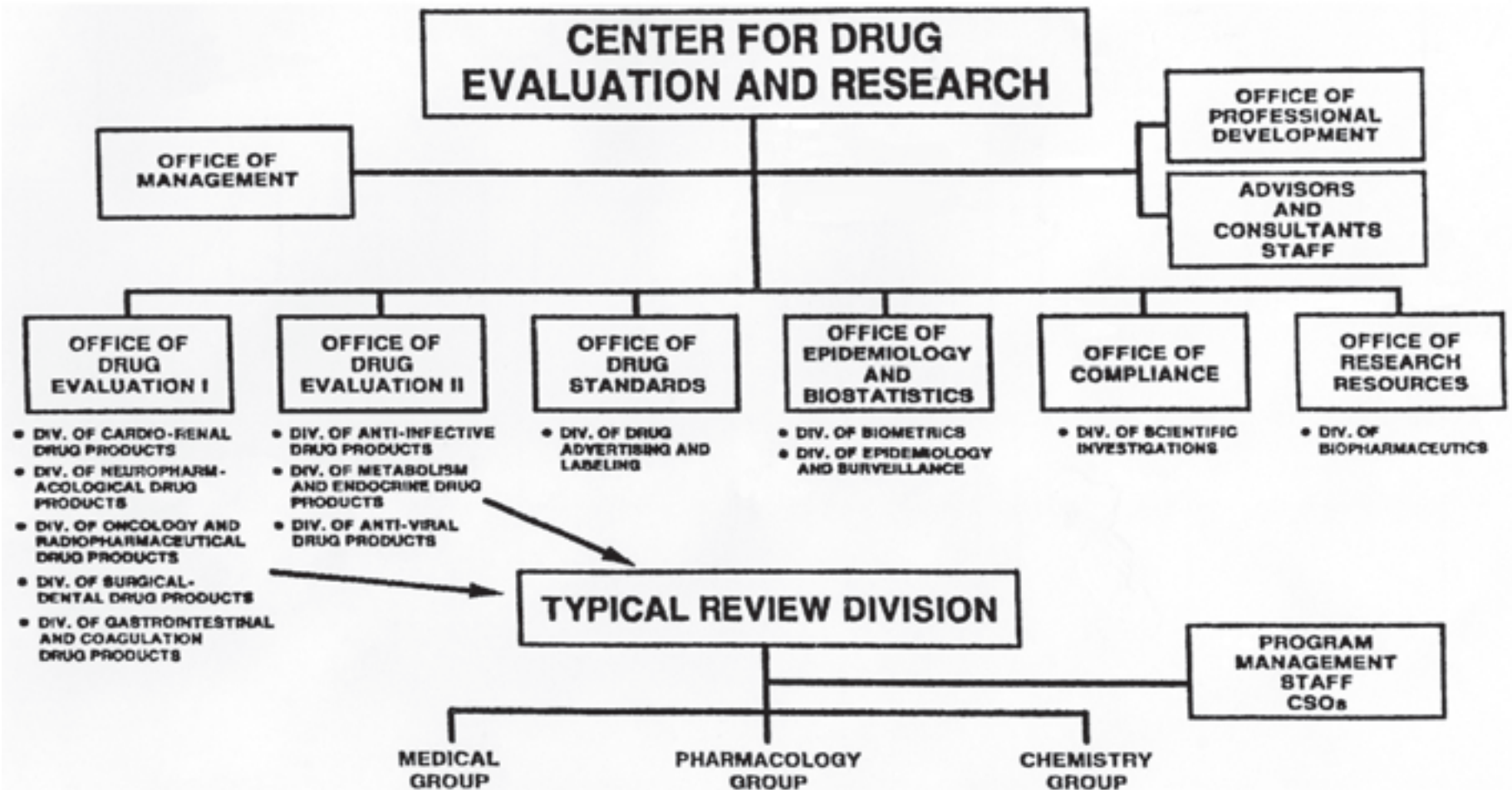
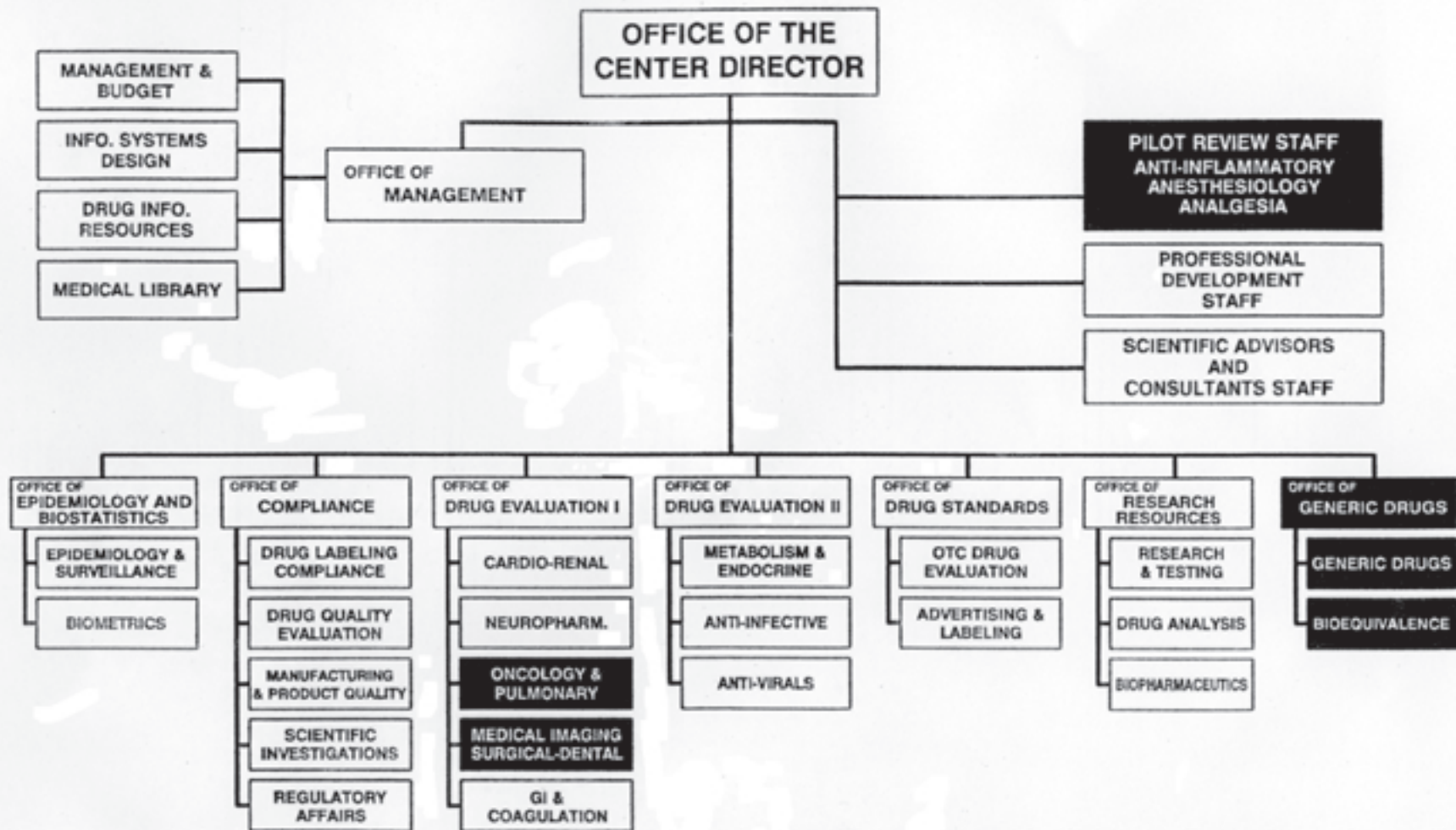


DEVELOPMENT OF REGULATIONS GOVERNING MEDICAL RESEARCH WITH PSYCHEDELICS AND MARIJUANA IN THE U.S.								
CELLS IN BOLD REPRESENT U.S. LAWS, REGULATIONS, GUIDELINES THAT DIRECTLY INFLUENCE RESEARCH								
						REVIEW OF	PHS REVIEW	
		CREATION OF FDA	FDA/NIDA	CONTROL OVER	DEA	NIH-FUNDED	OF MEDICAL	INT. TREATIES
INFORMED	IRB	PRIOR IND	Advisory Comm.	NON-MEDICAL	LICENSING OF	PSYCHEDELIC	MARIJUANA	REG. OF RESEARCH
CONSENT	APPROVAL	APPROVAL	Guidelines	USE OF DRUGS	PHYSICIANS	PROTOCOLS	PROTOCOLS	PROD. QUOTAS
						Fed. Funded Only	Priv. funded	
Nuremburg, 1947		Pure Food & Drug	NIDA Technical	Harrison Narcotic				Single
	FIRST NIH	Act of 1906	Review of	Act of 1914	Controlled	FDA/NIMH	HHS	Convention
1962 Amendments	Intramural	June 1906	Hallucinogens	December 1914	Substances	Committee	Guidelines	On Narcotic
to 1938 Act	Review, 1953		July 1992		Act of 1970	Review, 1967	May 1999	Drugs
October 1962				Marijuana Tax	October 1970			June 1967
	DHEW Rules,	1938 Amends.	FDA Drug Abuse	Act of 1937				
Helsinki, 1964	February 1966	to 1906 Act	Advisory Cmt	August 1937		Controlled		Psychotropic
Revised,		June 1938	July 1992			Substances		Substances Act
Hong Kong, 1989	DHEW Rules			Drug Abuse		Act of 1970		November '78
	May 1974	1962 Amends.		Control Amend.		Regulating		
Belmont, 1978		to 1938 Act		of 1965		Treatment of		US Ratifies
	HHS 45 CFR 46	October 1962		July 1965		Narcotic Addicts		Convention on
HHS 45 CFR 46	Rev., March 1983					October 1970		Psychotropic
Revised, March 1983				LSD Possession				Substances
				Restric. 1968		NIDA Guidelines		July 1980
Common Rule	Common Rule			October 1968		For Research		
16 Fed. Agencies	June 1991					With Drugs Of		UN Convention
June 1991	FDA Rules			Controlled		Abuse and Drug		Against Illicit
FDA Rules	June 1991			Substances		Abusers		Traffic in Narcotic
June 1991				Act of 1970		June 1997		Drugs and Psycho-
				October 1970				Tropic Substances
National Bioethics						NIMH Policy		1988
Advisory Committee				Emergency Sch.		Statement For		
June 1999				of MDMA, 1985		Research in		International
				July 1985	21 USC 823 (b)	Mentally-III		Conference on
FDA 21 CFR 50	FDA 21 CFR 56	21 CFR 312			21 CFR 1301	Patients		Harmonization
	HHS 45 CFR 46			Controlled		January 1999		Of Technical
				Substances				Requirements for
				Analogue Act				Registration of
				October 1986				Pharmaceuticals
								for Human Use
				21 USC (801)				1989
				21 CFR 1308.11				

ORGANIZATIONS CONCERNED WITH NDA REVIEW

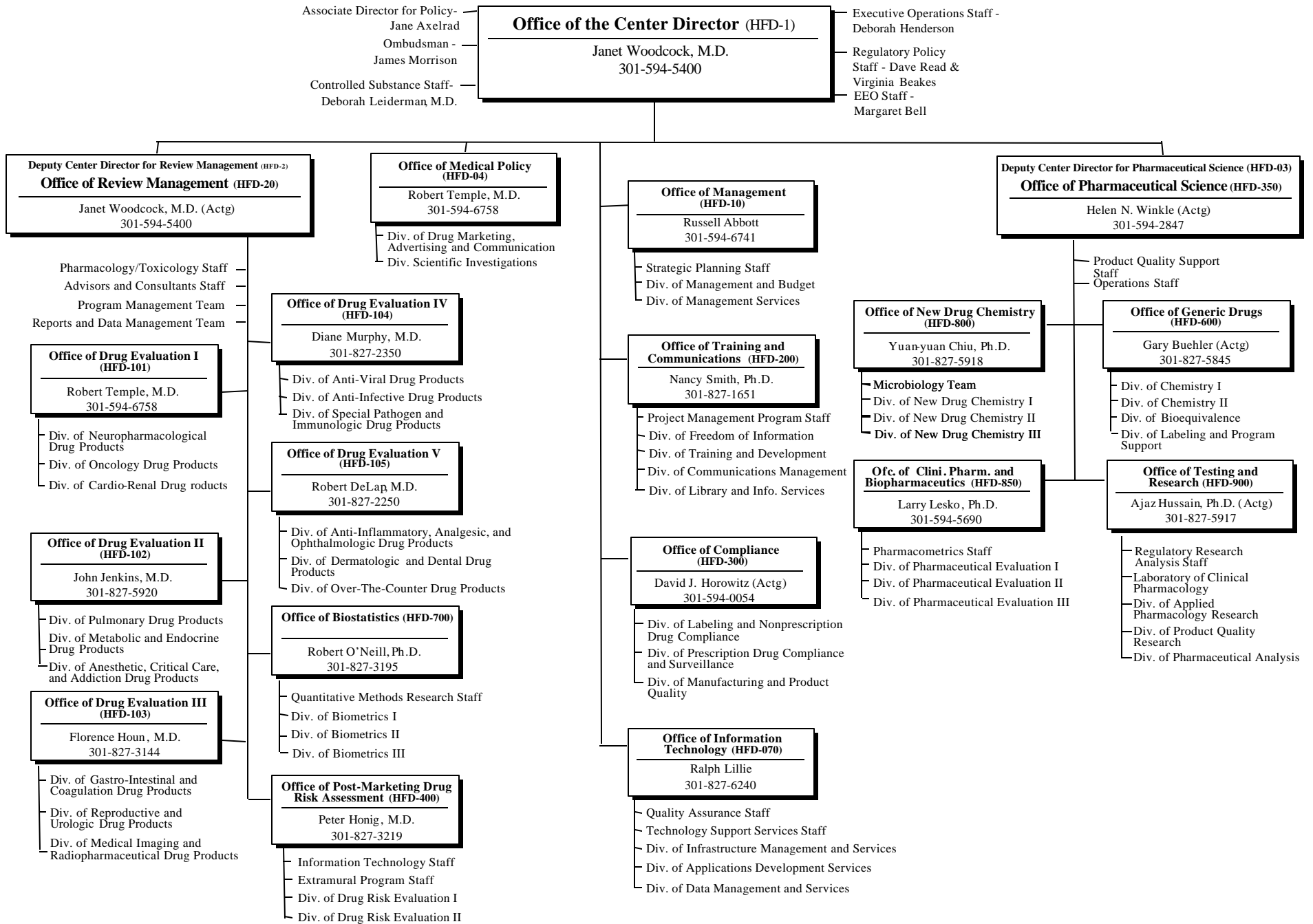


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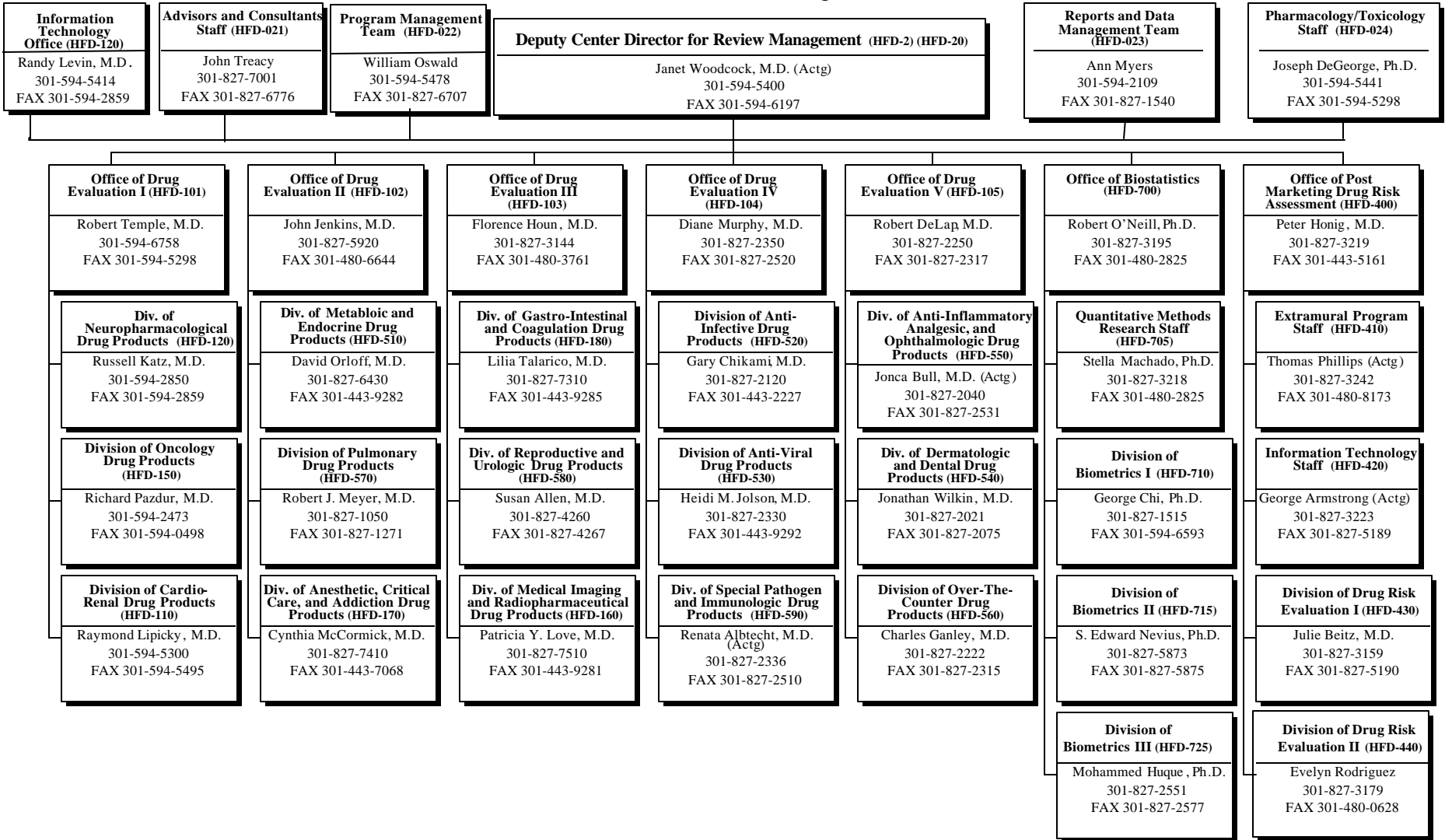
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Office of Review Management



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Note: * Reports to Deputy Commissioner
 ** Permanently assigned to ORA

New Organization
Effective 6/20/99

Commissioner of Food and Drugs
 Jane E. Henney
Deputy Commissioner
 Michael A. Friedman
 Senior Advisor for Science*

Office of the Senior Associate Commissioner
 Senior Associate Commissioner
 Linda Suydam

- Executive Secretariat
- Public Affairs
- Ombudsman
- Orphan Products
- Tobacco Programs
- Advisory Committee Oversight
- [Internal Affairs] **

Office of the Chief Counsel
 Chief Counsel
 Margaret J. Porter

Office of Equal Opportunity
 Director
 Rosamelia T. Lecea

Office of International and Constituent Relations
 Deputy Commissioner for International and Constituent Relations
 Sharon Smith Holston

- International Programs
- Consumer Affairs
- Special Health Issues
- Women's Health

Administrative Law Judge
 Administrative Law Judge
 Daniel J. Davidson

Office of Policy, Planning, and Legislation
 Senior Associate Commissioner for Policy, Planning, and Legislation
 William K. Hubbard

- Policy
- Planning
- Legislation
- Evaluation
- Policy Coordination
- Regulations Policy
- Management Initiatives
- Economics

Office of Management and Systems
 Deputy Commissioner for Management and Systems
 Robert J. Byrd

- Human Resources and Management Services
- Financial Management
- Facilities, Acquisitions, and Central Services
- Information Resources Management

Office of Regulatory Affairs
 Associate Commissioner
 Dennis F. Baker

National Center for Toxicological Research
 Director
 Bernard A. Schwetz

Center for Biologics Evaluation and Research
 Director
 Kathryn C. Zoon

Center for Drug Evaluation and Research
 Director
 Janet Woodcock

Center for Devices and Radiological Health
 Director
 David W. Feigal, Jr.

Center for Food Safety and Applied Nutrition
 Director
 Joseph A. Levitt

Center for Veterinary Medicine
 Director
 Stephen F. Sundlof

- Medwatch
- PDUFA Waivers
- Patent Term Restoration
- Scheduling of Controlled Subs. [from Health Affairs]
- Health Asses. Policy Staff