Legal Division
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755
Tel 212 573 2352 Fax 212 309 4420
Email johnsr8@pfizer.com

Rudy A. Johnson
Corporate Counsel
Food & Drug Law

Via Hand Delivery

February 7, 2000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Draft Guidance for Industry on Applications Covered by Section 505(b)(2), Docket No. 99D-4809

Dear Sir or Madam:

Pfizer Inc. hereby submits the attached comments on the draft guidance made available by the Food and Drug Administration on December 8, 1999, concerning new drug applications covered by section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

Sincerely yours,

Rudy A. Johnson

99D-4809

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Comments to the Food and Drug Administration Regarding Drug Approvals Under Section 505(b)(2)

Pfizer submits these comments to the Food and Drug Administration's (FDA) draft guidance on new drug applications (NDAs) covered by section 505(b)(2) of the Food. Drug, and Cosmetic Act (the Act) (the draft Guidance Document)[1] Pfizer objects to those parts of the draft Guidance Document that assert FDA's authority to approve new drug applications that rely on a prior Agency finding of safety and efficacy. For the reasons set forth below, Pfizer requests that FDA withdraw and reissue the draft Guidance Document to make clear that the Agency will not approve under section 505(b)(2) of the Federal Food Drug and Cosmetic Act a new drug application (NDA) that relies on a prior finding of safety and efficacy. To the extent that the draft Guidance Document reflects FDA's interpretation of 21 C.F.R. § 314.54, Pfizer also requests that FDA initiate rulemaking to modify that regulation in a similar manner.

Pfizer's objections are as follows. First, reliance on, or the unauthorized use of, an innovator's safety and efficacy data to approve a competitor's NDA is not supported by any reasonable construction of the Act, and conflicts with other statutory protections relating to the use of proprietary data.[2]

Second, the Act does not permit the Agency to apply a less rigorous safety and efficacy standard to a 505(b)(2) application than to a 505(b)(1) application.

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1 Guidance for Industry: Applications Covered by Section 505(b)(2), Draft Guidance, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), October 1999.

2 See e.g., 18 U.S.C. 1905 (Trade Secrets Act); 21 U.S.C. 331(j) (FFDCA prohibition against FDA disclosure of trade secret information)

Third, the reliance by FDA or an applicant on the Agency's prior finding of the safety and efficacy to approve a 505(b)(2) application constitutes an unconstitutional taking and, thus, is unlawful.

Accordingly, FDA may not implement the draft Guidance Document or rely on 21 C.F.R. § 314.54 to approve an application that is based on a prior finding of safety and efficacy for an innovator's drug product under section 505(b)(2) of the Act and must require such applications to be supported by the same scope of data necessary to support a 505(b)(1) application.

I. Section 505(b)(2) Does Not Authorize FDA to Approve a New Drug Application Based On the Agency's Prior Finding of Safety and Efficacy

In FDA's draft Guidance Document, the Agency has stated that it will accept and approve 505(b)(2) applications for new drug products that rely on "the Agency's finding of safety and effectiveness for an approved drug, without regard to a right to rely on such data."[3] See Guidance Document, at 2. In essence, therefore, the Agency intends to rely on the unauthorized use of an innovator's proprietary and commercially valuable safety and efficacy data to approve another company's drug product under section 505(b)(2) of the Act.[4] A proper construction of section 505(b)(2), consistent with the Hatch-Waxman Amendments, the legislative history of the Act, and other statutory protections for the proper and legal use of proprietary safety and effectiveness data,[5] however, do not support FDA's expansion of section 505(b)(2) to approve applications that rely on the use of an innovator's proprietary data without the innovator's authorization.

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3 Pfizer notes that FDA's recently articulated policy is the first formal declaration by FDA of the Agency's intention to permit a 505(b)(2) applicant to rely primarily on a prior finding of safety and effectiveness based on the unauthorized use of an innovator's data. See 21 C.F.R. § 314.54(a)(1)(iii) (no statement that FDA intends to allow the unauthorized use of prior finding of safety and efficacy). In addition, even if the FDA's actions were authorized by the Act, the Agency may not issue such a substantive change in policy in a Guidance Document, but must issue it as a rulemaking subject to notice and comment.

4 See Guidance Document, at 2 noting that the Agency will accept

The Hatch-Waxman Amendments added section 505(b)(2) to the Act to codify FDA's "paper NDA" policy which permitted an applicant to submit published literature to support the safety and efficacy of a duplicate of a drug product that was first approved for marketing after 1962.[6] The provision, therefore, was intended to allow an applicant to substitute literature to satisfy the "full reports" requirements of section 505 (b)(1) of the Act. See H.R. 98-857, Part I, 98th Cong. 2d. Sess. 36 *reprinted in* 1984 U.S. Code Cong. Admin. News 2647. 2649 (stating that "under the Paper NDA procedure, the generic manufacturer may submit scientific reports. instead of clinical trials. to support findings of safety and efficacy."). In fact, the Agency itself has recognized that the Act does not authorize the approval of 505(b)(2) applications based on an innovator's safety and effectiveness data. See 54 Fed. Reg. 28872, 28892 (July 10, 1989) (Agency recognition of the failure of the Hatch-Waxman Amendments to directly address the appropriate mechanism for obtaining approval of a significant product change that requires the review of clinical investigations and, therefore, is ineligible for approval under the 505(j) Abbreviated New Drug Application ("ANDA") mechanism.); see also 54 Fed. Reg. at 28875 (July 10, 1989) (recognizing that the term "paper NDA," as it was used when Congress passed the Hatch-Waxman Amendments, was defined and understood to encompass only applications for duplicate copies of drugs first approved after 1962 that met the "full reports requirements" of section 505(b)(1) of the Act through published reports in the medical literature establishing the drug's safety and effectiveness). Accordingly, FDA's proposed approval of this broad category of 505(b)(2) applications exceeds the Agency's statutory authority and, thus, is unlawful.

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a 505 (b)(2) application for a change in a drug when approval of the application relies on the Agency's previous finding of safety and/or effectiveness for a drug. This mechanism, which is embodied in a regulation . . . , essentially makes the Agency's conclusions that would support the approval of a 505 (j) application available to an applicant who develops a modification of a drug).

5 See e.g., 18 U.S.C. § 1905, 21 U.S.C. § 331(j).

6 The policy was limited to copies of drug products (or closely related forms) marketed after 1962 and offered for the same indications.

If Congress had intended for the Agency to approve applications under section 505(b)(2) of the Act as suggested in the draft Guidance Document, Congress would have included express language in that section, similar to the language included in section 505(j) of the Act, which allows an applicant to show that an unapproved drug product is the same as a previously approved drug product ("a listed drug product") and, thus, expressly authorizes the Agency to approve the generic drug based on a finding of safety and efficacy of an innovator's product. See 21 U.S.C. 355(j). Nothing in the Act, however, suggests that Congress intended to allow such approvals under section 505(b)(2). To allow the blurring of these two different mechanisms is to undermine the statutory framework of the Act and the deliberate differences which Congress expressly intended for drug approvals.

II. FDA's Proposed Reliance on Prior Findings of Safety and Efficacy Violates the Act by Allowing Approval of 505(b)(2) Applications Based on a Less Rigorous Showing of Safety and Efficacy than 505(b)(1) Applications

FDA's proposal to rely on prior findings of safety and efficacy would also violate the Act because it would allow the Agency to approve drug products that differ significantly from a listed drug product but that do not include the same scope of safety and efficacy data required for 505(b)(1) applications. Specifically, FDA's draft Guidance Document allows the Agency to approve drugs that differ significantly from a listed drug under section 505(b)(2) of the Act based on: (1) data on which neither the applicant nor the FDA has the right to rely; or alternatively (2) incomplete data not consisting of "full reports." Reliance on incomplete data would result in a less rigorous showing of safety and effectiveness under section 505(b)(2) than that required of applications that are submitted under section 505(b)(1) of the Act. See e.g. draft Guidance Document at 8 (stating that the Agency will accept 505(b)(2) applications for drug products that are different from a listed drug, that rely on the Agency's prior finding of safety and effectiveness of the listed drug and less than complete studies of safety and effectiveness ("bridging studies") to "provide an adequate basis for reliance upon [such a] finding").

Even the Agency has recognized that the scope of evidence demonstrating safety and efficacy are the same under section 505(b)(2). See, e.g., 21 C.F.R. 314.50(d)(2). (5), (6) (requiring reports of nonclinical pharmacological and toxicological studies, clinical data, and statistical data for both 505(b)(1) and (b)(2) applications); see 54 Fed. Reg. 28872, 28875, 28892 (July 10, 1989) (noting that applications that meet the description in section 505(b)(2) of the Act are subject to the same provisions that govern a full NDA). Section 505(b) requires both 505(b)(1) and 505(b)(2) applications to include: "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use" as described in section 505(b)(1)(A). Congress recognized that some of the critical data to support safety and efficacy may be found in studies not conducted by or for the applicant. Section 505(b)(2) allows an applicant to rely on such studies if they are in the public domain e.g., "published reports." 21 U.S.C. 355(b)(1), (b)(2). Nothing in the statute indicates that Congress intended to lessen the safety and efficacy showing for a 505(b)(2) application.

Moreover, Congress made clear that where it did intend to allow reliance on FDA's prior findings of safety and efficacy such as under section 505(j), it intended to allow such drugs to differ only in limited ways from the listed product. Under section 505(j), these specific limits include variations in route of administration, dosage form, strength, or where one of the active ingredients differs from those in the listed drug that is also a combination drug, without having to regenerate full reports of safety and efficacy. Id. See H.R. Rep. 9-857, Part 1, 98th Congress, 2d Sess. 36, *reprinted in* 1984 U.S. Code. Cong. Admin. News 2656 (stating that an applicant may petition for approval of a drug product that varies from the listed drug in route of administration, dosage form, strength, or where one of the active ingredients differs from those in a listed drug that is also a combination drug, and that "these are the only changes that are permitted").

To the extent, therefore, that the Agency relies on the draft Guidance Document and 21 C.F.R. 314.54 to approve 505(b)(2) applications for drug products that include other more

significant differences from the listed drug, and are based only on incomplete studies, i.e., limited bridging studies, the draft Guidance Document and regulation are illegal.

III. The Approval of a 505(b)(2) Application Based on FDA's Prior Finding of Safety and Efficacy Constitutes an Unconstitutional Taking

Finally, the Agency's proposed unauthorized use of an innovator's data is unsupported by the statute and legislative history, is fundamentally unfair to research-based companies, and constitutes an unconstitutional taking. Under the Fifth Amendment of the United States Constitution, the government may not appropriate another's property without just compensation. In its draft Guidance Document, however, FDA has stated that it will allow an applicant to rely without authorization on an innovator's property in direct contravention of these constitutional protections.

The inherent property right in safety and efficacy data that is submitted as part of an NDA has been historically recognized by the Courts, Congress, and the Agency. The courts, for example, have noted that safety data is property and, thus, protected by the Fifth Amendment. See Ruckelshaus v. Monsanto Co, 467 U.S. 986 (1984) (recognizing the inherent property right of safety data contained in applications for registration of pesticides to approve generic copies of previously approved pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"); see also Tri-Bio Laboratories, Inc. v. United States, 836 F.2d 135 (3d. Cir. 1987), *cert denied*, 484 U.S. 818 (1988) (recognizing that approval of a generic animal drug based on an innovator's ANADA is a taking of the innovator's rights in the data.). In addition, Congress also has acknowledged the inherent property rights in such information in several statutes, including the Trade Secrets Act, (18 U.S.C. 1905) and at 21 U.S.C. 331(j).

Moreover, the Agency has recognized the inherent and protected rights in such information. See e.g., 21 C.F.R. 314.50 (g) (FDA recognition of the inherent property right of clinical and other NDA data as trade secret and, thus, recognizing it as protected from public dissemination/disclosure by requiring an application that contains "a reference to information submitted to the agency by a person other than the applicant . . . to contain a written statement that authorizes the reference and that is signed by the person who submitted the information."); 39 Fed. Reg. 44635 (Dec. 24, 1974) (recognizing trade secret status of safety and effectiveness data in an NDA as a property right and the right to charge a competitor for reference to that data if the competitor wishes to obtain approval of a generic copy of the product); see also 46 Fed. Reg. 27396 (May 10, 1981) ("the Finkel Memorandum") (stating that "no data in an NDA can be utilized to support another NDA without express permission of the original NDA holder" and thus, stating that for "duplicate NDAs for already approved post [19]62 drugs, the Agency will accept published reports as the main supporting documentation for safety and effectiveness."). As such, the Agency may not implement or rely on the draft Guidance Document or 505(b)(2) regulation to the extent that it would permit FDA to rely on a finding of safety and efficacy of an innovator's drug product without authorization and thereby illegally appropriate the commercial value of that data.

IV. Conclusion

The Act is clear that FDA must require the same scope and quality of evidence of safety and efficacy for a drug approval under 505(b)(2) as that required under 505(b)(1). Nothing in the Act allows FDA to short circuit that requirement by illegally relying on data and prior findings of safety and efficacy which it has no right to divulge or reference. For the foregoing reasons, therefore, and to avoid engaging further in illegal and improper action that will significantly adversely affect research-based companies, the FDA should withdraw and/or reissue the 505(b)(2) draft Guidance Document and should not apply 21 C.F.R. §314.54 to approve NDAs that rely without authorization on proprietary data.

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PhRMA

Matthew B. Van Hook
DEPUTY GENERAL COUNSEL

April 3, 2000

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

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Re: **Draft Guidance for Industry on Applications Covered by Section 505(b)(2)**
Docket No. 99D-4809
64 Fed. Reg. 68697
(December 8,1999)

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits these comments on the draft guidance that the Food and Drug Administration (FDA) made available on December 8, 1999, concerning new drug applications covered by section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act).[1] PhRMA is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to research on medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's member companies invest approximately $24 billion annually to discover and develop new medicines. These companies are the source of nearly all new drugs that are discovered and marketed throughout the world.

[1] *Guidance for Industry: Applications Covered by Section 505(b)(2) (the "Draft Guidance")*, available at http://www.fda.gov/OHRMS/DOCKETS/98F/994809gd.pdf

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I. Introduction

The issuance of this procedural guidance signals FDA's intention to encourage and facilitate broader use of 505(b)(2) applications. However, PhRMA is concerned that FDA's efforts to expand the use of such applications will undermine the public health and intellectual property protections built into the new drug application (NDA) and abbreviated new drug application (ANDA) processes. Accordingly, for the reasons set forth below, PhRMA requests that FDA withdraw and reissue the draft guidance document to make clear that the Agency will not approve under section 505(b)(2) of the Act an NDA that relies on a prior agency finding of safety and efficacy or that in any fashion relies on an unauthorized reference to proprietary and trade secret safety and efficacy data contained in an innovator manufacturer's NDA that is otherwise not available in the public domain. To the extent that the draft guidance document reflects FDA's interpretation of 21 C.F.R. § 314.54, PhRMA also requests that FDA initiate rulemaking to modify that regulation in a similar manner.

Upon FDA recognition and acceptance of the above position, PhRMA does believe a 505(b)(2) guidance document would be useful. Much of the current draft provides a meaningful start. However, PhRMA has identified additional issues that must be given consideration and incorporated into any final guidance document. ***First,*** insofar as 505(b)(2) applications may be used for proposed modifications to approved drugs, the guidance document should define clearly the types of data needed to demonstrate that a modified drug is safe and effective. ***Second,*** as a practical matter,

there are likely to be few circumstances in which a 505(b)(2) applicant will rely on data that do not pertain to a listed drug. Thus, to ensure that drug manufacturers are able to protect their intellectual property rights, FDA should adopt a presumption that a 505(b)(2) application relies on data for a listed drug unless the applicant demonstrates otherwise.

II. Section 505(b)(2) Does Not Authorize FDA to Approve a New Drug Application Based On the Agency's Prior Finding of Safety and Efficacy

In FDA's draft guidance document, the Agency has stated that it will accept and approve 505(b)(2) applications for new drug products that rely on "the Agency's finding of safety and effectiveness for an approved drug, without regard to a right to rely on such data." See Guidance Document, at 2. PhRMA submits that section 505(b)(2) does not authorize FDA to follow this course of action.

Section 505(b)(2) was enacted in 1984 as part of the Hatch-Waxman generic drug amendments. The legislative history of the Hatch-Waxman Amendments indicates that section 505(b)(2) was intended only to codify FDA's "paper NDA" policy, which permitted approval of certain drugs based on published studies.[2] See H.R. 98-857, Part I, 98th Cong., 2d Sess. 32, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2665 (noting that section 505(b)(2) addresses filing of "Paper NDAs").

FDA is incorrect in interpreting section 505(b)(2) as authorizing the agency to approve a new drug by reference to a prior finding of safety and efficacy based on

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[2] The policy was limited to copies of drug products (or closely related forms) marketed after 1962 and offered for the same indications.

another company's proprietary data. The safety and effectiveness data a company submits when its seeks approval of an NDA are highly confidential, and thus are protected against unauthorized disclosure and use. See 18 U.S.C. § 1905, 21 U.S.C. § 331(j). The *only* circumstances in which FDA can rely on those data to approve another drug are the circumstances set forth in section 505(j), which provides for approval of generic drugs. Section 505(j) expressly authorizes FDA to approve a generic drug based on a prior finding of safety and efficacy for a pioneer drug, if the generic drug is "the same as" the pioneer drug in specified ways, and bioequivalent to it. Section 505(b)(2), by contrast, says nothing to authorize approval of a proposed new drug based on comparison with a previously approved product. Rather, section 505(b)(2) merely authorizes an NDA applicant to rely on published literature—as was permitted under the paper NDA policy—to satisfy the "full reports" requirement applicable to all NDAs. See H.R. 98-857, at 16, *reprinted in* 1984 U.S.C.C.A.N. at 2649 ("under the Paper NDA procedure, the generic manufacturer may submit scientific reports, instead of clinical trials, to support findings of safety and efficacy"). Thus, approval of 505(b)(2) applications based on prior findings of safety and efficacy is not authorized by section 505(b)(2) or any other provision of the Act, and would violate proprietary rights in the data.

III. Clear Procedural Guidance is needed for 505(b)(2) NDAs

The NDA (505(b)(1) and 505(b)(2)) and ANDA procedures are distinguished by the levels of clinical and non clinical data they require and the exclusivity protections for

which they are eligible. Recent FDA practices have blurred these distinctions, and this guidance does not clarify them. For example, FDA has approved versions of certain complex drug products under both 505(b)(2) and ANDA procedures. In 1998, FDA treated Ferring's Repronex as the "generic" equivalent of Serono's Pergonal through the ANDA process.[3] One year later, FDA approved Duramed's Cenestin under a 505(b)(2) application; however, Cenestin originally had been the subject of an ANDA referencing Wyeth-Ayerst's Premarin.[4]

In fact, an FDA representative has been quoted as stating that FDA's "generic" approval process for recombinant molecules will rely on the 505(b)(2) NDA "paper" mechanism: *"We are postulating a path for the recombinant molecule that gets an AB rating in the Orange Book, that does not come in under the [ANDA] route, it comes in under the (b)(2) route."*[5] This statement, in PhRMA's view, reflects a substantial and impermissible change in FDA policy. The pharmaceutical industry has long held the view that A ratings are reserved for generic copies approved through the ANDA process and simply are not available to modified drugs approved by 505(b)(2). PhRMA believes that the notion that modified drugs will be deemed substitutable is not what Congress intended when it enacted 505(b)(2).

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3 *Orange Book, at 3-216 (19th ed. 1999); Generic Recombinant Protein "Paper" NDA Approval Process Outlined by FDA,* THE PINK SHEET, at 32 (April 5, 1999).

4 *Id.*

5 *FDA Generic Recombinant Protein Approval Process Will Use "Paper" NDAs,* HEALTH NEWS DAILY, at 1 (March 30, 1999)(quoting Roger Williams, then Director, FDA Office of Pharmaceutical Science)(Emphasis added)> Subsequently, after leaving FDA, Dr. Williams, speaking as Acting Executive Vice President and CEO of U.S. Pharmacopoeia, suggested that 505(b)(2) procedures also could be applied to biological drugs related under the Public Health Service Act. *USP Monograph Could Substitute For ANDA Chemistry Review, Williams Says,* THE PINK SHEET, February 14, 2000, at 35.

Precisely because it is not clear how 505(b)(2) applications will be used, there is concern within the industry that the 505(b)(2) process might become a vehicle for the approval of a vast array of different salts and other chemical variants of approved small-molecule drugs in addition to its use with respect to certain large-molecule and other complex drugs. The experiences discussed above underscore the need for substantive as well as procedural guidance from FDA on this subject before FDA embarks further down this path.

1. FDA must ensure that 505(b)(2) applicants submit sufficient data to support all aspects of the safety and efficacy of the modified drug product.

As noted above, a section 505(b)(2) application is an NDA under 505(b) and as such, it must contain full reports to demonstrate that the new drug in question is safe and effective. Even when the 505(b)(2) application seeks minor modifications to an approved drug, significant questions of safety and effectiveness may arise. Because a 505(b)(2) application serves the same purpose as an NDA with respect to the modification to the drug or other proposed change (e.g., a change to the active ingredient), the same showing of safety and efficacy as is required for a full or supplemental NDA under section 505(b)(1) is also required to support a 505(b)(2) modification.

FDA has not yet advised the regulated industry what data will be required to support specific types of 505(b)(2) changes. FDA should address the substantive aspects of the 505(b)(2) process – specifically, the kinds of studies needed to prove the

safety and effectiveness of a 505(b)(2) modification – in this guidance document. The review of the clinical and other data supporting a 505(b)(2) application should be conducted pursuant to a clearly enunciated policy expressed in a publicly available guidance document.

Rather than establishing uniform substantive data requirements, the draft guidance indicates that a 505(b)(2) applicant should submit a plan to FDA before submitting the application. This plan should identify the components of the application to be supported by publicly available information (not previous FDA findings which as noted above are not permitted) and should describe any additional studies to be conducted. The guidance indicates that FDA "will critique the plan and provide guidance."[6] This suggests that the clinical studies and other data needed to support the 505(b)(2) application will be determined in large part by direction provided by FDA staff to individual applicants. This ad hoc approach suggests that FDA could apply a variable standard to such applications that would not necessarily track the rigorous uniform standards applied to full NDAs.

2. FDA should presume that a 505(b)(2) applicant is relying on data involving a listed drug unless the applicant demonstrates otherwise.

From the standpoint of the pioneer manufacturer, the significant problem with the 505(b)(2) is the "mismatch" between the publicly available data that the applicant may rely on and the patent protections that the pioneer manufacturer (which generated the data) can claim. This is best understood in comparison to the ANDA process. An

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[6] *Draft Guidance. at 9*

ANDA application may rely on data concerning a listed drug but remains subject to the patent and exclusivity protections for the same listed drug. A 505(b)(2) application, on the other hand, because it seeks approval of a drug that is different from a listed drug, might not provide meaningful patent and data exclusivity protection(s) to the pioneer.

As a practical matter, it is unlikely a 505(b)(2) application will rely on publicly available research that was *not* performed in connection with a listed drug. Thus, it would be reasonable for the FDA to presume that a 505(b)(2) applicant is relying on publicly available data involving a listed drug, notwithstanding that the drug under review is a modified drug or even a new chemical entity. A 505(b)(2) applicant who fails to identify one or more listed drugs should be required to demonstrate the reason why the data it relies on to support a finding of safety and/or efficacy for the modified drug has not been submitted in connection with a previously approved NDA or ANDA.

IV. Conclusion

The Act is clear that FDA must require the same scope and quality of evidence of safety and efficacy for a drug approval under 505(b)(2) as that required under 505(b)(1). Nothing in the Act allows FDA to short circuit that requirement by relying on data and prior findings of safety and efficacy which it has no right to divulge or reference. For the foregoing reasons, therefore, and to avoid engaging further in improper and statutorily unsupported action that will significantly adversely affect research-based companies, the FDA should withdraw and/or reissue the 505(b)(2) draft guidance document and should not apply 21 C.F.R. § 314.54 to approve NDAs that rely without authorization on non-public proprietary data. Reissuance of any revised

guidance must take into account additional substantive and procedural safeguards as discussed above to further ensure proper implementation of section 505(b)(2).

Sincerely yours,

Matthew B. Van Hook

cc: Khyati N. Roberts, CDER (HFD-6)
(5600 Fishers Lane, rm. 1061, Rockville, MD 20857)

Larry Moore
Vice President & North America Legal Counsel

Pharmacia Corporation
100 Route 206 North
Peapack, New Jersey 07977

tel 908.901.7111
fax 908.901.1863
larry.moore@am.pnu.com
www.pharmacia.com

PHARMACIA

September 1, 2000

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

Re: Draft Guidance for Industry on Applications Covered by Section 505(b)(2), Docket No. 99D-4809

Dear Sir or Madam:

Pharmacia Corporation hereby submits its comments on the Food and Drug Administration's (FDA) Draft Guidance made available on December 8, 1999 concerning new drug applications covered by Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Pharmacia objects to the parts of the 505(b)(2) Draft Guidance Document that would (1) permit Section 505(b)(2) applications to be approved on the basis of less than full reports of investigations to show that the drug is safe and effective for its intended use, or (2) permit 505(b)(2) applicants and/or FDA to rely on unpublished information in an innovator's New Drug Application (NDA). These policies violate the FFDCA and Congressional intent underlying it, FDA's regulations, and the Administrative Procedure Act. Moreover, the reliance on an innovator's proprietary data constitutes an illegal and unconstitutional taking of an innovator's intellectual property assets.

For the reasons set forth in the Pharmaceutical Research and Manufacturers of America's (PhRMA) comments to this docket, therefore, Pharmacia requests that FDA withdraw the 505(b)(2) Draft Guidance Document, and amend 21 C.F.R. § 314.54 to require that FDA only approve Section 505(b)(2) applications that include full reports of investigations to show that the drug is safe and effective for its intended use, without reliance on unpublished information in an innovator's NDA.

Very truly yours,

Larry Moore

99D-4809

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