DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 18 2002

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Francis C. Lynch, Esquire
Palmer & Dodge, LLP
One Beacon Street
Boston, MA 02108-3190

Re: Docket No. 99P-2775/CP1

Dear Mr. Lynch:

This responds to your citizen petition, dated August 12, 1999, requesting that the Food and Drug Administration (FDA) refuse to accept for filing[1] any abbreviated new drug application (ANDA) for gabapentin tablets in which Neurontin capsules are the reference listed drug product. As discussed below, we have considered the arguments presented in your petition in light of the applicable requirements for receipt of an ANDA, and have determined that your arguments are not persuasive. We would not refuse to receive an ANDA submitted for a gabapentin tablet or otherwise delay the review of such an application based on your arguments.

I. Background

You state that you believe "at least one generic drug company has completed or is performing bioequivalence studies comparing a single gabapentin tablet to multiple Neurontin Capsules with the intent of ultimately obtaining approval to market gabapentin tablets as a generic for Neurontin Tablets" (Petition at 1). You state that because Neurontin tablets are covered by listed patents, receipt of an ANDA for gabapentin tablets would require a paragraph IV certification, and the first company submitting an ANDA for which a generic product is substantially complete would be eligible for 180-day marketing exclusivity. You assert that an ANDA for a non-pharmaceutically equivalent gabapentin tablet cannot be substantially complete and should not be received (and the product should therefore not be eligible for 180-day marketing exclusivity) because the study used to show that the product seeking approval under the ANDA is bioequivalent to the reference listed drug cannot "purport to show bioequivalence" of the two products. (Petition at 1).

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[1]Your petition refers to the "filing" of an ANDA. Under 21 CFR 314.101, an ANDA is not "filed" by FDA but rather is "received."

II. Discussion

You are incorrect in your assertion that, under 21 CFR 314.127(a)(6)(i), an ANDA will not be received by FDA if the information submitted is insufficient to show that the applicant drug product is bioequivalent to the reference listed drug product (Petition at 2). Section 314.127 sets forth the reasons that FDA will refuse to *approve* an ANDA. The reasons that FDA will refuse to *receive* an ANDA are in § 314.101(d) and (e). Under § 314.101(a)(2), if FDA finds that none of the reasons in § 314.101(d) or (e) for refusing to receive an application apply, the Agency will receive the application. Although § 314.101(d) and (e) set forth several bases on which the Agency may refuse to receive an ANDA, the only one relevant to the arguments presented in your petition is in § 314.101(d)(3).

Under § 314.101(d)(3), the Agency may refuse to receive an ANDA if it is incomplete because it does not on its face contain information required under section 505(j) of the Federal Food, Drug, and Cosmetic Act or § 314.94 of the Agency's regulations. Thus, the Agency would refuse to receive an ANDA if, for example, no bioequivalence data required under § 314.94(a)(7) were included in the application, or the applicant drug were one for which a petition must be submitted under § 314.93 and no such petition was submitted.

You assert in your petition, however, that prior to acceptance, an ANDA must contain information sufficient to show that the applicant drug is bioequivalent to the reference listed drug product or that at least "purports to show" bioequivalence to the reference listed drug. This is incorrect for several reasons. Section 314.101(d)(3) states that an application may be refused if, *on its face*, the application does not contain required information. The section does not require FDA to make a determination about bioequivalence or about the approvability or likely approvability of an ANDA prior to accepting the ANDA for review, as your petition argues. In order to make such a determination, the Agency would need to conduct a thorough review of the information contained in an ANDA, which would in effect condition the acceptance of an ANDA on its approvability. This is clearly not the purpose of accepting an application, which, as stated in the regulations, is to make a threshold determination that the ANDA is sufficiently complete to permit a substantive review (21 CFR 314.101(b)(1)). Thus your request, insofar as it would necessitate a substantive Agency review of the information in an ANDA to determine whether the ANDA is approvable or likely to be approvable prior to the ANDA's acceptance, is denied on the grounds that such a review is not required or contemplated by Agency regulations.

III. Conclusion

FDA has concluded that the arguments in your petition are unpersuasive and will not refuse to receive or otherwise delay review of an ANDA that meets applicable requirements for receipt of an ANDA under § 314.101.

Sincerely yours,

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