Department of Health and Human Services, Food and Drug Administration: Importation of Prescription Drugs

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 "Importation of Prescription Drugs" (RIN: 0910-AI45). We received the rule on October 22, 2020. It was published in the Federal Register as a final rule on October 1, 2020. 85 Fed. Reg. 62094. The effective date of the final rule is November 30, 2020.

The final rule implements section 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act to allow importation of certain prescription drugs from Canada. Pub. L. No. 75-717, 52 Stat. 1040 (June 25, 1938). Under the rule, according to FDA, states and Indian Tribes, and, in certain future circumstances, pharmacists and wholesalers, may submit importation program proposals to FDA for review and authorization. FDA states that the rule contains all requirements necessary for a sponsor to demonstrate that their importation program will pose no additional risk to the public's health and safety, and requires that the sponsor explain how they will ensure their program will result in a significant reduction in the cost of covered products to the American consumer.

The Congressional Review Act (CRA) 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). The final rule was published in the Federal Register on October 1, 2020. 85 Fed. Reg. 62094. The Congressional Record does not indicate that either House of Congress received the rule. According to FDA, the rule was delivered to each House of Congress on October 23, 2020. Email from Regulations, Policy & Management Staff, FDA, to Senior Attorney, GAO (Nov. 5, 2020). The rule has an effective date of November 30, 2020. Therefore, the final rule does not have the required 60-day delay in effective date.
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. 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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Kenneth Cole  
Director, Regulations Policy and Management Staff, FDA  
Department of Health and Human Services
(i) Cost-benefit analysis

The Food and Drug Administration (FDA) stated the costs of this final rule include costs incurred by the federal government to implement the final rule and conduct oversight of authorized programs, and costs incurred by section 804 importation program (SIP) sponsors to prepare proposals, implement approved programs, and produce records and program reports. According to FDA, SIPs may offer cost savings to patients, as well as participating wholesale drug distributors, pharmacies, hospitals, and third-party payers. FDA stated that it was unable to estimate the present and annualized values of the costs and savings of the rule over an infinite time horizon because it lacked information about the likely size and scope of SIPs, the specific prescription drug products that may become eligible for importation, which eligible prescription drugs are produced by United States-based manufacturers, and the degree to which these imported drugs will be less expensive than non-imported drugs available in the United States.

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

FDA stated that because it does not have enough information about the effect of this final rule on small entities, it is not certifying that the 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

FDA determined that this final rule will not result in an expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. FDA concluded that the current threshold after adjustment for inflation is $156 million by using the most current (2019) Implicit Price Deflator for the Gross Domestic Product, and stated that this rule will not result in an expenditure in any year that meets or exceeds this amount.

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

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

On December 23, 2019, FDA published a proposed rule. 84 Fed. Reg. 70796. FDA stated it received over 1,200 comment letters on the proposed rule from consumers, consumer groups, trade organizations, industry, public health organizations, public advocacy groups, states, Canadian entities (including governmental agencies), and others. FDA responded to comments in this final rule.
Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501-3520

FDA determined that this final rule contains information collection requirements under PRA. FDA stated that the information collection requirements have been submitted to the Office of Management and Budget for review. FDA estimated an annual reporting burden of 4,680 hours; an annual recordkeeping burden of 1,240 hours; and an annual third-party disclosure burden of 480 hours.

Statutory authorization for the rule

FDA promulgated this final rule pursuant to sections 1333, 1453, 1454, 1455, and 4402 of title 15, United States Code; sections 1490 and 1491 of title 19, United States Code; sections 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 351, 352, 353, 355, 360, 360b, 360ccc, 360ccc-1, 360ccc-2, 360eee-1, 362, 371, 373, 374, 379j-31, 381, 382, 384, 384a, 384b, 384d, 387, 387a, 387c, and 393 of title 21, United States Code; sections 216, 241, 243, 262, 264, and 271 of title 42, United States Code; Public Law 107-188; and Public Law 111-353.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA stated that this final rule has been designated as a significant regulatory action as defined by the Order.

Executive Order No. 13132 (Federalism)

FDA determined that this final rule does not contain policies that have substantial direct effects on 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. FDA concluded that the rule does not contain policies that have federalism implications as defined in the Order.