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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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June 15, 2007

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are conducting an investigation into the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply.

As part of this investigation, Committee staff has reviewed documents you provided regarding the proposed closure of FDA laboratories. Although we are concerned with many aspects of the laboratory closure plan, we are particularly troubled with the plan to drastically cut the number of laboratory analysts as evidenced by the document entitled, "New Organization Staffing," dated December 11, 2006 (see attachments). This drastic cut comes at a time when the volume of food imports doubles every five years and at a time when the American public appears to be exposed to an increasing amount of unsafe, contaminated food. Thus, we are shocked to learn that FDA has plans to cut 196 microbiologists, chemists, and engineers from the Agency. This number represents 37 percent of the total number of laboratory analysts currently working in Office of Regulatory Affairs laboratories. This slashing of analysts comes after an already 24 percent reduction in lab analysts between 2003 and 2007. To say the very least, these numbers are deeply disturbing.

In order to assist the Committee in its investigation into the adequacy of the efforts of the FDA to protect the safety of the Nation's food supply, we request that you provide the Committee with the following information:

The Honorable Andrew C. von Eschenbach, M.D.

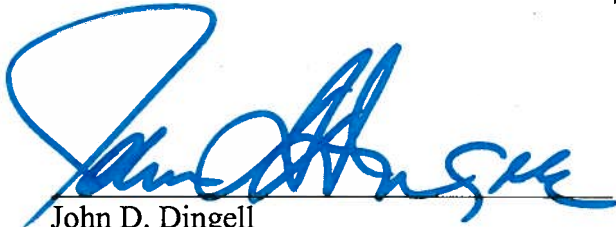
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1. The number and types of samples that FDA currently analyzes but will not be able to analyze due to the reduction in the number of laboratory analysts;
2. The type of domestic or import inspections that FDA currently performs that involve taking samples that will not be able to rely on FDA laboratory analyses in the future due to the reduction in the number of laboratory analysts; and
3. All records reflecting the plans, budget analyses, and contracts intended to replicate the work currently performed by the 196 analysts that you plan to eliminate from the Agency.

Please provide your response and supply all calculations and other records relating to the requested information no later than the close of business two weeks from the date of this letter. Please note that, for the purpose of responding to the above request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter.

If you have any questions relating to this request, please contact us or have your staff contact David Nelson or Kevin Barstow with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

UNDER ON-BOARD SHOWN IN (RED)

	Science Directorate			Immediate of Directorate				
	New Org.	Transition Staffing	On-Board	Short-term Placement Needs	New Org.	Transition Staffing	On-Board	Short-term Placement Needs
Directorate Director	556	562	782	200	4	4		(1)
Management/Program Analyst	1	1	0	(1)	1	1		(1)
Program Support Specialist/Secretary	1	1	0	(1)	1	1		(1)
QMS Officer	1	1	0	(1)	1	1		(1)
Division Director	1	1	1	0				
Office Automation	2	1	1	0				
Science Advisor	1	1	1	0				
Branch Director	3	3	2	(1)				
Chemist	9	6	6	0				
Microbiologist	7	7	7	0				
Consumer Safety Officer	2	1	1	0				
Program Analyst	4	3	3	0				
Lab Director	8	8	12	6				
Program Support Specialist	6	6	1	(5)				
QMS Manager	6	6	10	4				
Admin Officer	6	6	3	(3)				
Science Advisor	11	11	0	(11)				
Industrial Hygienist	6	6	8	2				
Biosafety Officer	3	3	0	(3)				
Electronic Engineer	5	5	0	(5)				
Special Assistant/Program/ Management Analyst	6	6	0	(6)				
Micro Branch Director	5	8	6	0				
Chem Branch Director	7	11	13	2				
Office automation	12	8	0	(8)				
1st Line Supervisor/Team Leader	31	41	57	18				
Microbiologist	140	140	183	43				
Chemist	238	238	374	138				
Engineer	0	0	17	17				
Branch Support	35	56	76	20				

In the Immediate Office of the Director, the Lab group recommended a bio-safety officer, special assistant, administrative officer, industrial hygienist. To maintain consistency among the directorates this recommendation was changed. We added a QMS Officer.

Row 32 - We are leaving the stand up figures for the remaining laboratory with on board staff. The TO may ultimately get larger or smaller as it relates to transitioning staff.

Row 30 - We are leaving the stand up figures for the remaining laboratory with on board staff. Supervisors are calculated based on supervisory ratios.

85 - The correct number of analysts needed to address increased workload, changing workloads or reductions that are possible with improved efficiencies are yet to be determined. The laboratory group is working toward determining the right size for these laboratories.

12/17/2006

15 Districts with 10 Compliance Branches		ORA TOTAL			
	New Org.	Transition Staffing	On-Board	Short-term Placement Needs	
	3,144	3,125	3,182	57	
ACRA OFFICE	25	20	14	(6)	
DACRA OFFICE	18	18	16	(2)	
Office of Criminal Investigations (OCI)	226	226	218	(8)	
Office of Resource Management (ORM)	119	108	94	(14)	
Office of Enforcement (OE)	53	52	33	(19)	
Office of Policy (OP)	33	20	6	(14)	
Office of Field Operations (OFO)	115	111	97	(14)	
Inspection/Compliance Directorate (ICD) Districts	10	13	30	17	
	1,766	1,766	1,724	(42)	
Science Directorate (SD)	556	582	782	200	
Office of Import Operations (OIO)	223	209	168	(41)	

New Org. is what ORA should look like at the end of the transition.
 Transition Staffing is what ORA needs to Stand-up ORA on October 1, 2007.
 On-board is ORA's current staffing as of the end of November of 2006.