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\*PRACTICE WITHIN THE DISTRICT OF COLUMBIA  
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October 12, 2004

**VIA HAND DELIVERY**

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

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

Dear Sir or Madam:

We submit the following in response to comments to the above captioned docket made by Schering-Plough Healthcare Products (Schering). Schering argues that Dkt. No. 81N-033 should not be reopened for consideration of data that has developed during the last 10 years that support the safety and efficacy of low dose cetylpyridinium chloride (CPC) for use as an oral antiseptic. The arguments Schering presents demonstrate indeed why the docket should be re-opened for consideration of data and views for this ingredient.

As Schering notes, CPC has been found by a U.S. Food and Drug Administration (FDA) panel to be safe for chronic oral use, albeit to suppress gingivitis and reduce plaque formation. 68 Fed. Reg. 32231 (May 29, 2003). Additionally, Schering agrees that CPC has been shown, *in vitro*, to be effective in the suppression of bacteria and fungi known to reside in the oral cavity – causative organisms in acute and chronic gingivitis and plaque formation, and superinfections of minor cuts, bruises, and sores, which is the proposed indication under the oral antiseptic drug product monograph. Historically, antimicrobial efficacy has been solidly based on appropriately performed *in vitro* studies. These two conclusions – that CPC is safe when administered chronically in the oral cavity and that CPC is effective in the suppression of superinfective organisms – were not acknowledged by the panel during its consideration of the oral hygiene monograph in 1982. Thus, as Schering sets out, the science regarding the safety and efficacy of

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CPC has evolved significantly since the 1982 panel and the above-captioned docket should be opened to permit submission of this and other data.

Two other additional events also demonstrate the need to reopen this docket. FDA amended the food additive regulations to provide for the safe use of CPC as an antimicrobial agent in poultry processing. 69 Fed. Reg. 17297 (April 2, 2004). FDA is also soliciting comments regarding topically applied nasal decongestants bearing sinusitis claims and nasal moisturizers. See 68 Fed. Reg. 75585 (Dec. 31, 2003) and 69 Fed. Reg. 46119 (Aug. 2, 2004). We also note that Schering has considerable economic stake in this matter – the promotion, marketing and sale of its line of over-the-counter antihistamines and decongestants.

Under the current situation, CPC is safe and effective for use as a daily mouthwash; it is safe for use as a spray on poultry; but its status remains undetermined for short-term use in the oro-nasal cavity. Plainly, the only way to resolve these conflicting positions is to re-open the docket.

Sincerely,



Jur Strobos, M.D.

Tish E. Pahl

Counsel to SinoFresh HealthCare Inc.

OFW/zkf