consider a manufacturer's basis for claiming GRAS status and suitability for use in meat or poultry products. In such cases, FSIS would make the determination in consultation with FDA as needed to ensure that appropriate advice is given and that FDA has notice of the determination.

This proposal would require, and lead to, greater harmonization, i.e., closer and more consistent cooperation, between FDA and FSIS. The agencies propose to enter into a memorandum of understanding (MOU) concerning the specifics of the agencies' working relationship under the proposed regulations. A draft of the MOU is appended to the FSIS proposal appearing elsewhere in this issue of the Federal Register.

FSIS and FDA believe that the public will be better served by having all permitted uses for food additives, color additives, and GRAS substances consolidated in one place—in Title 21 CFR—and intend to work toward that end. However, existing regulations on specific substances and substance uses in Titles 9 and 21 CFR would not be immediately affected by this proposal. Because of resource constraints, current FDA regulations would be amended to accommodate meat and poultry uses only in response to a food additive, color additive, or GRAS petition. FSIS will review its listings accordingly and eliminate those that are redundant with FDA's Title 21 listings.

This proposed rule would amend FDA regulations to provide for: (1) Specifying any meat, meat food product, or poultry product uses of substances approved by FDA for food use and listed in 21 CFR; and (2) petitioning FDA for listing in 21 CFR of substances intended to be used in meat, meat food products, or poultry products. FDA's regulations would be amended so that all petitions to permit new substances, new uses, or new use levels of substances in meat, meat food products, or poultry products would be filed only with FDA. FDA's regulations governing color additive petitions, petitions to affirm substances as GRAS, and food additive petitions in parts 71, 170, and 171 (21 CFR parts 71, 170, and 171), respectively, would be revised to provide for joint review by FSIS of petitions filed with FDA that propose use of the substance in meat or poultry products. (In the agencies' view, it is the petitioner's burden to identify the intended meat and poultry uses of a substance.)

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule to amend 21 CFR parts 71, 170, and 171 under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires analysis of options for regulatory relief for small entities.

The principal benefit of this proposed rule is to eliminate duplicative Federal effort. Under the proposed amendments and amendments FSIS is concurrently proposing to its regulations published elsewhere in this issue of the Federal Register, separate petitions to FSIS for use of substances in meat or poultry products would no longer be required. Obtaining approval for the use in meat and poultry products of new substances or for new uses of previously approved substances would be simpler, faster, and less costly for both industry and the Federal Government than under the current system.

With this proposed rule, those substances *not* authorized for meat and poultry use under existing FDA regulations would require only one petition for rulemaking—to FDA. (For a substance that is not affirmed as GRAS by FDA or otherwise listed in 21 CFR part 182 or 184, or a substance listed by FDA for general food use, FSIS would continue to consider the manufacturer's basis for claiming GRAS status of the substance and its suitability for a specified use in meat or poultry products.) Furthermore, all users of the Federal regulations concerning the addition of substances to foods should benefit by having fewer, clearer regulations. Thus, there would be a reduction in the duplication of effort and attendant costs for all concerned.

Therefore, FDA finds that this proposed rule would not have a significant adverse economic impact. In addition, FDA certifies that there is not a significant impact on a substantial number of small entities.

Nevertheless, this proposed rule has been deemed by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget to be a significant regulatory action as defined by section 3(f)(4) of Executive Order 12866 because it raises novel legal and/or policy issues arising out of the President's priorities, namely the reinvention of government and regulatory reform initiatives. Therefore, this proposed rule has been formally reviewed by OIRA in accordance with the provisions of Executive Order 12866.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Information collection requirements have been approved by OMB for color additive petitions, petitions to affirm substances as GRAS, and food additive petitions under OMB Nos. 0910–0185, 0910–0132, and 0910–0016, respectively. FDA has determined that the proposed rulemaking would entail no new information collection from the regulated industry or other private entities. Persons seeking Federal Government approval of substances for use in meat or poultry foods would not have to submit any information not currently required for approval. However, such persons would only have to submit petitions to FDA, rather than to both FDA and FSIS, as they do now. Thus, a current, duplicative information collection requirement would be eliminated.

FDA requests comments regarding its tentative conclusions on the paperwork burden.

VI. Comments

Interested persons may, on or before March 14, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 71

Administrative practice and procedure, Color additives, Confidential business information, Cosmetics, Drugs, Reporting and recordkeeping requirements.