



Boston University
Goldman School of
Dental Medicine

Oral and Maxillofacial Pathology

100 East Newton Street, G-04
Boston, Massachusetts 02118
617/638-4775 tel
617/638-4697 fax

July 21, 2003

Rec'd 7/24/03
16

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

**REF: Federal Register/Vol. 68, No. 103
May 29, 2003/Proposed Rules
Sanguinaria extract: Pages 32260 - 32262**

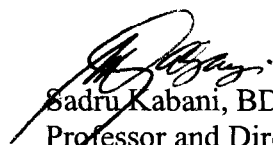
Dear Sir/Madame:

I am writing to offer comments on the recommendations of the subcommittee for proposed rulemaking regarding Sanguinaria extract.

At this point, I believe that Sanguinaria extract in oral hygiene products may not be safe or even desirable to use on account of observations that I have made since 1995 both clinically and microscopically. I have had experience with approximately 15-20 patients who have developed oral leukoplakia some of which have revealed dysplastic changes microscopically. Although the biologic behavior of this change has not been established, current research suggests that Sanguinaria may have a possible role in the pathogenesis of these oral changes.

I would also like to state that the research on Sanguinaria up to the end of 1998 on which the subcommittee makes its recommendations on has appeared in non-peer reviewed journals based on studies for a short duration of time. Based on the above, I believe it is premature to conclude that Sanguinaria is safe to use and I urge the FDA to be extremely cautious in approving its use in oral hygiene products.

Sincerely,


Sadru Kabani, BDS, DMD, MS
Professor and Director
Oral and Maxillofacial Pathology

SK/yc

81A-033P

C 11