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September 20, 2007

The Honorable Edward M. Kennedy
Chairman
The Honorable Michael B. Enzi
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable John D. Dingell
Chairman
The Honorable Joe Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting Hepatitis C Virus Infection ("Lookback")*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Food and Drug Administration (FDA), entitled "Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting Hepatitis C Virus Infection ("Lookback")" (RIN: 0910-AB76). We received the rule on September 5, 2007. It was published in the *Federal Register* as a final rule on August 24, 2007. 72 Fed. Reg. 48,766.

The final rule requires entities collecting blood or blood components to establish, maintain, and follow an appropriate "lookback" system for identifying prior blood and blood components previously donated by someone who later tests reactive for evidence of hepatitis C virus (HCV) infection. The rule requires collection entities to quarantine blood and blood components from such a donor, to notify consignees, and to perform further testing on the donor. The rule also requires, as appropriate, consignees to notify transfusion recipients of blood or blood components donated by such a donor. In addition, this final rule revises the human immunodeficiency (HIV)

"lookback" requirements to be consistent with the HCV "lookback" requirements, and it extends the record retention period to 10 years.

Enclosed is our assessment of the FDA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review indicates that the FDA complied with the applicable requirements.

If you have any questions about this report, please contact Michael R. Volpe, Assistant General Counsel, at (202) 512-8236. The official responsible for GAO evaluation work relating to the subject matter of the rule is Marjorie Kanof, Managing Director, Health Care. Ms. Kanof can be reached at (202) 512-7114.

signed

Robert J. Cramer
Associate General Counsel

Enclosure

cc: Edwin V. Dutra, Jr.
Director, Regulations Policy and
Management Staff
Food and Drug Administration
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS; NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HEPATITIS C VIRUS INFECTION ("LOOKBACK")"
(RIN: 0910-AB76)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) performed an analysis of the costs and benefits of this final rule. FDA estimates that the total annualized costs will be approximately $10.3 million and the net annualized benefits will be between $20.6 million and $133.6 million with a 3 percent discount rate over 10 years.

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603–605, 607, and 609

According to FDA, this final rule will not have a significant effect on a substantial number of small entities.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

According to FDA, this final rule will not create any intergovernmental or private sector mandates that would be great enough to trigger a written assessment under the Act.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

FDA promulgated this rule under the notice-and-comment procedures found in the Administrative Procedure Act. 5 U.S.C. § 553. FDA published a proposed rule on November 16, 2000. 65 Fed. Reg. 69,378. FDA received comments from 12 entities, to which it responded in the final rule. 72 Fed. Reg. 48,771–78. This rule has an effective date of February 20, 2008.

Paperwork Reduction Act, 44 U.S.C. §§ 3501–3520

This final rule contains information collection requirements requiring the approval of the Office of Management and Budget (OMB) under the Act. FDA has submitted these information collections to OMB. The title of the information collection is "Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting Hepatitis C Virus Infection ("Lookback")." FDA estimates that the total reporting and recordkeeping burden for the first year at 495,309.5 hours and the ongoing annual burden at 39,029.5 hours.

Statutory authorization for the rule

FDA promulgated this final rule under sections 351 and 361 of the Public Health Service Act and various sections of the Federal Food, Drug, and Cosmetic Act. 42 U.S.C. §§ 262, 264; 21 U.S.C. 321 et seq.

Executive Order No. 12,866

FDA determined that this final rule is economically significant under the order. FDA performed an analysis of the costs and benefits of this final rule. FDA estimates that the total annualized costs will be approximately $10.3 million and the net annualized benefits will be between $20.6 and $133.6 million with a 3 percent discount rate over 10 years. FDA considered alternatives in conducting this rulemaking.

Executive Order No. 13,132 (Federalism)

According to FDA, this final rule does not have federalism implications under the order.