



Zenith Goldline
P H A R M A C E U T I C A L S

August 8, 2000

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

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Re: Petition for Stay of Action Against Effective Approval
of an ANDA for Alendronate Sodium Tablets Prior to
Effective Approval of Zenith Goldline's ANDA 75-711

Dear Sir or Madam:

Zenith Goldline Pharmaceuticals, Inc., (Zenith Goldline) submits this Petition for Stay pursuant to 21 C.F.R. § 10.35. Zenith Goldline requests the Commissioner of Food and Drugs to stay the effective approval of any ANDA for Alendronate Sodium Tablets, 5 mg, 10 mg, 40 mg, until effective approval is granted to Zenith Goldline's ANDA 75-711 for this product.

A. Decision Involved

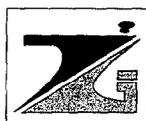
In an accompanying citizen petition,¹ Zenith Goldline requests the Food and Drug Administration (FDA) to issue a statement clarifying the applicability of the 180-day generic drug exclusivity provision to ANDAs submitted to the agency on the same day.

¹ Citizen Petition that FDA Issue a Statement that Paragraph IV ANDAs Delivered on the Same Day Are Submitted at the Same Time for 180-Day Exclusivity Purposes.

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The citizen petition describes a situation in which two ANDAs for Alendronate Sodium Tablets (alendronate) were submitted to FDA on September 29, 1999. The citizen petition sets forth reasons why FDA should issue a statement that ANDAs that contain paragraph IV certifications are concurrently submitted for 180-day exclusivity purposes if, as occurred with the alendronate ANDAs, they are submitted on the same day. Therefore, the FDA decisions involved in this petition for stay are the agency's decisions with respect to granting effective approval to the two or more alendronate ANDAs submitted on September 29, 1999.

Zenith Goldline's citizen petition explains that FDA's statute and regulations, in conjunction with the agency's existing practices, require that the two alendronate ANDAs be regarded as "previous applications" under 21 U.S.C. § 355(j)(5)(B)(iv) and that neither be regarded as "previous" or "subsequent" to the other. However, Zenith Goldline is unable to confirm that this standard will be applied when the alendronate ANDAs become eligible for approval, and is concerned that an arbitrarily defined order of priority will be imposed to withhold effective approval of the Zenith Goldline ANDA. Accordingly, this petition for stay is submitted as a precautionary matter in support of Zenith Goldline's right to have the approval of ANDA 75-711 made effective without regard to the 180-day exclusivity that defers effective approval of subsequent ANDAs.



B. Action Requested

1. Zenith Goldline requests FDA to stay the grant of effective approval for any alendronate ANDA until effective approval is granted to Zenith Goldline's ANDA 75-711. This request is subject to two exceptions, in which Zenith Goldline does not oppose the grant of effective approval of another ANDA in advance of effective approval of ANDA 75-711, as long as, in either case, effective approval of ANDA 75-711 is not delayed due to the 180-day exclusivity for the other ANDA.

2. If FDA denies Zenith Goldline's request for a stay, or if it denies the citizen petition, Zenith Goldline further requests FDA to stay the grant of effective approval for another alendronate ANDA until the completion of judicial review of FDA's decision on this petition and the citizen petition, if Zenith Goldline seeks judicial review within ten working days of receiving the decision.

C. Statement of Grounds

This petition should be granted, because it meets the standards of 21 C.F.R. § 10.35(e)(1) to (4).

1. Facts Relating to the Alendronate ANDA

The circumstances surrounding the submission of Zenith Goldline's alendronate ANDA on September 29, 1999, are described in the citizen petition. Zenith Goldline is aware that at least one other ANDA for this product was submitted on September 29, 1999. The NDA for alendronate qualified for five years of exclusivity as a new chemical



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entity. See 21 U.S.C. § 355(j)(5)(D)(ii). That provision of the statute does not permit earlier submission of paragraph IV ANDAs for listed drugs with five years of NCE exclusivity than four years from the date of approval of the listed drug. Therefore, no alendronate ANDAs could have been submitted prior to September 29, 1999. Zenith Goldline is not aware of any alendronate ANDAs other than the two ANDAs submitted on September 29, 1999.

The Zenith Goldline ANDA was accepted for filing pursuant to 21 C.F.R. § 314.101. Zenith Goldline provided the required paragraph IV notification to the holder of the NDA for the listed drug. A lawsuit pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) has been instituted and is pending at this time.

Zenith Goldline does not have facts concerning the other alendronate ANDA. It is possible that there are differences in the timing of paragraph IV notifications by the two ANDA applicants that would result in differences in the time of expiration of the 30-month period under § 355(j)(5)(B)(iii). It is also possible that FDA's substantive review of the ANDAs will affect the time when the ANDAs may be approved under § 355(j)(4).

This petition for stay does not request FDA to stay the effective approval of any alendronate ANDA submitted on September 29, 1999, based on either the earlier expiration of the 30-month period as to that ANDA compared with the Zenith Goldline ANDA, or on the earlier eligibility of such ANDA for approval under § 355(j)(4)



compared with the Zenith Goldline ANDA. However, in the event that any alendronate ANDA is approved before Zenith Goldline's ANDA on either of those bases, Zenith Goldline requests, as part of this petition for stay, that any letter issued to the ANDA applicant state that the grant of effective approval to that ANDA does not affect the time when effective approval may be granted to the Zenith Goldline ANDA upon expiration of the 30-month period applicable to that ANDA or the eligibility of that ANDA for approval under § 355(j)(4).

2. Standards for Issuance of a Stay

a. Irreparable injury. If FDA were to adopt an arbitrary order of priority for paragraph IV ANDAs submitted on the same day and, as a result, withhold effective approval of Zenith Goldline's ANDA on that basis, Zenith Goldline would not have authorization to compete with another company's alendronate product for at least 180 days after that product was either initially marketed or the "court decision" trigger was satisfied. 21 U.S.C. § 355(j)(5)(B)(iv). Zenith Goldline would be disadvantaged by not being able to market its alendronate product for 180 days, and, for a longer period, by the loss of market position it would otherwise have obtained by the opportunity to compete during that period. Both the immediate and the long-term disadvantages to Zenith Goldline would be irreparable, because they could not be compensated for by any action Zenith Goldline is in a position to take. For these reasons, this petition for stay is necessary to prevent irreparable injury to Zenith Goldline in the event FDA fails to grant

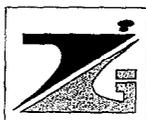


effective approval to ANDA 75-711 in due course on the ground that it is a “subsequent application.”

b. The case is not frivolous. Zenith Goldline relies on its citizen petition to demonstrate that its case is not frivolous.

c. Public policy. FDA itself has stated that the better policy is for paragraph IV ANDAs submitted on the same day to be given the benefit of 180-day exclusivity on an equal basis and not be subject to each other’s exclusivity. 64 Fed. Reg. 42873, 42876-77 (Aug. 9, 1999). As Zenith Goldline’s citizen petition explains, that is also the legally required result. Therefore, granting this stay petition will be consistent with both public policy and the law.

d. Countervailing public health and other interests. Granting this petition will result in the earliest legally and technically possible availability of one or two generic versions of alendronate. The only countervailing interest consists of awarding the sole right to ANDA approval to one ANDA applicant on the basis of undefined criteria for what constitutes the “first submission” of a paragraph IV ANDA on a given day. This interest, even if it were legally relevant, does not outweigh the public interests that would be served by granting the petition.

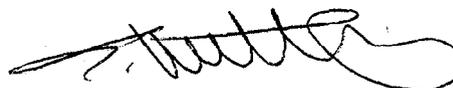


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Conclusion

For the foregoing reasons, the requested stay should be granted.

Sincerely,



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