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*PRACTICE WITHIN THE DISTRICT OF COLUMBIA
IS LIMITED TO MATTERS AND PROCEEDINGS
BEFORE FEDERAL COURTS AND AGENCIES

June 4, 2003

BY HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Citizen Petition to Reopen Docket No. 81N-033A: Oral Health Care Drug Products
for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic
Drug Products

Dear Sir or Madam:

On March 25, 2003, Sinofresh Research Labs, LLC (Sinofresh) submitted a petition pursuant to 21 C.F.R. § 10.30 requesting that the Food and Drug Administration (FDA) reopen the administrative record to allow for the submission and evaluation of additional data to support the Category I efficacy and safety classification of cetylpyridinium chloride (CPC) in the Oral Health Care Drug Products for Over-the-Counter (OTC) for Human Use Tentative Final Monograph (TFM) for Oral Antiseptic Drug Products, 59 Fed. Reg. 6083 (Feb. 9, 1994). We submit an additional Declaration in support of that petition.

Sincerely,



Tish Eggleston Pahl

TEP:dah
Enclosure

81N-033A

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