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October 23, 2013

The Honorable Tom Harkin
Chairman
The Honorable Lamar Alexander
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Unique Device Identification System*

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 "Unique Device Identification System" (RIN: 0910-AG31). We received the rule on September 24, 2013. It was published in the *Federal Register* as a final rule on September 24, 2013. 78 Fed. Reg. 58,786.

The final rule requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement. The labeler must submit product information concerning devices to FDA's Global Unique Device Identification Database, unless subject to an exception or alternative. The system established by this rule requires the label and device package of each medical device to include a UDI and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture technology. The UDI will be required to be directly marked on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

The Congressional Review Act requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). This final rule was published and received on September 24, 2013. In general, this rule has a stated effective date of December 23, 2013. However, the rule states that six provisions (sections 801.55, 830.10, 830.100, 830.110, 830.120, and 830.130) have an effective date of October 24, 2013. Further, according to the final rule, several provisions of the rule have compliance dates later than the effective date, including section 801.55. To the extent that any provisions of this final rule would purport to take effect on October 24, 2013, those provisions do not have the required 60-day delay.

Enclosed is our assessment of 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 of the procedural steps taken indicates that FDA complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Kenneth Cohen
Director, Regulations Policy and Management Staff
Food and Drug Administration
Department of Health and Human Services

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
"UNIQUE DEVICE IDENTIFICATION SYSTEM"
(RIN: 0910-AG31)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) analyzed the costs and benefits of this final rule. FDA determined that the final rule will have the qualitative benefit of more accurate and prompt identification of device-related adverse events, which should lead to more rapid actions to reduce the incidence of the adverse events and to more effectively targeting and managing medical device recalls. FDA estimates the total present value of the domestic costs of this rule over 10 years will be \$642.2 million using a 7 percent discount rate and \$737.7 million using a 3 percent rate. FDA also estimates that the total annualized costs will be \$85.7 million using a 7 percent discount rate and \$84.1 million using a 3 percent discount rate.

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

FDA determined that the potential impact of this final rule on some small entities may be significant, and, therefore, prepared a regulatory flexibility analysis. According to that analysis, about 96 percent of domestic labelers are small firms according to Small Business Administration size standards. The average annualized costs of compliance for domestic labelers as a percentage of annual receipts exceed 1 percent for about 32 firms with fewer than 19 employees that label multiple-use devices subject to the direct marking requirements. Without direct marking, the impact on small firms does not exceed 1 percent of average annual receipts.

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

FDA determined that the estimated costs for this final rule will exceed the \$100 million (\$141 million adjusted for inflation) threshold under the Act.

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

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

On July 10, 2012, FDA published a proposed rule. 77 Fed. Reg. 40,736. On November 19, 2012, FDA published an amendment to the proposed rule. 77 Fed. Reg. 69,393. FDA received approximately 270 submissions of comments from approximately 225 sources including individuals (health care professionals, academics, consumers, and others), organizations (consumer groups, hospitals, health care associations, military and government sources, and others), and private industry (device manufacturers, industry associations, distributors, and

others). These comments provided approximately 1,700 pages of feedback and commentary concerning the proposed rule. FDA responded to comments in the final rule.

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

FDA determined that this final rule contains information collection requirements under the Act with the title “Unique Device Identification System” and Office of Management and Budget (OMB) Control Number 0910-0720. FDA estimated the total first-year burdens to be 2,662 hours for reporting, 11,055 hours for recordkeeping, 23,790 hours for third-party disclosure related to the unique device identifier, and 623,298 hours for third-party disclosure related to date format. FDA also estimated the total ongoing annual burdens to be 7,289 hours for reporting, 302,121 hours for recordkeeping, and 270,143 hours for third-party disclosure.

Statutory authorization for the rule

FDA promulgated this final rule under the authority of sections 502, 510, 519, and 701 of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. §§ 352, 360, 360i, 371.

Executive Order No. 12,866 (Regulatory Planning and Review)

FDA determined that this final rule is economically significant under the Order.

Executive Order No. 13,132 (Federalism)

FDA determined that this final rule does not contain policies that would have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.