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June 26, 2003

BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1051, HFA-305
5630 Fishers Lane
Rockville, MD 20857

Re: Docket Number 02P-0447

Dear Madam or Sir:

Pfizer Inc. (Pfizer) submits these further comments to its October 11, 2002 citizen petition (Pfizer Petition) to re-emphasize the central premise of that petition -- that section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) does not authorize reliance on proprietary data contained in another company's new drug application (NDA). As FDA is aware, Dr. Reddy's Laboratories, Inc. (Reddy), seeks to rely on the data contained in Pfizer's Norvasc® (amlodipine besylate) NDA in support of its 505(b)(2) application for a product containing a different active ingredient, amlodipine maleate. Contrary to Reddy's arguments, such reliance is not authorized by section 505(b)(2) or 505(j), and cannot be justified under FDA's "Parkman Policy."

Section 505(b)(2) merely authorizes an applicant to submit reports of investigations "not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted . . . ." 21 U.S.C. § 355. Reddy, however, has not submitted such reports in support of its application. Rather, as it has conceded, Reddy instead seeks to rely on Pfizer's Norvasc®

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NDA data in support of its 505(b)(2) application for amlodipine maleate. The only statutory mechanism for one applicant to rely on the data contained in another's NDA is through the abbreviated new drug application (ANDA) provisions of section 505(j); however, as discussed below, no ANDA for Norvasc® may be obtained by Reddy at this time. *See* 21 U.S.C. § 355(j).

Currently, patents preclude Reddy from obtaining approval of an ANDA referencing Norvasc®. After patent expiry, expiration of a statutory 30 month stay, or a successful patent challenge, Reddy could obtain an ANDA for amlodipine besylate. At that point, Reddy could perhaps obtain approval of certain product changes. However, if it does not have its own data, or there are not sufficient publicly available data, to support the change it seeks, it would have to wait until the NDA data are made available. Nevertheless, regardless of what the result may be once Reddy is eligible for an ANDA referencing Norvasc®, Reddy cannot now obtain approval of an amlodipine maleate product by selectively plucking data out of Pfizer's Norvasc® NDA. Section 505(b)(2) does not furnish any authority or basis for such cherry-picking. FDA should not support Reddy's attempts to use that provision as a mechanism for relying on Pfizer's data while circumventing its legitimate patent rights. Again, section 505(j) provides the only statutory mechanism for reliance on pioneer data. That mechanism, however, is available only to generic drugs that are the "same" as the pioneer product or with certain statutorily permissible variations. *See* 21 U.S.C. § 355(j).

Pfizer is aware that FDA has approved modified generics under its informal "Parkman" procedure. Irrespective of whether Pfizer agrees that the policy is an appropriate

administrative shortcut, Pfizer is not currently objecting to that policy.[1] Rather, it objects to Reddy's attempt to rely upon data not available to it either under section 505(j) or otherwise to obtain approval of its 505(b)(2) application. This situation simply is not "Parkman." In its letter describing the "Parkman policy," the Agency properly observed that reliance on the approval of the listed drug is allowed "only to the extent that such reliance would be allowed under section 505(j): to establish the safety and effectiveness of the underlying [reference] drug." Thus, "Parkman" is properly applied only where an applicant could have obtained an ANDA on the reference drug and supports the change with data that belong to the applicant or are publicly available. Moreover, "Parkman" allows only changes that can be approved through a suitability petition or an NDA supplement. Such changes include changes in (1) dosage form, (2) route of administration, (3) strength, (4) formulation (i.e., inactive ingredient requiring safety data), (5) one active ingredient in a combination product, and (6) indications or conditions of use (i.e., Rx to OTC, new indication supported by data or publications). Those are the only changes permitted for applications under section 505(j).

Reddy's application does not fall within the "Parkman policy," because Reddy is seeking a change to an ANDA that may not be made under §505(j): approval of a new single active ingredient -- i.e., approval of a new drug.[2] Moreover, even if that change were permitted for an ANDA under §505(j), Reddy seeks approval at a time when Pfizer's patents prevent

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[1] Reddy appears to read Pfizer's April 28, 2003 comments as sanctioning the "Parkman" policy. In that submission, however, Pfizer was simply characterizing that policy and how it differed from the position advanced in the Agency's 1999 Draft Guidance. Pfizer expressed no opinion as to whether the policy itself was permissible.

[2] *See* 21 C.F.R. § 314.3(b) (equating terms "drug substance" and "active ingredient").

approval of an ANDA in the first instance. Thus, regardless of whether "Parkman" allows for approval of alternate salts once an applicant can obtain an ANDA and submits adequate data, it is clear that Reddy's application does not meet the requisite "Parkman" criteria.[3]

Reddy would read Pfizer's objections to its application as simply an objection to the use of section 505(b)(2) to obtain approval of a new salt form of an active ingredient. That is not the case. Pfizer's objection is to Reddy's attempt to rely upon data not available to it either under section 505(j) or otherwise to obtain approval of its application.[4]

Respectfully Submitted,

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cc: Daniel E. Troy, Esquire, General Counsel, FDA
Jeffrey B. Chasnow, Senior Corporate Counsel, Pfizer Inc.

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[3] Reddy cites two instances in which it alleges that the Agency has approved a 505(b)(2) application for approval of a new salt based upon pioneer NDAs. Pfizer is not aware of the circumstances surrounding those specific approvals. Either or both could have been true "paper NDAs." Alternatively, the NDA holder may not have objected to the use of its data. Regardless of the exact circumstances, an inappropriate approval to which the NDA holder did not object is not valid precedent to shape FDA's 505(b)(2) policy.

[4] Moreover, there is no policy rational in favor of allowing approval of such an application. Such a drug is not a true generic and may not be substituted for the pioneer product. Indeed, Reddy has not seriously asserted that its proposed product would be therapeutically equivalent to Pfizer's Norvasc®. Rather, it appears that the only reason Reddy is seeking approval of the maleate form is to avoid Pfizer's patent on the reference listed drug.