

LAMAR ALEXANDER
TENNESSEE

United States Senate

WASHINGTON, DC 20510

December 5, 2003

Mr. Amit K. Sachdev
Food and Drug Administration
Parklawn Building
5600 Fishers Lane, Room 15-47
Rockville, Maryland 20857

Dear Mr. Sachdev,

I am enclosing comments recently received from one of my constituents, John Zeiser. John is concerned about recent proposals regarding food packaging.

I'd appreciate it if you would contact him directly and provide what information you can. It would also be very helpful if you could copy my office on any reply that you send. Thanks for your assistance.

Sincerely,



SOUTHERN CHAMPION
TRAY, LP

220 COMPRESS ST. • P.O. BOX 4066
CHATTANOOGA, TENNESSEE 37405-0066
TELEPHONE 423-756-5121
FACSIMILE 423-756-5163



August 20, 2003

Visit our website: www.sctray.com

[Handwritten signature]

Back
FDA

Senator Lamar Alexander
302 Hart Senate Office Building
Washington, DC 20510

Dear Senator Alexander:

I am writing on behalf of Southern Champion Tray, LP to express my concern about three regulatory proposals the Food & Drug Administration (FDA) issued earlier this year under the 2002 Bioterrorism Act. These proposals will impose significant burdens and costs on facilities that manufacture materials that may end up in food packaging without significantly reducing security risk to the food supply. Specifically, these proposals would require facilities that produce any materials ultimately used to package food to register annually with the FDA and update the documentation monthly, establish and maintain records, and provide advance notice of arriving imported goods.

In February 2003, FDA issued two proposals, one of which requires registration by food packaging facilities, and the other prior import notification. In both of these proposals, FDA defined "food" in an exceptionally broad way to include food packaging. Thus, the proposals apply not only to food processing facilities, *but also to plants that manufacture packaging materials for food as well as their component suppliers*. In May, FDA issued two additional proposals requiring record-keeping and giving FDA broad authority to detain suspicious materials. FDA used the same definition of "food" as in the two prior proposals.

Several organizations filed comments with FDA objecting to the inclusion of facilities that make materials that are used for food packaging in the proposals, citing legislative history contrary to such intent, and detailing the significant burdens and costs that these proposals would impose. The statutory language addressing the facility registration requirement refers to "food for consumption." Plainly, food packaging is not "for consumption," and therefore was not intended to be covered by the registration requirements.

The legislative history regarding the prior import notice is even clearer, the Conference Report explains that "[t]he Managers intend that the requirements of this section [307] *should not be construed to apply to packaging materials* if, at the time of importation, such materials will not be used for, or in contact with, food as defined under section 201 of the [FD&C Act]." H. R. Rept. No. 107-481, 107th Cong., 2d Sess. 137 (May 21, 2002). Rep. Shimkus (R-IL), one of the Managers of the Bioterrorism Act, provided further clarification on the House floor: "Section 307 dealing with prior notice of imported food shipments should not be construed to apply to

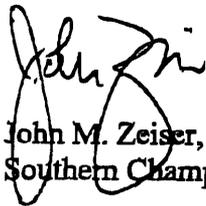
307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are not used in food." 148 Cong. Rec. E916, (daily ed. May 24, 2002).

In addition to not being mandated by statute, these proposals also impose huge burdens and costs on food packaging facilities without making the food supply any safer. The registration and recordkeeping provisions exist to allow law enforcement and public health officials to pinpoint the source of contamination *after a bioterrorism event has occurred*. Given the remote chance that contamination would occur through food packaging and the fact that purchase orders, contracts and transport documentation would allow for easy traceback, the provisions seem to provide little if any benefit while creating a number of unintended consequences.

FDA is planning to finalize two of the rules by October, 2003, since there is a statutory deadline for the requirements to take effect by December 12, 2003. We understand that FDA, in response to comments received, is carefully reviewing the statutory language and legislative history regarding Congressional intent. We urge you to contact FDA and express your concern that these provisions are contrary to Congressional intent and will impose significant burdens without reducing risk to the food supply.

Thank you for your consideration.

Sincerely,



John M. Zeiser, President/CEO
Southern Champion Tray, LP

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United States Senate

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December 5, 2003

Mr. Amit K. Sachdev
Food and Drug Administration
Parklawn Building
5600 Fishers Lane, Room 15-47
Rockville, Maryland 20857

Dear Mr. Sachdev,

I am enclosing comments recently received from one of my constituents, Jim Solka. Jim is concerned about the mandatory posting of nutrition facts on restaurant menus.

I'd appreciate it if you would contact him directly and provide what information you can. It would also be very helpful if you could copy my office on any reply that you send. Thanks for your assistance.

Sincerely,



FOIA

jawrmsg.txt
Capitol Correspond
Incoming Email Message

Constituent ID: 74168

Solka, Jim
1336 Benjamin Blvd.
Sevierville, TN 37876
Email: Imreszoke@juno.com

Activity Created: 10/28/2003
Activity ID: 86807
Interest Code(s):

Incoming Message:

Subject Desc: - Health Care

Date Received: 10/27/2003 2:33:47 PM

why oh why is the FDA considering menus to include calories, etc. at restrauants?

I thought we would have less government with the Bush Administration.

who pays for this? Is this another opportunity for the lawyers to sue if the calories aren't correct?

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TENNESSEE

United States Senate

WASHINGTON, DC 20510

December 5, 2003

Mr. Amit K. Sachdev
Food and Drug Administration
Parklawn Building
5600 Fishers Lane, Room 15-47
Rockville, Maryland 20857

Dear Mr. Sachdev,

I am enclosing comments recently received from one of my constituents, Darrel Easter. Darrel is concerned about FDA hiring policies for veterans.

I'd appreciate it if you would contact him directly and provide what information you can. It would also be very helpful if you could copy my office on any reply that you send. Thanks for your assistance.

Sincerely,





3165 Woodsman LN
Bartlett, TN 38135
Tele: 901-385-3565

*Buck
FOIA*

Honorable Lamar Alexander
United States Senate
Washington, DC 20510

Dear Senator Alexander:

It is my understanding that the President and our government are supportive of positive veteran hiring practices especially within the federal system. Indeed, there are laws giving preference to the hiring of veteran's in the federal government/civil service arena. These laws may appear to promote positive hiring practices; yet my experiences (with a 10 point preference rating) truly indicate that it is not working.

I will cite several examples. I had responded to a federal vacancy announcement for the FDA putting me in a pool for the position of "Consumer Safety Officer". I am well qualified and was awarded a high rating for these positions. I was selected from this pool for five (or more) positions yet was bypassed in each case for a candidate chosen from the US Public Health "Commissioned Corps". It seems the FDA is permitted to do this as per response to my appeal via the local veteran's employment representative.

I responded to a vacancy under a DEU announcement and was telephone interviewed for the position. It was felt by the interviewer that I would be a good match to the needs yet the position was awarded to another person I would presume to be a non-veteran. There was no recourse for appeal under this DEU announcement.

I would feel that if candidates were on a near equal footing, the choice should be the veteran as promoted under the law. I am greatly disappointed with this and ask that you investigate and correct the law. Hopefully you agree that veterans are deserving of this consideration. Reference the attached information.

Respectfully,

Darrel Easter

Darrel Easter

Appeal

Vets-1010 Supplemental Attachment: Darrel Easter
Page 1 of 2

I responded to vacancy announcement FDA-7-0904 (FDA: Consumer Safety Officer) and received a rating via letter dated October 22, 2002 which was good for 180 days. I requested an extension of 180 days and received another rating notification dated May 28, 2003.

Positions
eligible
for

I received the following "Inquiry As To Availability" notices and responded immediately to them. These are Certificate Numbers (Item 2 on the Inquiry form): FDA-1-3-3765 (GS-9, Falls Church, VA); FDA-1-3-3766 (GS-11, Falls Church, VA); FDA-1-3-3767 (GS-9, Baltimore, MD); FDA-1-3-3768 (GS-11, Baltimore, MD); FDA-1-3-3657 (salary range given, Rockville, MD).

On July 9, 2003, I received an e-mail from Jacquie Johnson requesting to set up a telephone interview. An interview was set for July 14, 2003. On July 14, 2003, a three-way telephone conversation was held between myself, Matt Henciak (Baltimore, MD FDA Office, tele: 410-779-5438) and Melanie Mayer (Falls Church FDA Office, tele: 703-235-8440 ext 505).

During the telephone interview, I relayed (as listed on my resume), that I had worked in the pharmaceutical industry and was familiar with FDA regulations (cGMP) pertinent to this industry. I was advised there would be an initial training period followed by on the job training most likely in food production inspection. A number of other questions were addressed. At the end, I asked if they had any concerns with my application and none were expressed.

As an additional note, I was never contacted by the Rockville Office following the "Inquiry As To Availability" notice.

I was requested to and did provide a reference list via e-mail as directed to Melanie Mayor and Matt Henciak. One reference relayed to me that he had been contacted.

I called Melanie Mayer's office on August 15, 2003 and left a voice mail message inquiring as to the status of my application. I was later that day called back by Carol Nash (tele: 703-235-8440 ext 506) and informed that although I was high on the list, another candidate had been chosen. I asked for feedback from the interviewers as to what I may have lacked in order to make myself a stronger candidate and also asked for advice on if this decision could be appealed as I do hold veteran preference privileges (10 pt veteran). Carol replied that she would pass my request on but to date, I have had no response.

I wish to appeal the decision not to hire me based on veteran's preference privileges. Also, I hold an appropriate background for the position (BS Chemical Engineering, BA Chemistry, and experience within an FDA regulatory environment in the pharmaceutical industry) and held a high rating. I felt I was a suitable and strong candidate, well suited for this position. I would hold great disappointment if this position was awarded to a non-veteran unless there was some very outstanding quality that this individual had that would absolutely put the person ahead of my application. I am an unemployed veteran.

**Vets-1010 Supplemental Attachment: Darrel Easter
Page 2 of 2**

I also wish a check against the Rockville, MD FDA office to confirm that I was not by-passed for another candidate after receiving a notice of "Inquiry As To Availability". That is: There was no follow up from that office for interviewing.

I would seek all corrective actions that may be afforded me under the law which could include awarding of back pay and benefits in addition to being awarded the position. I wish to discuss this with appropriate authorities if the FDA has been found to be non-compliant with government laws/regulations regarding application of veteran's preference and hiring of veterans.

Documents included in this appeal attached in the following order:

Vacancy announcement FDA-7-0904

Notice of Rating dated May 28, 2003

Notice of "Inquiry As To Availability" (5 separate notices)

E-mail from Jacqueline Johnson dated July 9, 2003 indicating interest to set up an interview.

E-mail from Melanie Mayor dated July 24, 2003 stating that references had been received (and my e-mail sending the references on that same sheet).

DD-214

Letter from VA used to verify disability rating and 10 pt veteran preference

U.S. Department of Labor

Office of the Assistant Secretary for
Veterans Employment and Training

Veterans Employment and Training Service
1309 Poplar Avenue
Memphis, Tennessee 38104
(901) 543-7853

Date: October 3, 2003

Received October 6th

Darrel Easter
3165 Woodsman Ln.
Bartlett, TN. 38135

Certified Letter
Case#: 04-TN-2003-010-VPH

Easter
Dear Mr. ~~Walker~~;

This is to advise you that the Department of Labor is closing its investigation of your complaint relating to veterans' preference that was filed with this agency on August 22, 2003. Your claim was filed in a timely manner in accordance with Section 3330a(a)(2)(A) of Title 5 of the United States Code (U.S.C.)

Your position is that you were not afforded your veteran's preference because the U.S. Dept. of Health and Human Services hired another person on vacancy FDA-7-0904. A Human Resource Specialist replied to my request for information on the announcement. Their reply stated you were determined to be qualified for the position, you were given your 10 point preference, rated, given a score and placed on the certificates of eligibles. They stated the program managers reviewed your application and those of other applicants. "In all the reference cases the program chose Commissioned Corps officers. The Commissioned Corps also has a highly qualified group of officers who apply to positions in the FDA. This is an alternative source of recruitment that is frequently utilized at the FDA."

Their reply further stated; "The FDA has many openings in headquarters and various field locations and we encourage Mr. Easter to apply to our future vacancies. Mr. Easter's application will remain on file for the CSO register in headquarters until Nov. 24, 2003 and he will be given proper consideration. Mr. Easter can also request an extension of his eligibility for the CSO register and we will be happy to accommodate his request."

Based upon this Investigator's review, it is determined that your claim does not have merit. Certificates of eligibility and individual applications were reviewed to insure that veterans' preference points were added to all qualified applicants. However, veterans' preference does not require an agency to use any particular appointment process. Agencies have broad authority under the law to hire from any appropriate source of eligibles including special appointing authorities.

Section 3330a(d) of Title 5 U.S.C. provides that you may appeal your case to the U.S. Merit System Protection Board (MSPB). Should you elect to appeal to the MSPB, you have fifteen days (15) from receipt of this letter to do so. Your appeal should be sent to:

Atlanta Regional Office 401 W. Peachtree Street, N.W. Suite 1050 Atlanta, GA 30308
(404) 730-2751 Fax(404) 730-2767

A copy of the MSPB Appeal Form is enclosed for your convenience.

If you have any questions concerning the appeal process, you may call MSPB at 1-800-209-8960. The MSPB also has an Internet site, "How to File an Appeal". This site may be found on the Internet at: <http://www.mspb.gov/>

Sincerely,



George Pearson
Assistant Director