

FOIA MARKER

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Agency Submissions-FDA [Food & Drug Administration]

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FDA

Area: Therapeutic Agents

Goal: Ensure the safety and effectiveness of therapeutic agents

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constit Involve-ment	
			FY 1995	FY 1996 (proposed)			
Expedite access and approval of safe and effective drugs and biologics	Encourage quality applications and data submissions to review division to ensure timely and efficient pre- and postmarket review	Conduct meetings with sponsors to discuss drug development plans; expanded access programs; accelerated approval	25,235	25,536	All	All	N/A <i>enough staff?</i>

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What does this figure represent: cost of reviews? staff?

Area: Vaccines

Goal: Ensure the safety and effectiveness of immunization and therapeutic vaccines

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constit Involve-ment	
			FY 1995	FY 1996 (proposed)			
Expedite regulatory review of promising products for immunization and therapeutic vaccines	Expand partnership between FDA and its counterparts from outside organizations involved in vaccine development	Encourage early consultation; develop guidance documents; exchange information; and work with other agencies and international organizations	11,863	12,005	All	All <i>Constit. membership on FDA Advisory Boards</i>	N/A <i>2nd yr 6/84</i>

Area: Diagnostic Reagents/Test Kits

Goal: Ensure the effectiveness of test methodologies for HIV detection

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Expedite improved test methodologies for HIV detection, confirmation, and viral load	Ensure timely and efficient pre- and postmarket review	Encourage early consultation with sponsor and develop guidance documents	8,732	8,836	All	All <i>Bolud memberships</i>	N/A <i>more staff</i>

Area: Blood and Blood Products

Goal: Reduce transfusion-transmitted HIV infection

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constit. Involve-ment	
			FY 1995	FY 1996 (proposed)			
Ensure supply and safety of the national blood supply	Establish policies, expedite review of product applications, conduct approval inspections, establishment surveillance, and enforcement activities	Encourage high risk donors to exclude themselves; update list of unsuitable donors; quarantine and test blood; investigate incidents to identify and rectify common errors in blood banks	17,458	17,667	All	All	N/A

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Tom Study

Area: Medical Devices

Goal: Ensure the safety and effectiveness of HIV-related medical devices

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constit. Involvement	
			FY 1995	FY 1996 (proposed)			
Expedited access and approval of safe and effective medical devices	Encourage quality application and data submissions to ensure timely and efficient pre- and postmarket review	Conduct meetings with sponsors on study design; produce guidance documents	9,457	9,570	All	All <i>on any 2 boards?</i>	N/A <i>Staff</i>

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MEMORANDUM

Date: May 24, 1994

From: Associate Commissioner for AIDS and Special Health Issues

To: Arthur J. Lawrence, Ph.D.
Acting Director
National AIDS Program Office

Subject: Federal HIV/AIDS Research Compendium

The Office of AIDS and Special Health Issues has contacted the Offices and Centers within the Food and Drug Administration (FDA) to provide specific information on the FDA HIV/AIDS research programs to be included in the "Compendium of Federal HIV/AIDS Research Programs."

Our response, attached, follows the questions outlined in your April 22 note to AIDS Coordinators. Negative responses are included.

If you have any questions, please contact me or Donald Pohl of my staff at (301) 443-0104.

Randolph F. Wykoff, MD, MPH & TM

Attachment