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PHARMACIA

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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**Re: Draft Guidance for Industry on Applications Covered by Section 505(b)(2),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**

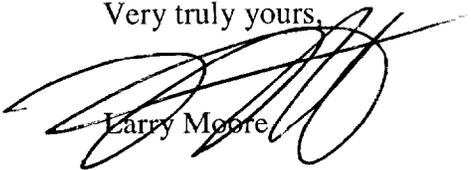
Dear Sir or Madam:

Pharmacia Corporation hereby submits its comments on the Food and Drug Administration's (FDA) Draft Guidance made available on December 8, 1999 concerning new drug applications covered by Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Pharmacia objects to the parts of the 505(b)(2) Draft Guidance Document that would (1) permit Section 505(b)(2) applications to be approved on the basis of less than full reports of investigations to show that the drug is safe and effective for its intended use, or (2) permit 505(b)(2) applicants and/or FDA to rely on unpublished information in an innovator's New Drug Application (NDA).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of America's (PhRMA) comments to this docket, therefore, Pharmacia requests that FDA withdraw the 505(b)(2) Draft Guidance Document, and amend 21 C.F.R. § 314.54 to require that FDA only approve Section 505(b)(2) applications that include full reports of investigations to show that the drug is safe and effective for its intended use, without reliance on unpublished information in an innovator's NDA.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,

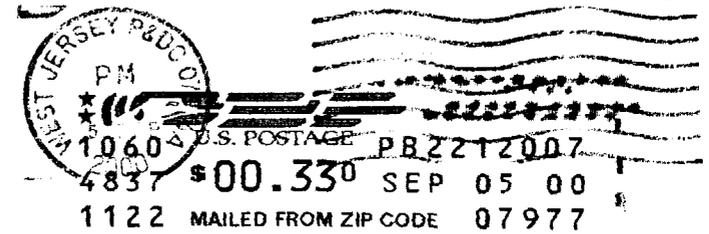

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