

ANATOMY OF A FDA FIELD OFFICE



Kansas City District



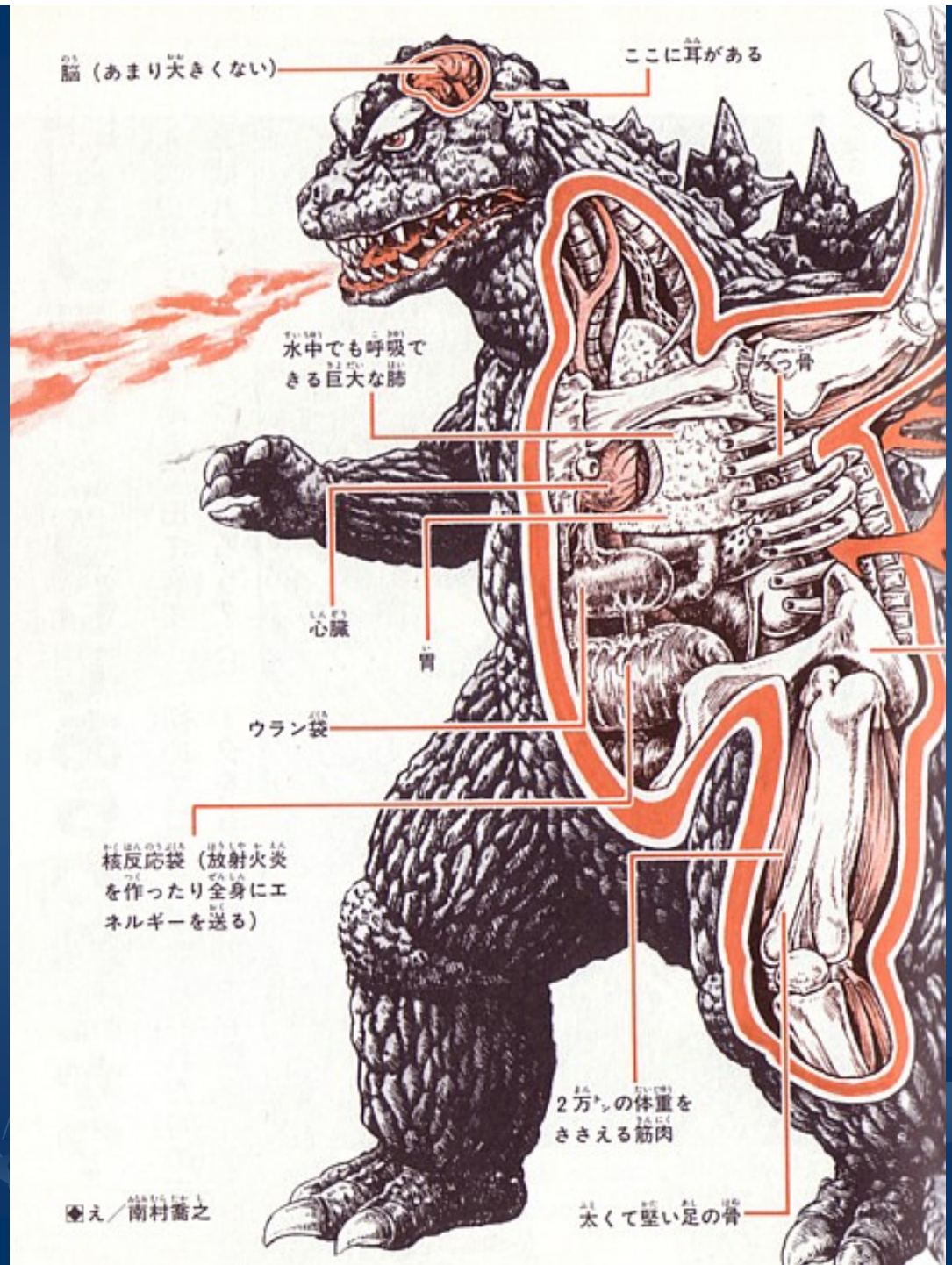
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One hypothesis...



What FDA regulates



Including, but not limited to:

BIOLOGIC PRODUCTS

- product and manufacturing establishment licensing
- safety of the nation's blood supply – inspections of blood banks, plasma centers & tissue banks
- research to establish product standards and develop improved testing methods

COSMETICS

- safety
- labeling
- inspections of manufacturers

DRUGS



- product approvals – center review and pre-approval inspections
- OTC and prescription drug labeling
- drug manufacturing standards
- post market surveillance inspections

FOODS

- labeling
- safety of all food products (except meat and poultry) – facility inspections
- bottled water

MEDICAL DEVICES

- premarket approval of new devices – center review
- manufacturing and performance standards
- tracking reports of device malfunctioning and serious adverse reactions
- post market inspections

RADIATION-EMITTING ELECTRONIC PRODUCTS

- radiation safety performance standards for microwave ovens, television receivers, diagnostic x-ray equipment, cabinet x-ray systems (such as baggage x-rays at airports), laser products, ultrasonic therapy equipment, mercury vapor lamps, and sunlamps
- accrediting and inspecting mammography facilities

VETERINARY PRODUCTS

- medicated and non-medicated livestock feeds
- pet foods
- veterinary drugs
- veterinary devices

MISCELLANEOUS

i.e. other duties as required

- baby turtles
- game meat
- chicken laying houses
- lead in dinnerware
- chewing gum
- tissue residues
- hard surface disinfectant
- toothpicks

What FDA Doesn't Regulate

- advertising
- alcohol
- consumer products – household goods
- drugs of abuse
- health insurance
- meat & poultry
- pesticides
- restaurant and grocery stores
- water

KANSAS CITY DISTRICT

Iowa

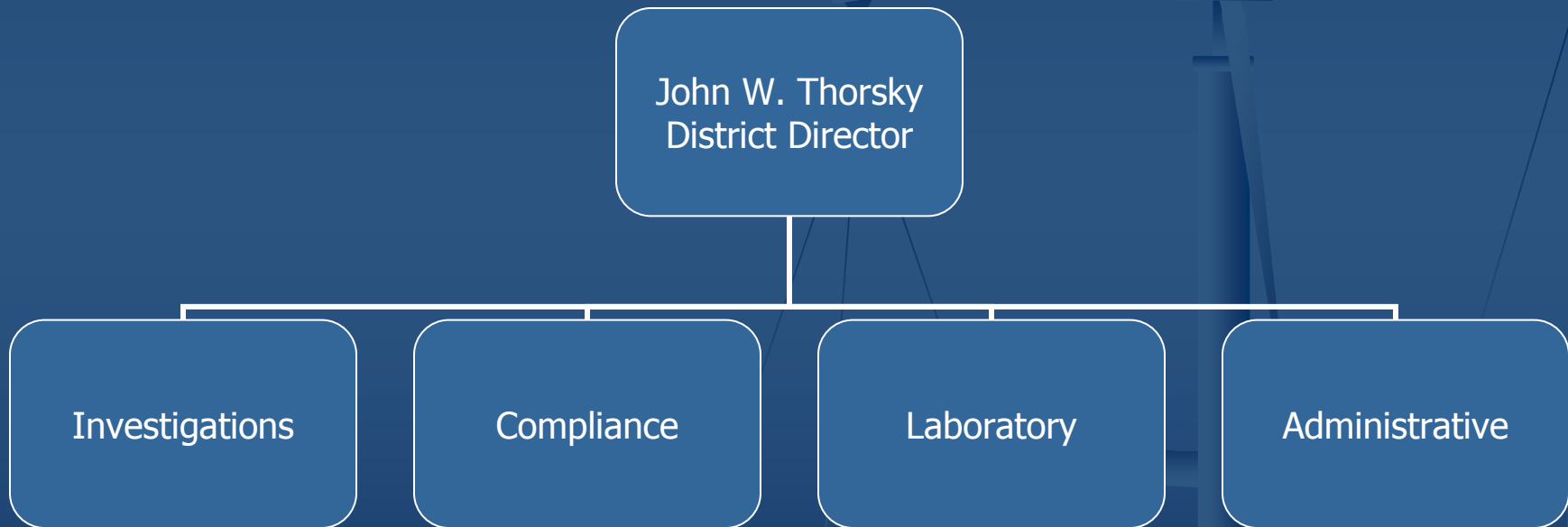
Kansas

Missouri

Nebraska

KANSAS CITY DISTRICT OFFICE

approximately 170 employees total



LABORATORY BRANCH

Director - Ann Adams

<u>Drug Lab:</u>	<u>Pesticides (GC) Lab:</u>	<u>Metals Lab:</u>	<u>Pesticides (LC) Lab:</u>	<u>Total Diet Pesticide Research Center</u>
Human/Animal Drugs Dioxins Filth – Food Sanitation and Feeds	Total Diet Pesticides (NonFat & Fat Items; CPA 's) Regulatory Pesticides – Human Foods (Domestic & Imports), Animal Feeds	Total Diet Toxic Elements Regulatory Toxic Elements – Food, Foodware	Total Diet Pesticides (ETU, Benomyl, Carbamates, Phenylureas & Acrylamides) VOCs Mycotoxins	Method Development
8 ANALYSTS	15 ANALYSTS	12 ANALYSTS	12 ANALYSTS	7 ANALYSTS


COMPLIANCE BRANCH

Director - C. R. Pendleton

- COMPLIANCE OFFICERS (5) - case review, draft Warning Letters & Untitled Letters; Judicial Action recommendations, 483 response letters
- RECALL COORDINATOR (1)
- LEGAL INSTRUMENT EXAMINERS (2) – Freedom of Information requests, public disclosure

Investigations Branch

Director – Gerald Bromley

Supervisor (KAN-DO)	Supervisor (KAN-DO)	Supervisor (KAN-DO & Omaha)	Supervisor (Springfield & STL)	Supervisor (KAN-DO & Wichita)	Supervisor (St. Louis)	Supervisor (Des Moines & Davenport)	Assistant Director
<i>9 or 10 CSO 1 Support Staff</i>	<i>9 or 10 CSO 1 Support Staff</i>	<i>9 or 10 CSO 1 Support Staff</i>	<i>9 or 10 CSO 1 Support Staff</i>	<i>9 or 10 CSO 1 Support Staff</i>	<i>9 or 10 CSO 1 Support Staff</i>	<i>9 or 10 CSO 1 Support Staff</i>	<i>1 support staff</i>
<u>Inspections of Medical Devices</u>	<u>Inspections of Interstate Travel Sanitation Program</u> <u>Dietary Supplements</u> <u>Medical Food</u>	<u>Inspections of Human Drugs</u>	<u>Inspections of Foods</u>	<u>Inspections of BSE</u> Medicated Animal Feeds Veterinary Drug 	<u>Inspections of Bioresearch Monitoring:</u> Clinical Investigators Institutional Review Boards	<u>Inspections of Biologics:</u> Blood Banks Plasma Centers Tissue Banks	Training Consumer Complaints
CDRH Medical Device Registration	State Food Contracts	CBER Drug Registration		CVM Licensing and Registration		CBER Registration	
				State BSE Med Feed Contracts			

WHAT IT TAKES TO BE A FDA INVESTIGATOR



- At least a Bachelors Degree in science
- Clean background record (driving, criminal and credit)
- First year of employment involves 6 weeks classroom training plus OJT
- Probationary period

DIFFERENT CATEGORIES OF INVESTIGATOR

- Level I Certified
- Level II Certified
- Pharmaceutical Inspectorate
- Specialist
- Generalist
- Supervisor

HIERARCHY OF REGULATION

Law

Regulation

Guidance Document



It really does take an act of Congress
for us to get anything done.