B)(iv).

FDA has carefully considered the issues raised in your petition and is ~~has responded by~~ issuing a guidance document that essentially grants your requests as to issue (1) identified above. Enclosed is a copy of the guidance document, *180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day.* As to issue (2), Ranbaxy's eligibility for 180-day exclusivity for modafinil 100-mg and 200-mg tablets under the approach described in the guidance will be determined when one or more ANDAs for that drug product are ready for approval.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Enclosure

Tseng, Elaine

From: Beakes, Virginia G
Sent: Wednesday, July 30, 2003 1:36 PM
To: Tseng, Elaine
Subject: Fw: CP responses/exclusivity

Fyi

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Buehler, Gary J <BUEHLER@cder.fda.gov>
To: Beakes, Virginia G <BEAKESV@cder.fda.gov>
Sent: Wed Jul 30 13:02:18 2003
Subject: RE: CP responses/exclusivity

No changes to either of them.

Gary

-----Original Message-----
From: Beakes, Virginia G
Sent: Wednesday, July 30, 2003 11:26 AM
To: Buehler, Gary J
Subject: Re: CP responses/exclusivity

Thanks Gary! Did you make any changes - if not, I'll give to Jane while we wait for the mail. Ginny
---
Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Buehler, Gary J <BUEHLER@cder.fda.gov>
To: Tseng, Elaine <TsengE@cder.fda.gov>
CC: Parise, Cecelia M <PARISEC@cder.fda.gov>; Beakes, Virginia G <BEAKESV@cder.fda.gov>
Sent: Wed Jul 30 10:20:13 2003
Subject: RE: CP responses/exclusivity

Elaine

I signed them early yesterday, and they went in the mail back to you in the AM. Ou should be receiving them today.

Gary

-----Original Message-----
From: Tseng, Elaine
Sent: Wednesday, July 30, 2003 9:32 AM
To: Buehler, Gary J
Cc: Parise, Cecelia M; Beakes, Virginia G
Subject: FW: CP responses/exclusivity

Gary:

As Liz's e-mail below notes, it looks like the "camping" guidance will be publicly disclosed tomorrow. In light of this, we'd like to get the responses to the Zenith Goldine (now Ivax) and Ranbaxy CPs regarding shared 180-day exclusivity out by tomorrow as well. You should have been routed a copy of these responses (which you and Cecelia previously

reviewed in draft form). Would you mind providing expedited clearance to facilitate meeting tomorrow's timeline?

Please let me know if you did not receive copies of these responses or if you have any other questions.

Many thanks!
Elaine

-----Original Message-----
From: Dickinson, Elizabeth
Sent: Tuesday, July 29, 2003 7:36 PM
To: Beakes, Virginia G; Tseng, Elaine
Subject: CP responses/exclusivity

The 180-day exclusivity "camping" guidance will probably go on the web on Thursday, and the notice will publish on Friday.

Liz

Elizabeth H. Dickinson
Office of the Chief Counsel
edickins@oc.fda.gov
(301) 827-1126