

Consumer Care Division

December 20, 2002

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 10-61
5630 Fishers Lane
Rockville, MD 20857

**Re: Submission of Amendments dated December 11, 2002 and December 16, 2002
to the March 20, 2002 Citizen's Petition for Phenylephrine Bitartrate
Docket No. 76N-052N/CP18**

Ladies and Gentlemen:

Please refer to our citizen's petition dated March 20, 2002, submitted under Docket No. 76N-052N/CP18, for phenylephrine bitartrate recognition as a generally safe and effective (GRASE) nasal decongestant active ingredient in the Cough, Cold, Allergy, Bronchodilator, and Anti-asthmatic Drug Products for Over-the-Counter Human Use: Final Monograph for OTC Nasal Decongestant Drug Products 59 FR 43364 published August 23, 1994.

As requested by the Agency in the December 10, 2002 and December 16, 2002 facsimiles, the analytical methods and the assay validation data for the determination of total phenylephrine in both human plasma and urine in pharmacokinetic study S01-144 are provided in this submission.

Originals and one copy of each were originally submitted directly to FDA's Division of Over-the-Counter Drug Products on December 11, 2002 and December 16, 2002, respectively. Enclosed are copies for submission as amendments to the Docket No. 76N-052N/CP18 intended for public view.

Please contact the undersigned at 973-408-8045, or Toni Ann Dudor, Associate Director of Regulatory Affairs at 973-254-4778, with any questions concerning this submission.

Sincerely,
Bayer Corporation, Consumer Care Division



Annette C. Owens
Manager, Regulatory Affairs

76N-052N

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Enclosure Analytical method and assay validation data for the determination of total phenylephrine in human plasma in pharmacokinetic study S01-144, submitted December 11, 2002
Analytical method and assay validation data for the determination of total phenylephrine in human urine in pharmacokinetic study S01-144, submitted December 16, 2002