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United States General Accounting Office  
Washington, DC 20548

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B-292460

June 25, 2003

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

The Honorable W.J. "Billy" Tauzin  
Chairman  
The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Energy and Commerce  
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration:  
Applications for FDA Approval to Market a New Drug: Patent Submission  
and Listing Requirements and Application of 30-Month Stays on Approval of  
Abbreviated New Drug Applications Certifying That a Patent Claiming a  
Drug Is Invalid or Will Not Be Infringed*

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 "Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed" (RIN: 0910-AC48). We received the rule on June 18, 2003. It was published in the Federal Register as a final rule on June 18, 2003. 68 Fed. Reg. 36676.

The final rule amends FDA's patent submission and listing requirements for new drug applications (NDAs). It clarifies the types of patents that must and must not be submitted and revises the declaration that NDA applicants must provide regarding their patents to help ensure that NDA applicants submit only appropriate patents. The rule, among other things, states that there is only one opportunity for a 30-month stay in the approval date of each abbreviated new drug application and section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act application.

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 James W. Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation work relating to the subject matter of the rule is William Scanlon, Managing Director, Health Care. Mr. Scanlon can be reached at (202) 512-7114.

signed

Kathleen E. Wannisky  
Managing Associate General Counsel

Enclosure

cc: Ann Stallion  
Regulations Coordinator  
Department of Health and  
Human Services

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE  
ISSUED BY THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
FOOD AND DRUG ADMINISTRATION  
ENTITLED  
"APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG:  
PATENT SUBMISSION AND LISTING REQUIREMENTS AND  
APPLICATION OF 30-MONTH STAYS ON APPROVAL OF  
ABBREVIATED NEW DRUG APPLICATIONS CERTIFYING  
THAT A PATENT CLAIMING A DRUG IS INVALID  
OR WILL NOT BE INFRINGED"  
(RIN: 0910-AC48)

(i) Cost-benefit analysis

The FDA has estimated the 10-year cost of the final rule to be \$51.584 billion and the annualized cost to be \$4.871 billion. The 10-year benefit is estimated to be \$53.940 billion and the annualized benefit is \$5.093 billion.

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

The Commissioner of FDA has certified that the final rule will not have a significant economic impact 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

The final rule contains a mandate on the private sector of more than \$100 million in any one year and the FDA has prepared the required statement as part of its economic impact analysis, which is contained in the preamble to the final rule.

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

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

The final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On October 24, 2002, the FDA published a Notice of Proposed Rulemaking in the Federal Register. 67 Fed. Reg. 65448. In response, the FDA received over 35 comments that are discussed in the preamble to the final rule.

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

The final rule contains several information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. According to the data submitted to OMB, the FDA estimates the total annual burden for all the collections to be 499,805 hours.

Statutory authorization for the rule

The final rule is promulgated under the authority found in section 505 of the Federal Food, Drug, and Cosmetic Act and the FDA's general rulemaking authority in section 701(a) of the Act (21 U.S.C. 371).

Executive Order No. 12866

The final rule was reviewed by OMB and found to be an "economically significant" regulatory action under the order.

Executive Order No. 13132 (Federalism)

The FDA has found that the final rule does not have sufficient federalism implications to require a federalism summary impact statement.