May 2, 2001

Dear Ms. Titus,

Harvard Pilgrim Health Care appreciates this opportunity to submit comments to the FDA in support of Citizen Petition 98P-0610/CP1, requesting the conversion of Claritin, Allegra and Zyrtec to Over-the-Counter Status. 3697 01 MAY 10 A7:02

In the experience of our organization, which serves over 3/4 of a million enrolled members, these three agents have established a clear record of safety, superior to that of the first generation anti-histamines, including Benadryl and Chlor-trimeton, which are available to the American public OTC. In fact, in their direct-to consumer advertising ,especially that by Schering Plough, the manufacturer of Claritin, the pharmaceutical industry has attested to the relative safety and absence of serious side effects of these products. Similarly, in securing OTC status in Europe and Canada, similar arguments have been presented by the drug industry to those governments attesting to the great safety record of these agents.

Considering the requirements of Section 502(f) of the FD&C Act, these drugs do not meet the criteria for requiring prescription dispensation, namely they have no evidence of "...toxicity or other potentiality for other harmful effect ...(and, therefore) is not safe for use except under the supervision of a licensed practitioner ..."

In a similar vein, 21 CFR & 310.200 indicates the conditions under which the FDA can switch an agent from prescription requiring to OTC status, conditions clearly applicable in the case in question:

> Any drug limited to prescription use under Section 503(b)(1)(C) of the Act shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potential for harmful effect , or the method of its use,.and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling

It is not the responsibility of the FDA to protect the pharmaceutical industry's price position in the marketplace, one maintained at an artificially high level by the requirement for a prescription. Our entire nation is concerned about the need to make affordable drugs available to our citizens. The requirement for a physician's office visit for an evaluation and the writing of the prescription is an unnecessary and costly burden to impose for no good purpose on the American public. In countries where these drugs are already available on an OTC basis, the price range for a month's supply is $10-20. In this country, with the prescription requirement, the drug product alone costs $60-80 for a month's supply, plus the costs to the consumer in time and money associated with the unnecessary visit to the prescribing physician's office.

We believe these drugs should be available on an OTC basis to the American public. We urge you to use the powers accorded the FDA in the FD&C Act and in the FDA's implementing regulations to switch each of these three products from prescription requiring to OTC status.

Thank-you for your attention to this important matter.

Sincerely,

Joseph L. Dorsey, MD
Corporate Medical Director

98P-0610

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DORSEY AT HARVARD