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May 16, 2008

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:
Substances Prohibited From Use in Animal Food or Feed*

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 "Substances Prohibited From Use in Animal Food or Feed" (RIN: 0910-AF46). We received the rule on May 2, 2008. It was published in the *Federal Register* as a final rule on April 25, 2008. 73 Fed. Reg. 22,720.

The final rule prohibits the use of certain cattle origin materials in the food or feed of all animals to further reduce the risk of the spread of bovine spongiform encephalopathy (BSE) within the United States. FDA states that the intent of the final rule is to strengthen the safeguards designed to prevent the spread of BSE in U.S. cattle, as well as to reduce further any risk posed to humans from the agent that causes BSE. The final rule is effective on April 27, 2009.

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 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 Michael R. Volpe, Assistant General Counsel, at (202) 512-8236.

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

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
"SUBSTANCES PROHIBITED FROM USE IN
ANIMAL FOOD OR FEED"
(RIN: 0910-AF46)

(i) Cost-benefit analysis

FDA performed a cost-benefit analysis of the final rule. FDA stated that although the animal and public health benefit associated with the additional BSE risk reduction is paramount, the U.S. economy may also benefit from regained market access in countries that remain fully or partially closed to U.S. beef and beef products to the extent that the final rule persuades foreign governments that more U.S. beef products are safe to import. FDA estimates that the recurring costs and capital costs are approximately \$100 million. FDA also included a table of annualized and incremental costs associated with two regulatory alternatives.

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

FDA determined that the final rule will have a significant impact on a substantial number of small entities. Therefore, FDA prepared a final regulatory flexibility analysis that complies with the requirements of the Act; for example, FDA considered regulatory alternatives that would reduce the impact on small businesses.

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

FDA concludes that the final rule imposes no mandates on government entities, and does not require the expenditure of over \$122 million in any one year by the private sector.

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

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

On October 6, 2005, FDA published a Notice of Proposed Rulemaking and Request for Comment in the *Federal Register* regarding the proposed rule on substances prohibited from use in animal food or feed. 70 Fed. Reg. 58,570. FDA received

more than 840 comments on the proposed rule and responds to those comments in the final rule.

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

The final rule contains information collection provisions that were submitted to the Office of Management and Budget (OMB) for review under the Act. Prior to the effective date of the final rule, FDA will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule.

Statutory authorization for the rule

The final rule is promulgated under the authority of 21 U.S.C. §§ 321, 342, 343, 348, and 371.

Executive Order No. 12,866

FDA finds that the final rule constitutes an economically significant regulatory action as defined in Executive Order 12,866 because the sum of the recurring costs and capital costs that could be incurred in one year rounds to \$100 million.

Executive Order No. 13,132 (Federalism)

FDA determined that the final rule does not contain policies that 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.