

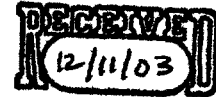
EMORD & ASSOCIATES P.C.

BURKE PROFESSIONAL CENTER
5282 LYNGATE COURT
BURKE, VIRGINIA 22015

1050 SEVENTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20036

PHONE: (202) 466-6937 • FAX: (202) 466-6938
WEB SITE: www.emord.com
E-MAIL: aferrenz@emord.com

December 10, 2003



VIA OVERNIGHT MAIL

Dr. Julie Schrimpf
CFSAN, FDA
5100 Paint Branch Pkwy
HFS-830
College Park, MD 20740

Re: Calcium and Hypertension Health Claim Petition

Dear Dr. Schrimpf:

Please find attached two copies of references 251, 322 and 320 as discussed in my email earlier today. 322 is a duplicate of the facsimile sent earlier today. 320 is a translation of that article sent with the original submission. Finally, we are substituting the attached article (Pryer J, Cappuccio FP, Elliott P. Dietary calcium and blood pressure: a review of the observational studies. *J Hum Hyperten.* 1995 Aug; 9(8):597-604) for the abstract by Stamler et al. previously cited as 251. As stated in my email, the Stamler abstract apparently was a poster presentation and is unavailable. The attached Pryer et al. article cites to the Stamler abstract and contains the information for which 251 was cited in our scientific report.

Please do not hesitate to contact me if you have any further questions.

Sincerely,

A handwritten signature in black ink, appearing to read "JW Emord".

Jonathan W. Emord
Andrea G. Ferrenz

Enclosures

2004 Q - 009P

LET3

EMORD & ASSOCIATES, P.C.

BURKE PROFESSIONAL CENTER
5282 LYNNGATE COURT
BURKE, VIRGINIA 22015

1050 SEVENTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20036

PHONE: (202) 466-6937 • FAX: (202) 466-6938
WEB SITE: www.emord.com
E-MAIL: afferenz@emord.com

FACSIMILE COVER SHEET

TO: Dr. Julie Schrimpf
Company: FDA - CFSAN
Fax No.: 301-436-2651
Client Code: 70414

FROM: Andrea Ferrenz
Date: Wednesday, December 10, 2003
No. of Pages: 2 (including this cover sheet)

MESSAGE:

Julie – Please find attached reference 322 for the Calcium and Hypertension petition. Let me know if you would like me to send it in as a hard copy as well. I hope to have the last reference, 251, to you by the end of the day.

Thanks,



Andrea Ferrenz

Notice: This is a confidential communication intended for the recipient listed above. The content of this communication is protected from disclosure by the attorney-client privilege and the work product doctrine. If you are not the intended recipient, you should treat this communication as strictly confidential and provide it to the person intended. Duplication or distribution of this communication is prohibited by the sender. If this communication has been sent to you in error, please notify the sender and then immediately destroy the document.

ad a significant
} + 0.42 umol/l)
pendent
calciuretics com-
ase differences
us 1.96 + 0.14%}
duced calci-
duced urinary
rted in pre-
ular filtration.
hypocalcemia

INDUCED
sion Division,
02115 USA
n demonstrated in
be indicative of
However, diabetics
levation in GFR.
hypertension
s study was to
measured in 26
th PIH and type I
betes. Women with
motive 3rd
women with PIH and
its (both 0.4) to 0.05
ve 3rd trimester
on or glyco-
posed to PIH in
ed with an
nsive 3rd
diabetic is

85

**CALCIUM SUPPLEMENTATION DECREASES THE INCIDENCE OF PREGNANCY-INDUCED HY-
PERTENSION (PIH) AND PRE-ECLAMPSIA (PE). D. Montanaro, G. Boscutti, G. Mio-
nt, P. Di Iul, G. Tosolani, Div. Nephrology, Div. Obstetric, Udine - Italy**
Recent studies have shown that calcium (Ca) supplementation lowers pres-
sure response to angiotensin II in pregnant women. The possibility of pre-
venting PIH and PE with an oral Ca supplementation was investigated in
a randomized, single-blinded trial. We have studied 170 pregnant women
aged between 19 to 35,92 primigravidae and 78 multigravidae. None of
the women had a history of hypertension or cardiovascular or renal dise-
ase or PIH - PE during previous pregnancies. All the pregnant women ve-
re normotensive at the beginning of the 24 week of gestation. 84 of the
received 2 g. daily of Ca per os starting from 24 week until delivery.
The supplemented group and the control group were comparable with respe-
ct to age, bodyweight, blood pressure, parity, social class, smoking ha-
bits, nutrient intake. In the control group PIH and PE developed in 14
and 9 cases, respectively, whereas in the Ca group 7 women had PIH and
2 PE. ($p < 0,01$ and $p < 0,03$ respectively). There were no adverse effects
of Ca supplementation in mothers or infants.
Ca supplementation represents a safe, well-tolerated, nonpharmacologic
intervention that prevents PIH-PE in normotensive pregnant women.

91

**Schrimpf, Julie**

From: Andrea Ferrenz [AFerrenz@Emord.com]
Sent: Wednesday, December 10, 2003 4:10 PM
To: Schrimpf, Julie
Subject: Calcium and Hypertension Articles

Julie -

Earlier today I faxed to your attention Reference 322 (Montanaro et al). We have determined that reference 251 is unavailable (we believe it was a poster presentation) and in its place we are now citing to the following article:


Pryer, J, Cappuccio, FPand Elliott P. Dietary calcium and blood pressure: a review of the observational studies. J Hum Hyperten 1995; 9:597-604.

That article references the Stamler abstract and contains the information for which we cited the Stamler abstract. I will send the original of the Montanaro abstract and reference 251 to your attention for receipt tomorrow via overnight mail. Also included in that package will be a copy of the translation for reference 320. I believe that with those articles that is everything requested.

Let me know if you have any further questions,
Andrea



Andrea G. Ferrenz
Emord & Associates, P.C.



2/17/2004