

August 29, 2000

5955 '00 SEP -8 A9:48

Docket 00N-0930
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

This letter is to support the nomination of Dr. Prakash Nagarkatti to serve on the working group of the FDA, focusing on the area of biomarkers to identify drug-induced vasculitis. Prakash has extensive experience in the area of immunotoxicology particularly identifying and characterizing biomarkers that are affected following exposure to chemical insult. Furthermore, another aspect of his research involves studies on the role of adhesion molecules in induction of vasculitis and vascular damage.

Prakash is aware of the nomination and is willing to serve as a member of this working group.

Some of the relevant papers include:

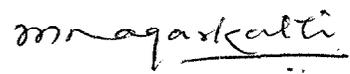
1. Rafi-Janajreh, A. Q., Chen, D., Schmits, R., Mak, T. W., Grayson, R. L., Sponenberg, D. P., Nagarkatti, M. and Nagarkatti, P. S. Evidence for the involvement of CD44 in endothelial cell injury and induction of vascular leak syndrome by interleukin-2. **J. Immunol.** 163:1619-1627, 1999.
2. Kamath, A. B., Camacho, I., Nagarkatti, P. S. and Nagarkatti, M. Role of Fas-Fas ligand interactions in 2, 3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)-induced immunotoxicity. **Toxicol. Appl. Pharmacol.** 160:141-155, 1999.
3. Bradley, M. J., Zeytun, A., Rafi-Janajreh, A., Nagarkatti, P.S. and Nagarkatti, M. Role of spontaneous and IL-2 induced NK activity in the cytotoxicity and rejection of Fas+ and Fas- tumor cells. **Blood** 92:4248-4255, 1998.
4. Rafi, A.Q., Zeytun, A., Bradley M. J., Sponenberg, D.P., Grayson, R. L., Nagarkatti, M. and Nagarkatti, P. S. Evidence for the involvement of Fas ligand and perforin in the induction of vascular leak syndrome. **J. Immunol.** 161:3077-3086, 1998
5. Kamath, A. B., Nagarkatti, P. S. and Nagarkatti, M. Characterization of phenotypic alterations induced by 2,3,7,8-tetrachlorodibenzo-p-dioxin on thymocytes *in vivo* and its effect on apoptosis. **Toxicol. Appl. Pharmacol.** 149: 117-124, 1998.
6. Kamath, A. B., Xu, H., Nagarkatti, P. S. and Nagarkatti, M. Evidence for the induction of apoptosis in thymocytes by 2,3,7,8-tetrachlorodibenzo-p-dioxin *in vivo*. **Toxicol. Appl. Pharmacol.** 142:367-377, 1997.
7. Rafi, A., Nagarkatti, M. and Nagarkatti, P. S. Hyaluronate-CD44 interactions can induce murine B cell activation. **Blood** 89:2901-2908, 1997.

00N-0930

cl

Please find enclosed a c.v.. If you need further information, kindly contact me.

Sincerely,

A handwritten signature in cursive script that reads "mitzi nagarkatti". The signature is written in black ink and is positioned above the printed name.

Mitzi Nagarkatti, Ph.D.
Professor

Subject: Re: Nomination

Date: Thu, 03 Aug 2000 17:11:32 -0400 (EDT)

From: "David Morley 301-594-5684 FAX 301-594-2503" <MORLEYD@cder.fda.gov>

To: "mnagark" <mnagark@hsc.vcu.edu>

CC: "James MacGregor" <MACGREGORJ@cder.fda.gov>,
"Kathy Jordan" <JORDANK@cder.fda.gov>

Thank you for nominating Dr. Prakash Nagarkatti. It is important that we identify the leading technical experts to participate in this collaborative effort.

Although it is hoped that resources will eventually be available to support the proposed projects, financial resources are limited at the present time. Thus, individuals who agree to serve should recognize that they might need to provide their own resources to participate in these projects. Limited travel funds may be available to support university and other members who require support to attend meetings, but even travel support is limited at the moment. Thus, the individuals nominated should have sufficient resources to attend planned meetings.

To complete the nomination -

Please provide no later than September 29, 2000 appropriate biographical material, a brief (one-half page maximum) endorsement, a list of scientific publications relevant to the working groups focused on biomarkers to identify or predict drug-induced: 1) cardiac tissue injury, or 2) vasculitis, and a statement that the nominee is aware of the nomination and is willing to serve as a member of the working group if selected to:

Docket 00N-0930
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

Please note any information submitted to the Docket may be publicly available.

We appreciate your assistance in this matter,

Dave

>I would like to nominate Dr. Prakash Nagarkatti. Kindly let me know
> if you need a cv and any other information.

Vagarkatti

DEPARTMENT OF MICROBIOLOGY & IMMUNOLOGY
COMMONWEALTH UNIVERSITY
BOX 980678 MCV
RICHMOND, VA 23298-0678



Docket 00N-0930
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852