Blood Action Plan

FDA/CBER is responsible for regulatory oversight of the U.S. blood supply. FDA promulgates and enforces standards for blood collection and for the manufacturing of blood products, including both transfusible components of whole blood, pharmaceuticals derived from blood cells or plasma, and related medical devices. FDA also inspects blood establishments and monitors reports of errors, accidents and adverse clinical events. CBER works closely with other parts of the Public Health Service (PHS) to establish blood standards, and to identify and respond to potential threats to blood safety or supply.

CBER initiated a Blood Action Plan in July 1997, to increase the effectiveness of its scientific and regulatory actions, and to ensure greater coordination with our PHS partners. The Action Plan addresses highly focused areas of concern such as emergency operations, response to emerging diseases, and updating of regulations. The Department of Health and Human Services (HHS) accepted this plan in March 1998. The plan is being jointly implemented by CBER, other FDA components (i.e., Office of Regulatory Affairs, Office of Chief Counsel, and Office of Policy), the Centers for Disease Control (CDC), the National Institutes of Health (NIH), and the Health Care Financing Administration (HCFA).

Documents published as part of the Blood Action Plan may be obtained at: www.fda.gov/cber/blood/bldpubs.htm.

ISSUE	Updating Blood Regulations
	FDA needs to update obsolete requirements, provide certain product standards, and convert some guidance into regulation.

PROPOSED SOLUTION	FDA will be undertaken to completely review, revise and rewrite the blood regulations.
NECESSARY STEPS	a) CBER will create a database of all regulations, guidance and other instructions for industry; b) CBER will create a list of needed, but currently non-existent regulations; c) FDA will prioritize the list; d) In the priority order each document will be reviewed, revised, up-dated written or rewritten; and e) CBER will explore ways of rapidly producing and disseminating new regulation to industry.
COMPLETED TASKS	a) The database of all existing documents was completed by September, 1997; b) The list of needed regulations was completed by September, 1997; c) An initial priority list was developed by October, 1997; d) The priority list will be reassessed annually to identify emerging needs; e) FDA has completed the list of highest priority regulations; and f) FDA published several proposed updates of the blood regulations by October 31, 1999.
PRESENT INITIATIVES	a) FDA is reviewing the comments to the proposed regulations; b) FDA is developing several additional regulations to incoporate existing guidance documents and identified needs; and c) FDA continues to assess and prioritize needed regulations.
OUTCOME	a) Reduce the number of exemptions to outdated regulations; b) Reduce the number of guidance documents lacking enforceability through regulations; and c) Increase Industry's compliance with standards.

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ISSUE	**Reinvention of Blood Regulation**
	The current application process is administratively complex and inefficient. There is a need to develop streamlined application procedures and to increase self-auditing of quality assurance by industry.

PROPOSED SOLUTION	Implement a simplified Biologics License Application (BLA) for blood products in lieu of application review. In addition, develop product and manufacturing standards. Educate the industry and take effective compliance actions to insure adequate quality assurance and full compliance with good manufacturing practices by the industry.
NECESSARY STEPS	a) CBER will develop the information technology infrastructure to support introduction of a simplified BLA; b) FDA will identify the manufacturing and product standards for blood products for which regulatory standards and regulations would be appropriate in lieu of application submissions; and c)FDA will develop an industry education and compliance program to support expedited application review and industry's full compliance with GMPs.
COMPLETED TASKS	a) The first phase was to implement a simplified BLA. This was completed prior to December 1999. CBER has also written and published guidance for industry on how to use the simplified BLA for both plasma derivatives and blood components; b) The second phase was to develop additional manufacturing and product standards in lieu of detailed application submissions. An inventory of suitable product standards and procedures has been developed. A proposed pilot program for Gamma Irradiation of Blood and Blood Products was published January 1998 to determine the feasibility of this approach. The final rule for this pilot program was published in March 1999.
PRESENT INITIATIVES	a) A proposed pilot program for Red Blood Cell Immunization is being developed; b) If these pilot programs are successful other programs which contain suitable standards and procedures will be added.
OUTCOME	a) More rapid and efficient application review; b)Decreased number of submissions to FDA; and c)Improved execution of GMPs and quality assurance by the industry.

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ISSUE	**Emerging Infectious Diseases**
	There are constantly emerging potential threats to the blood supply which require timely action and a coordinated approach. Examples include new HIV variants; new hepatitis agents; human herpes virus type 8; Creutzfeld-Jakob Disease; human parvovirus B19; and bacterial contamination of blood products.
PROPOSED SOLUTION	A specific scientific and regulatory strategy will be developed for each identified potential threat. The agency, in collaboration with CDC and NIH, will actively engage in the scientific investigation of the emerging infectious agents, which would include assessment of the risk to the blood supply, diagnostic methods, standards development, and regulatory controls.

NECESSARY STEPS	a) CBER will develop and maintain a database characterizing the effort underway to manage potential threats to the blood supply; b) FDA will work closely with NIH and CDC to develop for each recognized emerging agent strategies that lead to appropriate studies, risk assessment, communication, and any needed prevention strategies or regulatory controls to protect the blood supply; c) Proposed prevention strategies or regulatory controls will be brought to public meetings and Advisory Committees as appropriate to assess implementation proposals; and d) CBER will meet with PHS agency and other public representatives to discuss current risk assessment every 6 months.
COMPLETED TASKS	a) A current database of potential threats to the blood supply has been developed and includes appropriate teams to address each threat; b) Proposed regulatory actions will be presented as appropriate at the monthly conference call. c) A chronicle of actions taken by PHS Agencies, since the beginning of the Blood Action Plan, has been developed.
PRESENT INITIATIVES	The chronicle of actions taken by PHS Agencies will be reviewed and updated annually.
OUTCOME	a) Improved coordination of FDA efforts with other PHS efforts to address emerging infectious diseases, and b) Prevention of transfusion transmitted disease.

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ISSUE	**Insuring Compliance of Plasma Fractionation Establishments**
	The routine inspection of blood and plasma collection establishments has been the responsibility of ORA for many years. As part of a broader plan to transfer responsibilities for biologic inspections to the field the responsibility for inspection of plasma fractionators has been transferred effective November 1996. Additional training in compliance needs to be developed to enhance the transfer.
PROPOSED SOLUTION	a) Complete the transfer of the biologics inspection to ORA; b) Program guidance will be developed and training will be planned and conducted; and c) A systematic process for reviewing all blood related inspectional findings will be developed to assure that any industry wide problems are quickly identified and addressed.

NECESSARY STEPS	a) FDA will complete draft Team Biologics Action Plan; b) FDA will implement Team Blood as defined in the Team Biologics plan; c) FDA staff will be trained in the newly defined procedures and develop compliance programs as needed to implement Team Blood; and d) The existing transition will require periodic oversight. The Deputy Director, CBER and the ACRA will meet with appropriate staff until all blood related regulatory activities are in conformance with ORA standards.
COMPLETED TASKS	a) The Team Biologics Implementation Plan has been completed; b) Team Blood has been implemented; and c) All Fractionation and Blood Establishments have been inspected by the appropriate cadre of investigators.
OUTCOME	a) Improve industry compliance with FDA regulations, and b) Improve agency consistency and efficiency in compliance actions.

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ISSUE	**Notification and Lookback**
	Recipients of blood and plasma products are not routinely notified in a timely manner when products are recalled. Permanently deferred donors are not routinely notified of the medical conditions resulting in their deferral. Current look-back requirements address only a narrow range of conditions.
PROPOSED SOLUTION	a) FDA will develop regulations and other effective strategies that will clarify the responsibility of industry to be able to notify product end-users in recall and look-back situations; b) FDA will re-evaluate the circumstances under which direct patient notification is appropriate; and c) CBER will develop regulations to require medical notification of permanently deferred donors. *(Assigned to the updating Blood Regulations Group)*
NECESSARY STEPS	a) Regulations will be written by FDA that require adequate record keeping and an effective mechanism to identify and notify recipients when a product is implicated in a health hazard; b) Regulations will be written that require "look-back" for relevant infectious agents. The list of "relevant" infectious agents will be developed by a team of FDA, NIH, and CDC scientists and reviewed by the appropriate Advisory Committees; and c) CBER will develop a regulation for notification of permanently deferred donors. *(Assigned to the Updating Blood Regulations Group)*

COMPLETED TASKS	a) A notice of proposed rulemaking for "recipient notification" was published by FDA August 19, 1999; b) The list of relevant infectious agents potentially qualifying for "look-back" was developed by an interagency team and presented to appropriate Advisory Committees. The proposed regulation was published by FDA on August 19, 1999; c) FDA has published proposed regulations for the notification of permanently deferred donors on August 19, 1999. *(Assigned to the Updating Blood Regulations Group)*
PRESENT INITIATIVES	Comments to the proposed regulations are being reviewed.
OUTCOME	a) Donors are notified of their medical deferral leading to opportunities for treatment and reduced secondary transmission, and b) Recipients are notified of potential transfusion related risks leading to opportunities for treatment and reduced secondary transmission.

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ISSUE	**FDA Response to Emergencies and Class I Recalls Affecting Blood Safety**
	FDA needs to use standardized procedures for handling emergencies affecting blood safety.
PROPOSED SOLUTION	FDA needs to implement a standardized procedure for managing emergencies related to blood safety.
NECESSARY STEPS	a) Finalize emergency procedures and develop checklists where useful; b) Train FDA staff; c) Systematically evaluate FDA's response to blood emergencies to assure that the process functioned smoothly and appropriately; and d) Early decisions on Class I product recalls.
COMPLETED TASKS	a) Procedures for responses to Emergencies and Class I recalls have been finalized; b) FDA staff has been educated in the changes made in handling emergency operations; and c) A team of senior managers to conduct systematic reviews of blood emergencies has been selected.
OUTCOME	a) Increase speed, efficiency, and coordination of FDA response to an emergency affecting blood safety, and b) Enhanced public health protection in the face of threats to blood safety.

ISSUE	Monitoring and Increasing the Blood Supply
	PHS Agencies need to monitor and evaluate the adequacy of the blood supply and take steps to increase supplies as required.
PROPOSED SOLUTION	PHS Agencies will establish and oversee data collection mechanisms to permit timely prediction of blood shortages. PHS Agencies will develop and implement strategies to increase the blood supply.
NECESSARY STEPS	a) Monitor the blood supply; b) Encourage more donations by eligible donors; c) Improve donor relations as part of recruitment and retention; d) Remove restrictions to safe donation; and e) Address economic issues facing the blood industry.
COMPLETED TASKS	a) NHLBI has funded a pilot monthly surveillance program for three years starting in November 1999; b) DHHS is committed to continue to encourage and cooperate with coordinated private sector initiatives on public service announcements related to blood donor campaigns. Senior health officials have met with industry to develop a general statement concerning the national blood supply. DHHS has developed a plan to enlist national philanthropic and other private sector organizations to take a lead role in promoting blood donations at times of shortage; c) The first workshop on Donor Incentives was held February 28, 2000; d) NHLBI has had internal discussions to explore the feasibility of initiating studies on the development of educational programs to encourage blood donation as a civic responsibility; and e) The first joint CDC/FDA workshop concerning donor suitability issues was held on June 26-27, 2000.
PRESENT INITIATIVES	a) A decision will be made within PHS by October 1, 2001 whether to create a long term PHS Agency responsibility for monitoring the blood supply. b) FDA will publish guidance on use of Donor Incentives. c) NHLBI will continue to support evaluation of blood donor incentive models to encourage donation through workshops and studies to be completed by October 1, 2002. d) FDA will issue draft guidance to industry on recruitment practices. e) Based on the results of ongoing NHLBI supported research, FDA will issue guidance on use of computer assisted interviews.

	f) FDA will coordinate a joint government/industry initiative on simplifying and abbreviating the donor questionnaire to commence by January 1, 2001. A workshop to discuss the donor questionnaire issues will be held October 16, 2000. g) FDA will issue guidance on labeling and frequency exemptions for therapeutic hemochromatosis donations. h) As funds permit, CDC and FDA have agreed to continue to co-sponsor workshops in FY2000 and FY 2001 to determine the safety and efficacy of policy changes regarding current donor suitability criteria, test requirements and reentry. Where feasible, FDA will issue guidance to eliminate unnecessary restrictions. i) FDA and NHLBI will co-sponsor a workshop with industry to identify and define "best practices" in donor recruitment on July 6-7, 2000. j) PHS is committed to bring to discussion at the PHS AC BSA potential safety measures with significant cost implications. Funding strategies to address implementation of NAT screening and leukoreduction are being addressed. DHHS is working to clarify policies on reimbursement for blood services and products.
OUTCOME	a) Improve the ability to predict and respond to blood shortages; and b) Increase the availability and elasticity of the blood supply.

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Questions/Comments about the Blood Action Plan, send e-mail to BAP@CBER.FDA.GOV

Privacy Statement

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