



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740-38

OCT 10 2008

Mr. Thomas K. Thompson, Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region I  
Division of Nuclear Materials Safety  
Commercial and R&D Branch  
475 Allendale Road  
King of Prussia, Pennsylvania 19406-1415

Br. 2

RE: NRC License Amendment Request  
License No. 19-30771-01  
Docket No. 03036120  
Control # 141772

RECEIVED  
REGION I  
OCT 23 AM 10:50

Dear Mr. Thompson:

This letter is to confirm the telephone conversation on August 20, 2008, regarding a change in the U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition's (CFSAN) executive management representative, between Mr. Thomas K. Thompson, U.S. Nuclear Regulatory Commission, Region I and Ms. Constance Rosser, U.S. FDA, CFSAN, Radiation Safety Officer.

Mr. Thomas D. Williams, M.B.A., Executive Officer for CFSAN, has been designated to serve as the executive management representative. Mr. Williams may be reached at the Department of Health and Human Services, FDA/CFSAN, Harvey W. Wiley Building, Room 4C-004, HFS-650, 5100 Paint Branch Parkway, College Park, Maryland 20740. His telephone number is (301) 436-2114. A copy of the Center's organizational chart is enclosed for your record.

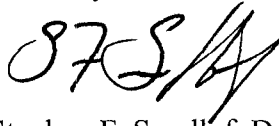
Ms. Constance Rosser will continue to serve as the Center's Radiation Safety Officer. She has served in this position and administered the Center's radiation safety program for the past eight years. A copy of the Delegation of Authority for the Radiation Safety Officer is also enclosed for your record.

142950  
NI'SS/RGN MATERIALS-002

Page 2 – Mr. Thomas K. Thompson

Questions regarding this amendment request should be addressed to Mr. Williams at (301) 436-2114 or Ms. Constance Rosser at (301) 436-2105.

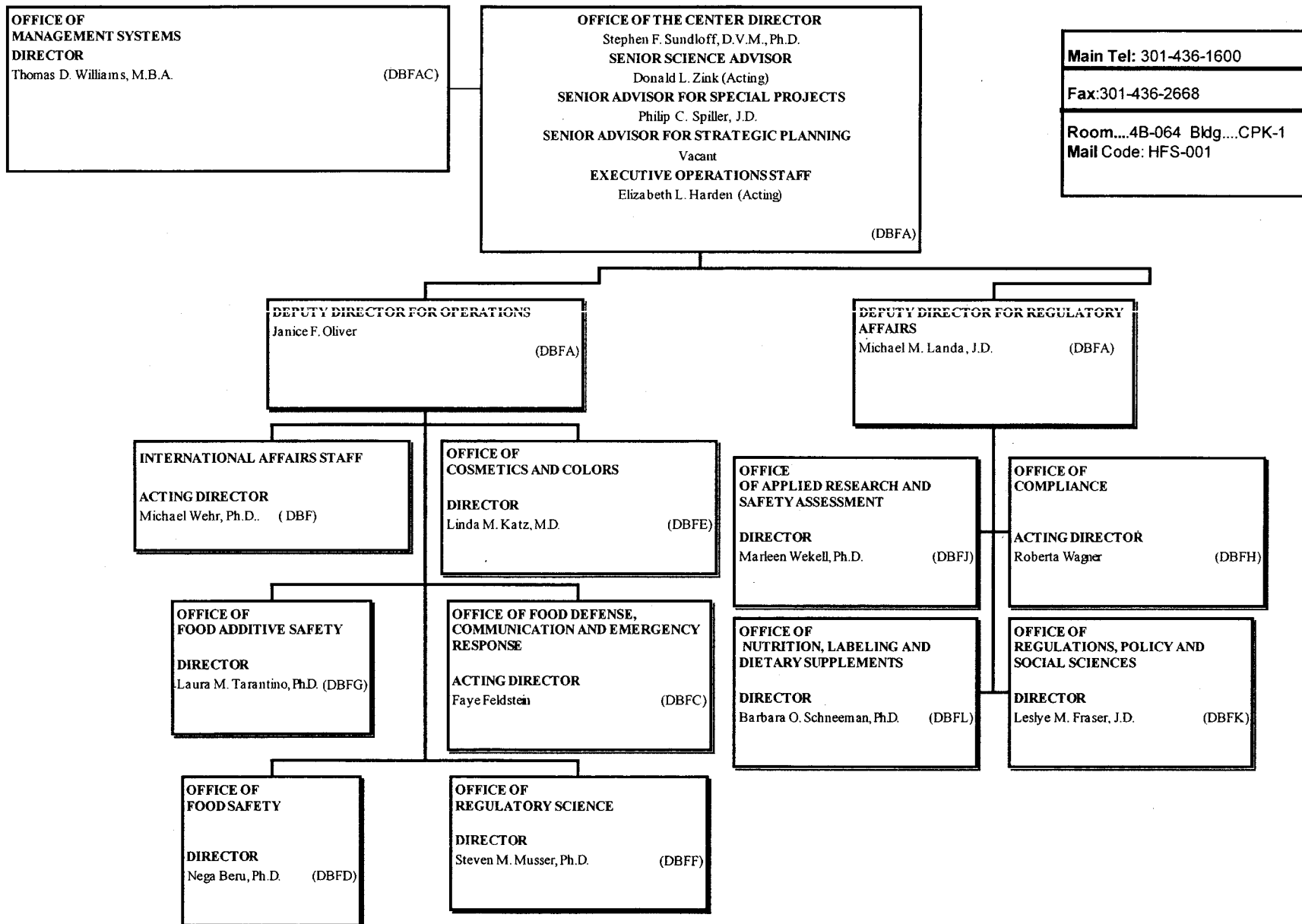
Sincerely,

A handwritten signature in black ink, appearing to read 'SFS/A', written in a cursive style.

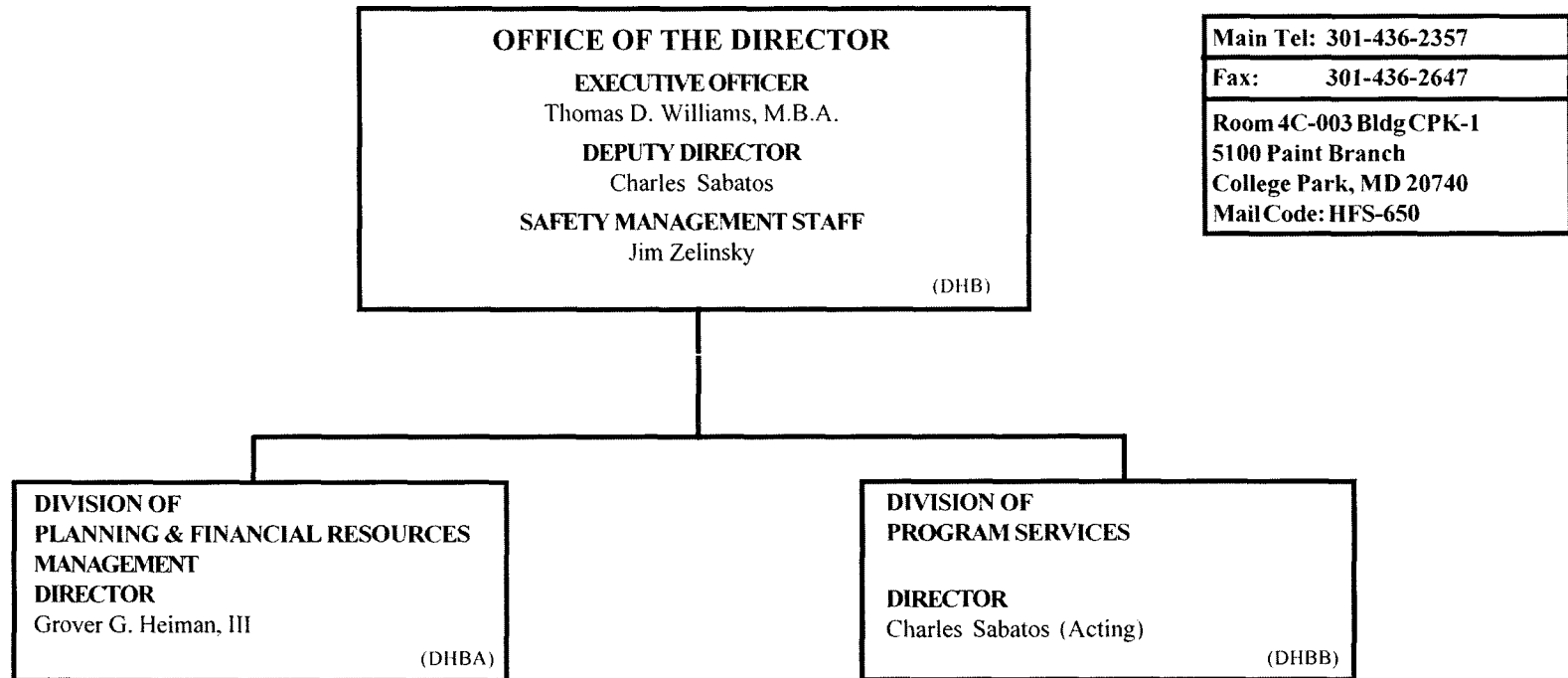
Stephen F. Sundlof, D.V.M., Ph.D.  
Director  
Center for Food Safety  
and Applied Nutrition

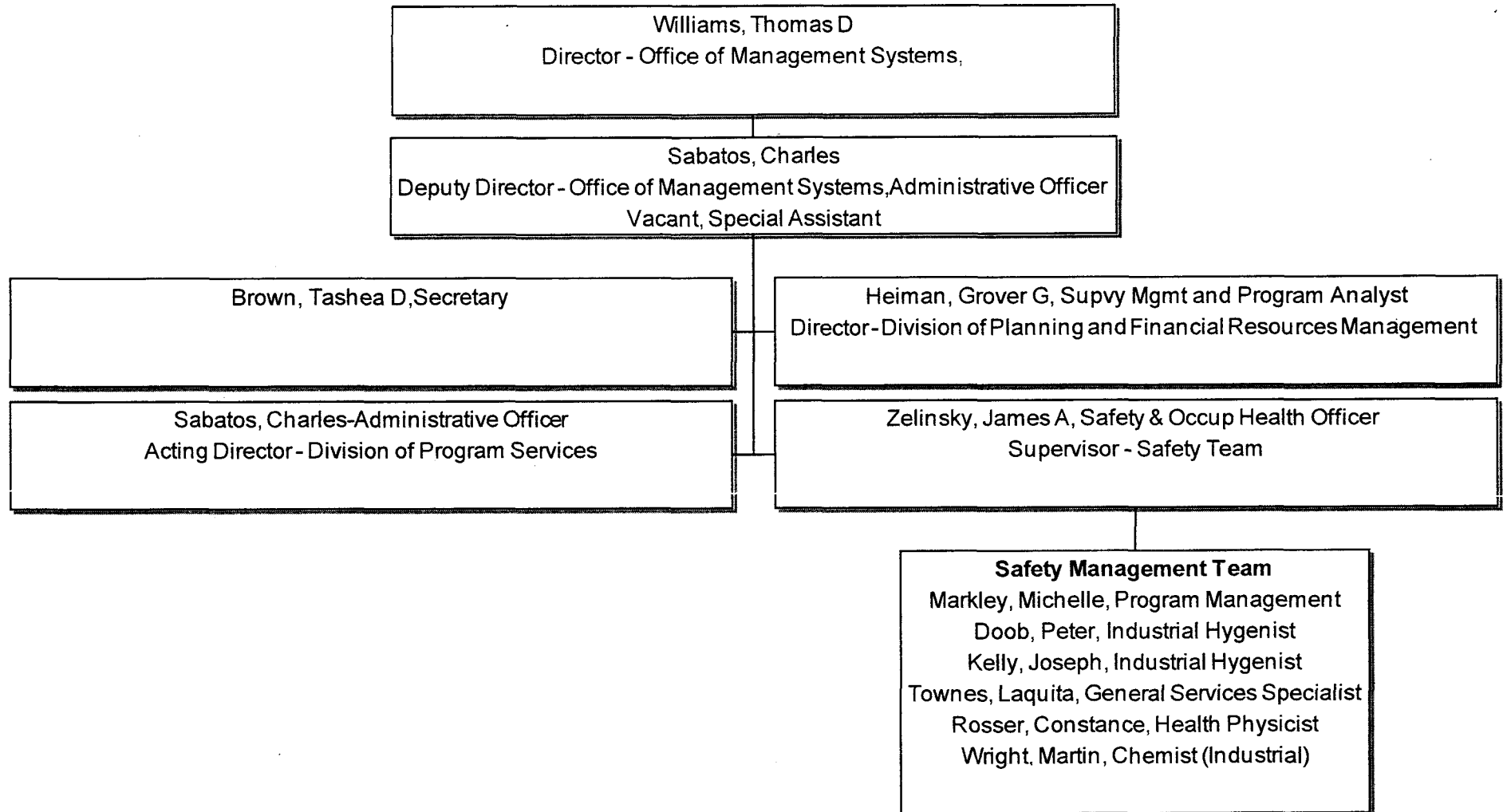
Enclosures

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**  
**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**  
**OFFICE OF THE CENTER DIRECTOR**



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**  
**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**  
***OFFICE OF MANAGEMENT SYSTEMS***







DEPARTMENT OF HEALTH & HUMAN SERVICES


Public Health Service

Memorandum

Date OCT 10 2008  
From Executive Officer  
Subject Delegation of Authority for Radiation Safety Officer  
To CFSAN Management Council

The CFSAN Nuclear Regulatory Commission Materials License was renewed on September 6, 2005. The Center is authorized to possess byproduct material for research and development as defined in 10 CFR 30.4, to include animal studies. Ms. Constance Rosser will continue to serve as the CFSAN Radiation Safety Officer whose responsibility is to ensure the safe use of radioactive material. She will be responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending or providing corrective actions; and ensuring compliance with regulations for the use of radioactive material. Ms. Rosser is hereby delegated the authority necessary to meet these responsibilities.

Ms. Rosser has the authority to immediately stop any operations involving the use of by-product material in which health and safety may be compromised or may result in non-compliance with Nuclear Regulatory Commission requirements.



Thomas D. Williams, M.B.A.

cc:  
HFS-22(Wheeler, Owens for Director's reading file)  
HFS-650(Williams)  
HFS-657(Zelinsky)  
HFS-657(C. Rosser)  
HFS-125(R. Bronaugh)  
HFS-025(C. Kim)  
HFS-025(M. Kotewicz)  
HFS-025(U. Babu)  
HFS-025(M. Calvo)  
HFS-717(M. Kraeling)  
HFS-711(S. Monday)  
HFS-707(S. Etheridge)  
HFV-512(B. Shaikh)  
HFV-520(R. Reimschuessel)  
HFV-504(B. Bradley)

This is to acknowledge the receipt of your letter/application dated

10/10/08, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment C19-30771-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 142950.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.