U.S. Small Business Administration
Office of Advocacy

Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act, Calendar Year 1996

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To the President and Congress of the United States:

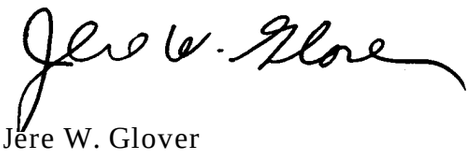
The Regulatory Flexibility Act of 1980 (RFA) requires federal agencies to consider the effects of their regulatory actions on small businesses and other small entities and to minimize any undue disproportionate burden. As the SBA's Chief Counsel for Advocacy charged with monitoring federal agency compliance with the act, I am pleased to submit to you this report covering activities undertaken in calendar year 1996.

In 1996, the Office of Advocacy reviewed some 2,500 proposed, interim, and final rules for their small business impacts. The review reflected a wide spectrum of agency compliance.

This is the Office of Advocacy's first RFA report since the implementation of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). Among other provisions, the SBREFA allows small businesses, appealing from an agency's final action, to seek review of an agency's compliance with the RFA. This revision in the law provides an additional incentive for federal agencies to take the RFA requirements seriously, and to analyze their regulations and select options that will achieve the regulatory objective without unduly burdening small entities.

The Office of Advocacy played an active role in implementing the new law in 1996, meeting with hundreds of federal regulators and trade association representatives concerning the law's impact on the RFA, preparing relevant guides and information. To enhance access to information on agency activities, the Office of Advocacy publishes its regulatory comments, testimony, policy briefings, and other materials on its Internet home page at *http://www.sba.gov/ADVO/*.

I look forward to seeing the new law's positive results and I encourage small businesses and small business advocates to maximize the SBREFA's effectiveness by making use of the new law wherever it is appropriate.



Jere W. Glover
Chief Counsel for Advocacy
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Contents

Abbreviations

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
BIA	Bureau of Indian Affairs
BLM	Bureau of Land Management
CAM	compliance assurance monitoring
CFR	Code of Federal Regulations
DEA	Drug Enforcement Administration
DOC	U.S. Department of Commerce
DOD	U.S. Department of Defense
DOI	U.S. Department of Interior
DOJ	U.S. Department of Justice
DOT	U.S. Department of Transportation
EPA	Environmental Protection Agency
FAA	Federal Aviation Administration
FAR	Federal Acquisition Regulation
FARA	Federal Acquisition Reform Act
FASA	Federal Acquisition Streamlining Act of 1994
FBI	Federal Bureau of Investigation
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FERC	Federal Energy Regulatory Commission
FHWA	Federal Highway Administration
FMC	Federal Maritime Commission
FR	Federal Register
FRA	Federal Railroad Administration
FRFA	final regulatory flexibility analysis
FS	Forest Service
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
GSA	General Services Administration
HACCP	hazard analysis and critical control point systems
IRFA	initial regulatory flexibility analysis
IRS	Internal Revenue Service
MMS	Minerals Management Service
MSA	medical savings account
MSHA	Mine Safety and Health Administration
NASA	National Aeronautics and Space Administration
NIOSH	National Institute of Occupational Safety and Health
NLRB	National Labor Relations Board
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NPRM	notice of proposed rulemaking
NPS	National Park Service
OFPP	Office of Federal Procurement Policy
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration

OTP	Office of Tax Policy (Treasury Department)
PL	Public Law
PRA	Paperwork Reduction Act
PWBA	Pension and Welfare Benefits Administration
RFA	Regulatory Flexibility Act
RIN	regulatory information number
RSPA	Research and Special Programs Administration (DOT)
SBA	U.S. Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act of 1996
SIC	standard industrial classification
SIMPLE	Savings Incentive Match Plans for Employees
STAWRS	Simplified Tax and Wage Reporting System
TRI	toxic release inventory
UBIT	unrelated business income tax
USC	United States Code
USDA	U.S. Department of Agriculture
USTR	U.S. Trade Representative
VOC	volatile organic compound

Executive Summary

The Chief Counsel for Advocacy's annual report to Congress and the President on implementation of the Regulatory Flexibility Act (RFA) provides insight into whether federal agencies are promulgating regulations in compliance with the RFA. When Congress enacted the RFA in 1980, it was concerned that agency regulations were disproportionately burdensome on small businesses. Congress also believed that the disproportionate burden interfered with small business growth and innovation.

Monitoring agency compliance is required to determine whether federal agencies are meeting the goals of the RFA. The annual report on regulatory flexibility compliance provides Congress and the President an opportunity to review the effects that agency actions may have on small entities and to determine whether the agencies are meeting both the intent and the letter of the law.

This report is divided into three parts. The first part provides an overview of the RFA, as recently amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The overview describes the purposes of the law, how it is to be implemented by agencies and why it is important to the small business community. The second part of the report describes the role of the Office of Advocacy in rulemaking. The third part profiles specific agency compliance and other RFA activity.

This is the first RFA report since implementation of the Small Business Regulatory Enforcement Fairness Act on March 29, 1996. This legislation was the culmination of many years of effort by small businesses and a bipartisan group of senators and representatives to improve the effectiveness of the RFA's implementation.

The law contains significant new RFA provisions. Most important, the law permits judicial review of agencies' compliance with the Regulatory Flexibility Act. Since the RFA's passage in 1980, and as noted in previous Advocacy RFA reports, many agencies have neglected to comply with the law. The Office of Advocacy's view — and that of many small business advocates — is that this non-compliance was caused, in large part, by the lack of enforcement provisions in the law.

With the passage of the SBREFA, a small entity that is adversely affected or aggrieved by a final rule may, on appeal from the rule, seek review of an agency's failure to comply with the RFA. This revision in the law is expected to have a beneficial effect on the regulatory process. In order to avoid judicial review, agencies will now be more inclined to do the kind of analysis required by RFA and select the regulatory options that will achieve the regulatory objectives without imposing a disproportionate burden on small entities.

This report also includes two appendices: Appendix A contains a listing of all regulatory comment letters filed by the Office of Advocacy in 1996; Appendix B contains the full text of the Regulatory Flexibility Act of 1980 (P.L. 96-354), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121).

The Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires each federal agency to review its regulations to ensure that small entities are not disproportionately or unnecessarily burdened.[1] The major goals of the Act are to increase federal agency awareness and understanding of the impact of regulations on small business, to require that agencies communicate and explain their findings to the public, and to provide appropriate regulatory relief to small entities.

In enacting the Regulatory Flexibility Act of 1980, Congress found that regulations often:

- adversely affect competition, discourage innovation, and restrict improvements in productivity;
- create entry barriers in many industries and discourage entrepreneurs from introducing beneficial products and processes;
- apply the same provisions to small entities even though the problems that gave rise to government action may not have been caused by those entities; and
- impose unnecessary burdens on the small entities.

Recognizing that small business is a major source of competition and economic growth, Congress established a process to be followed by agencies in analyzing how to design regulations that will help achieve statutory and regulatory goals efficiently without harming or imposing undue burdens on the major source of competition in the nation's economy — small business.

The RFA does not seek preferential treatment for small businesses, nor does it mandate that agencies adopt regulations that impose the least burden on small entities. Nor does it require exemptions for small entities. Rather it establishes an analytical process to be followed in determining how public policy issues can

1 5 U.S.C. §§ 601–12. Section 601 of the Regulatory Flexibility Act defines "small entities" as small businesses, small organizations, and small governmental jurisdictions; therefore most of the references in this report apply equally to small organizations and small governments. The definition of small business for each standard industrial classification is located at 13 CFR Part 121.

best be resolved without erecting barriers to competition. The law seeks a level playing field for small business, not an unfair advantage. It calls for regulations that are "right-sized" —regulations that require small business compliance only to the extent to which small businesses contribute to the problem the regulation is designed to eliminate or control. To this end, agencies must analyze the impact of proposed regulations on different-sized entities in various industry sectors, estimate the effectiveness of the proposal in addressing the source of the problem, and consider alternatives that minimize obstacles to compliance and compliance costs.

The law in essence is asking agencies to be creative, to know the economic structure of the industries they regulate, and, in the end, to regulate in a manner that does not unduly burden that sector of the economy that contributes significantly to economic growth, namely, small business.

In addition to permitting judicial review of agency compliance with the RFA, the SBREFA amendments to the Act increase opportunities for small business to participate in the regulatory process, and create forums in which small businesses can be heard on agency enforcement actions and practices.

With this as background, it should be clear that the procedures established by the RFA are not mechanical obstacles to be overcome. Instead, they outline a process for regulating in a more informed and rational manner, and for giving decisionmakers better information on which to rely in drawing regulatory conclusions.

Agency Compliance Requirements

The RFA has three key compliance provisions: agencies must review existing rules periodically, publish a semi-annual agenda of planned regulatory activities, and propose rules that appropriately accommodate small entities.

Periodic Review

The RFA requires agencies to review all regulations within 10 years of promulgation to assess their impact on small entities and determine whether the rules should be revised or eliminated.

Semi-Annual Agendas

In April and October of each year, federal agencies are required to publish a regulatory agenda listing all rules expected to be published in the *Federal Register* during the subsequent year that will likely have a significant economic impact on a substantial number of small entities.

Publication of these agendas increases the amount of time that the small entities will have to react to agency proposals.

Analysis of New Rules

Depending on a rulemaking's expected impact, agencies are required by the RFA either to certify that "the rule will not have a significant economic impact on a substantial number of small entities," and provide a factual basis for the determination, or to prepare a regulatory flexibility analysis.

Initial Regulatory Flexibility Analysis

If a proposed rule is expected to have a significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis (IRFA) must be prepared and published in the *Federal Register*. If the analysis is lengthy, the agency may publish a summary and make the analysis available upon request. This initial analysis must describe the impact of the proposed rule on small entities and address the following:

- reasons why the agency is considering regulatory action;
- objectives and legal basis for the proposed rule;
- number and kind of small entities to which the proposed rule will apply;
- projected reporting and other compliance requirements of the rule; and
- all federal rules that may duplicate, overlap or conflict with the proposed rulemaking.

The initial analysis must also contain a description of alternatives to the proposed rule that would minimize the impact on small entities. This important analysis must include the advantages and disadvantages of the various regulatory alternatives that minimize burdens on small entities, but still achieve the regulatory purpose.

Final Regulatory Flexibility Analysis

When an agency issues a final rule, it must prepare a final regulatory flexibility analysis (FRFA) or certify that the rule will not have a significant impact on a substantial number of small entities and provide a statement of the factual basis for such certification. The final regulatory flexibility analysis is required to:

- summarize the issues raised by public comments on the IRFA and the agency's assessment of those issues;
- describe and estimate the number of small entities to which the rule will apply or explain why no such estimate is available; and
- describe the steps followed by the agency to minimize the economic impact on small entities consistent with the stated objectives of the applicable statutes; give the factual, policy, and legal reasons for selecting the alternative(s) adopted in the final rule;

and explain why other alternatives were rejected.

The FRFA may be summarized for publication with the final rule; however, the full text of the analysis must be available for review by the public.

Certification

If a proposed regulation is found not to have a significant economic impact on a substantial number of small entities, the head of an agency may certify to that effect by providing a factual basis for this determination. This certification must be published with the proposed rule in the *Federal Register* and is subject to public comment in order to avoid an erroneous certification.

New Requirements for OSHA and EPA

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 amends the RFA by requiring the Environmental Protection Agency (EPA) or the Occupational Safety and Health Administration (OSHA) to take extra steps to include small businesses in regulation development.[2] If either agency is preparing an initial regulatory flexibility analysis, it must seek input from representatives of small entities prior to publication of the proposed rule. A Small Business Advocacy Review Panel is convened consisting of representatives from the rulemaking agency, the Office of Advocacy, and the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) to review and comment on the draft proposed rule and related agency analyses. The panel solicits small business views on the draft proposal and submits a report to the agency. The agency may reconsider the draft proposal and its economic analysis after receipt of the panel's report. The Chief Counsel for Advocacy may waive the panel requirement under certain circumstances.

Judicial Review

The Small Business Regulatory Enforcement Fairness Act amended the RFA by permitting judicial review of agency compliance with the law.

2 P.L. 104-121, sec. 201 et seq.

This provision allows a small entity claiming to be adversely affected or aggrieved by an agency's final action to seek review of an agency's compliance with the RFA. Judicial review also applies to appeals from interpretative rulemakings promulgated by the Internal Revenue Service that have information collection requirements.

It is this provision, long sought by the small business community, that strengthens the RFA and appears to be generating increased compliance.

Additional Reforms: A Snapshot of the SBREFA

In addition to amending the RFA, the SBREFA amendments provide small entities with additional regulatory compliance assistance from federal agencies and new mechanisms for addressing enforcement practices by agencies. The following are among the key provisions of the amendments.

Compliance Guidance

Agencies are required to publish compliance guides for all rules with significant small business impacts. The guides must explain in plain language how the firms can comply with the regulations. In addition, agencies that regulate small businesses must have a process for answering small business questions about regulatory compliance.

Ombudsman and Fairness Boards

The new law requires the Administrator of the U.S. Small Business Administration to designate a Small Business and Agriculture Regulatory Enforcement Ombudsman and to establish a Small Business Regulatory Fairness Board in each SBA regional office.

Ombudsman

The Small Business and Agriculture Regulatory Enforcement Ombudsman works with each agency to review complaints from small businesses concerning enforcement-related activities conducted by agency personnel. The Ombudsman is required to report annually to Congress on agency enforcement efforts.

Regional Boards

Small Business Regulatory Fairness Boards are established regionally to advise the Ombudsman on regulatory issues and agency enforcement activities that affect small businesses. Board members are small business owners and operators appointed by the SBA Administrator after consultation with the leadership of the House and Senate Small Business Committees.

Penalty Policy

Under the SBREFA, each agency must establish a policy to provide for the reduction and, under appropriate circumstances, the waiver of civil penalties for violations of statutory or regulatory requirements by a small business. The language in this section is similar to a statement and executive memorandum issued by President Clinton in 1995.[3]

Equal Access to Justice

The SBREFA amendments to the RFA expand the ability of small entities to recover attorney fees in litigation with the government under the provisions of the Equal Access to Justice Act of 1980. In administrative and judicial proceedings, if the government's demand is found unreasonable when compared with the judgment or decision, the small business can be awarded attorney fees and other expenses related to defending against the action. Under the new law, allowable attorney fees were increased from $75 per hour to $125 per hour.

3 "Regulatory Reform — Waiver of Penalties and Reduction of Reports," memorandum of April 21, 1995.

The Role of the Office of Advocacy in Rulemaking

The Office of Advocacy's statutory responsibility is to represent the interests of small business before the federal government and to monitor federal agency compliance with the Regulatory Flexibility Act. During 1996, the Office of Advocacy reviewed some 2,500 proposed, interim, and final regulations and submitted 92 formal comments on regulatory proposals. In addition, the Office of Advocacy responded to various congressional inquiries into agencies' compliance with the Act.

The Office of Advocacy encourages compliance with the RFA through a variety of methods, only one of which is the formal submission of comments. The Office of Advocacy is becoming increasingly involved in the rulemaking process at the very outset, raising issues as to the potential impact of a rule on small entities and recommending modifications before it is formally proposed.

One of the most important functions of the Office of Advocacy is outreach to the regulated small business community. This is accomplished through:

- a network of delegates to the 1995 White House Conference on Small Business, with whom there are regularly scheduled conference calls;
- meetings with small business trade associations;
- regional advocates in each of the SBA's 10 regional offices who maintain a network of contacts with local leaders.

Through these efforts, the Office of Advocacy remains in touch with the everyday concerns of small businesses and the impact regulatory proposals will have on small entities. Through meetings and written materials such as a monthly newsletter, *The Small Business Advocate*, small businesses and the Office of Advocacy communicate about RFA and specific regulatory concerns.

Networking with trade associations is maintained on a regular basis through roundtable discussions such as the Procurement Roundtable, a group of 25 individuals representing small business trade associations and other small business groups. The Office of Advocacy also leads the SBA Environmental Roundtable, a similar group of 130 stakeholders from both the private and public sectors

who meet to bridge the differences between government and business. The Environmental Roundtable has been a major force in the successful effort to seek regulatory relief in key rules in recent years. Other roundtables were held in 1996 in the areas of telecommunications, occupational safety and health, and transportation.

The Office of Advocacy is also a member of the Executive Committee of the Securities and Exchange Commission's Annual Government-Business Forum on Small Business Capital Formation. This forum brings together a cross section of small business owners, policy-makers, experts, and academics to make recommendations to Congress and federal agencies on small business securities, tax, and credit issues.

Since the passage of the Small Business Regulatory Enforcement Fairness Act of 1996, the Office of Advocacy has met with hundreds of small business trade associations to discuss the law's impact on the Regulatory Flexibility Act and has distributed *A Guide to the Regulatory Flexibility Act*.

The Office of Advocacy conducted four training sessions and drafted a guide for federal agencies on how to comply with the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996. More than 600 agency representatives attended the training and received copies of the draft guide.

The Office of Advocacy also met individually with officials of the Office of Information and Regulatory Affairs of OMB, the Environmental Protection Agency, the Department of Defense, the Occupational Safety and Health Administration, the Securities and Exchange Commission, the Federal Communications Commission, and the General Services Administration to discuss the impact of the new legislation on agency processes and regulatory analyses. In addition, the Office of Advocacy has worked with both the EPA and OSHA in establishing the Small Business Advocacy Review Panels required by the law.[4]

To enhance access to information on the law, the Office of Advocacy publishes all of its regulatory comments, testimony, policy briefings, reports, and other materials on its Internet home page at *http://www.sba.gov/ADVO/*.

4 The Small Business Advocacy Review Panels are a creation of the SBREFA amendments to the RFA. They are convened when significant new regulations that would affect small entities are being formulated by the EPA or OSHA. The SBREFA requires these two agencies to work with the Office of Advocacy and the OIRA before a new rule is published, in order to determine its impact on small entities. See discussion on page 6.

Agency Experiences with the RFA in 1996

During 1996, the Office of Advocacy submitted 92 formal regulatory comments to federal agencies. The Office of Advocacy commented on agency proposals as well as on deficiencies in agency RFA compliance.

The Office of Advocacy cannot be involved in every regulation that may potentially affect small entities. It therefore targets resources to those regulations where its involvement could make a difference or where small business interests are significant, but underrepresented. In other instances, the Office of Advocacy takes action because of longstanding RFA compliance problems at an agency, Advocacy's objective being to institutionalize the RFA process within the particular regulatory body.

What follows are highlights of Advocacy comments on specific regulatory proposals. (A complete list of comments submitted in 1996 is contained in Appendix A, beginning on page 41.)

Procurement Reform at Defense, GSA, and NASA

The Federal Acquisition Reform Act (FARA) of 1996 (P.L. 104-106) and the Federal Acquisition Streamlining Act (FASA) of 1994 (P.L. 103-355) have had a significant impact on the federal procurement process. Both laws, signed by the President during the last two years, represent major reform initiatives that are intended to reduce paperwork burdens on federal contractors, facilitate the acquisition of commercial products, enhance the use of simplified procedures for small purchases, and improve the efficiency of the laws governing the procurement of goods and services.

The stated purpose of the reforms is to make the government operate more like a commercial buyer and make it easier and more appealing for businesses to participate in government markets. Implementation of the legislation has been, and continues to be, accomplished through regulations proposed and managed by the Department of Defense (DOD), the General Services Administration (GSA), and the National Aeronautics and Space Administration

(NASA) and published in the *Federal Acquisition Regulation* (FAR). These three agencies, through the FAR Council, are responsible for jointly promulgating most procurement regulations.

The Office of Advocacy supported the procurement reforms, but expressed concerns regarding several key implementing rules which, in the Office of Advocacy's opinion, were not in compliance with the RFA and/or misinterpreted the reform legislation.

Competitive Range Determinations

A July 31, 1996, proposal published by the Federal Acquisition Regulation Council to implement a provision in the FARA would give contracting officers the authority to limit the "competitive range" to the number of bidders that would foster "efficient" competition on the procurement.[5] Under the proposal, only offerors viewed as "highly likely" to receive an award would be included in the "competitive range" — that is, bids from only these firms would be considered.

The Office of Advocacy and many small business groups were concerned that the proposal went beyond the intent of the statute and would hamper small business competition in federal contract markets. Advocacy was further concerned that the FAR Council did not conduct a sufficient initial regulatory flexibility analysis. The Office of Advocacy's letter to the FAR Council stated, "The IRFA indicates only that the proposed rule will apply to all large and small entities that offer goods and services to the government in competitive negotiated acquisitions. There is no estimated measure or quantification of small business impact or number and dollar value of federal contracts likely affected."

Simplified Procedures, FACNET, and Micro-Purchases

A final rule implementing the simplified acquisition threshold, the Federal Acquisition Computer Network (FACNET), and micro-purchases authorized under the FASA was published in July 1996.[6] The Office of Advocacy's comments to the FAR Council suggested that the FRFA was incomplete, insufficient and misleading.

In its February 13, 1995, comments on the proposed rule, the Office of Advocacy had urged the FAR Council to ". . . re-solicit comments after preparing a proper initial regulatory flexibility analysis and publishing it with an amended micro-purchase procedures interim rulemaking." The Office of Advocacy found the initial regulatory flexibility analysis to be insufficient, stating ". . . the analysis

5 61 FR 40116 (July 31, 1996).

6 61 FR 39189 (July 26, 1996).

seems to skirt the intent of the law and does not provide an accurate assessment of the rule's impact."

The micro-purchases allowed by the reform legislation removed longstanding small business set-asides for government acquisitions at or below $2,500. The majority of the over 18 million contract actions entered into each year by the federal government are for purchases of less than $3,000. Of all the rules implementing the Federal Acquisition Streamlining Act, the micro-purchase procedures will likely have the most significant and adverse effect on the small business community.

The Office of Advocacy objected to the absence of an analysis of the rule's impact on small business. But the rule on micro-purchase procedures was finalized as originally proposed.

Task and Delivery Order Contracts

Expanded provisions for task and delivery order contracts mandated by the FASA were finalized in a rule published in July 1996.

The Office of Advocacy provided comments on the changes proposed in this rule in a May 15, 1995, letter to the FAR Council. Advocacy stated ". . . the [proposed] rule expands the use of task order contracts, especially in the areas of advisory and assistance services. The Office of Advocacy and the small business community are concerned that these provisions will only further encourage bundling of contract requirements in a manner that will effectively prevent small firms from competing."

In addition, Advocacy found the initial regulatory analysis to be deficient noting, ". . . the analysis provides very limited information, conflicts with statements in the body of the rule and does not paint an accurate picture regarding how the rule will impact small firms."

Further, Advocacy's May 1995 letter suggested, ". . . the [rule] should be sensitive to the bundling issue and the growing problem in this area. It should caution agencies and guide against the unnecessary aggregation of contracts." Advocacy also argued that the rule should ". . . include provisions that would make subcontract participation by small, minority and women-owned firms a substantial factor in the award of such contracts."

No changes were made to the final rule in response to the Office of Advocacy's comments. In addition, the final regulatory flexibility analysis did not explain, describe, or quantify the impact the rule would have on small firms.[7]

7 NPRM at 60 FR 14346 (March 16, 1995); final rule at 61 FR 39186 (July 26, 1996).

Simplified Procedures to Certain Commercial Items

The FASA significantly expanded the definition of commercial items and the FARA authorized the application of "special simplified procedures" for certain commercial item purchases up to $5 million. In a November 5, 1996, letter to the FAR Council, the Office of Advocacy expressed concerns about the proposal to include alternative negotiation techniques or "auctioning" in the rulemaking. The Office of Advocacy also found the regulatory analysis to be deficient in measuring the rule's impact on small firms.

Advocacy believes auctioning would restrict competition by favoring large businesses with deep pockets, forcing small firms out of federal markets. Although small business groups have consistently opposed such alternative techniques, the rule's analysis indicates the proposed rule would benefit small businesses.

In its comments, the Office of Advocacy stated that it "finds the analysis deficient in content and very misleading. How can the analysis boldly suggest that small firms will benefit from the rule, when this issue has been vigorously debated, there is no data supporting small businesses [sic] benefits, and it includes the controversial auctioning technique opposed by many small firms?"

FAR Part 15 Rewrite

A proposed rule published on September 12, 1996, would alter significantly Part 15 of the FAR and change how the government negotiates contracts. The Office of Advocacy addressed the proposal in a public meeting and in its written comments to the FAR Council as having an insufficient regulatory analysis.

Advocacy also stated that many small business groups believe the proposal may restrict competition, while the FAR Council believes the proposal would benefit all firms. "The polarization on this issue has been caused by several factors. The initial regulatory flexibility analyses on [the rule] suggest the proposal will benefit small firms, yet provide no supporting information or quantitative data measuring impact."

Advocacy and numerous small business groups believe the requirements of the Regulatory Flexibility Act have been skirted in this instance, with insufficient analyses provided to support speculative conclusions.

Department of Agriculture

Food Safety and Inspection Service

In 1995, the Office of Advocacy commented three times on a proposed rule — labeled by the meat and poultry processing industry that would be affected by it as the "mega reg" — issued by the Food Safety and Inspection Service (FSIS). The rule would implement,

for meat and poultry inspection, a seven-step process to prevent foodborne pathogens, a process known as the hazard analysis and critical control points (HACCP) system. The process would replace old methods that relied heavily on the visual inspection of carcasses to detect contamination. Because of an increasing number of *E. coli* and salmonella outbreaks nationwide, the meat and poultry processing industry and the FSIS supported the notion that significant change was necessary. However, the FSIS failed to do a proper regulatory flexibility analysis and proposed a rule that would have put thousands of meat and poultry processors out of business without necessarily making food safer for consumers.

Largely because of its initial comments on the proposed rule, the Office of Advocacy was able to accomplish a number of significant changes. Advocacy's comment letter of July 5, 1995, harshly criticized the FSIS for failure to comply with the RFA. This comment letter was subsequently brought to the attention of the Secretary of Agriculture.

The HACCP final rule, published in 1996, reflected a number of major revisions requested in the Office of Advocacy's comments.[8] Cooling requirements, anti-microbial treatment requirements, and daily per-species salmonella testing requirements were removed from the final rule. Most significantly, the FSIS adopted the SBA's size standard for small processors and extended the implementation date for some small businesses to a maximum of 42 months.

The Office of Advocacy also had an opportunity to comment on the final rule prior to its publication. (The OMB encouraged the FSIS to provide the Office of Advocacy with an advance copy of the final rule, in light of Advocacy's continuing interest in the matter.) In those comments, Advocacy expressed concern over the new anti-microbial testing requirements as well as the new sanitation standard operating procedure requirements that had been added to the rule. Advocacy argued that the accelerated time for implementation was overly burdensome. Moreover, the requirements were duplicative and unnecessary within a HACCP environment. The OMB agreed with Advocacy's position, but the rule was finalized without modification.

8 61 FR 38806 (July 25, 1996).

Applicability of the RFA to Marketing Orders

The Agricultural Marketing Service (AMS) has long held that it is exempt from the RFA because its programs are different from those of any other agency; that is, the orders are established at the behest of growers. Industry concerns are allegedly addressed during the process of developing the orders; therefore, it is argued, there is no impact on small entities for RFA purposes.

Because of this agency-wide belief, the AMS has demonstrated a continuing disregard for its statutory obligations under the RFA. The AMS claims that its programs are designed to maintain orderly markets that will establish parity prices and protect the interests of consumers — a requirement of the Agricultural Marketing Agreement Act of 1937. Quality and quantity control measures as well as promotion and research provisions were designed to remove the chaos that until that time had surrounded the failure of voluntary efforts by cooperatives to regulate the production of agricultural commodities and accomplish their statutory objectives. The orders are established at the behest of growers and impose restrictions on the sale of commodities by handlers who hold the goods for resale.

Although the controls instituted by the 1937 Act were to address marketing anomalies that existed 50 years ago, the AMS has consistently refused to provide any analyses as to the impact of its orders on small entities — growers, handlers, and processors. It provides no data demonstrating that the orders will maintain order in the markets to which they apply. The AMS argues that because nearly all of the regulated community is composed of small firms and therefore is not disproportionately affected, no analysis is necessary. The AMS, however, fails to recognize that many of the entities dominating the marketing order process are truly big businesses in the form of large co-ops, such as ConAgra and Sunkist. Moreover, the agency has been able to hide behind rules requiring the "exhaustion of administrative remedies" (that is, within the department that issues the orders), which effectively have shielded the agency from lawsuits.

Rather than issue comments to the AMS as in the past, the Office of Advocacy opted to work directly with the AMS to achieve general compliance with the RFA. Therefore, no specific comments were written on regulations.

Following implementation of the Small Business Regulatory Enforcement Fairness Act of 1996, the AMS developed a great interest in RFA compliance. In addition to several agency briefing sessions held by Advocacy at SBA offices (which were well attended by many AMS officials), the AMS requested a specialized briefing at the AMS to address specific concerns. It was a breakthrough that

has allowed for a dialogue between the Office of Advocacy and the regulation drafters at the AMS. Since the briefing session, Advocacy has received many calls from AMS staff requesting guidance on size standards and other related matters.

Although the AMS has made recent overtures in an attempt to determine their obligations under the RFA, the AMS still has failed to satisfy the RFA in one very important regard. The AMS has never done an economic analysis to validate the stated purpose of their programs — that is, the orderly functioning of markets. Does a generic advertisement for California peaches improve the market for California peaches (that is, create a constant demand from consumers and prevent a drop in peach sales or hikes in peach prices)? How can AMS continue to certify that there will be no significant economic impact on a substantial number of small entities when the impact is not known? Are small producers being required to pay assessments for programs that may or may not carry out the statutory goals of the AMS? These were the types of questions asked during a 1996 Supreme Court case concerning the generic advertising programs.[9] A decision is expected in the summer of 1997.

National Organic Program

The organic industry has grown exponentially over the past decade. However, there are no uniform standards defining what can be labeled "organic." Eleven states have their own procedures, in addition to programs of about 33 private certifying companies. A food product considered "organic" in one state may not be in another. An effort is under way at the Organic Standards Office of the AMS to create a consistent federal standard/definition for organic foods (except meat and poultry). This rulemaking contains many regulatory flexibility issues that warrant careful consideration.

Staff of AMS' Organic Standards Office requested a meeting with the Office of Advocacy prior to publication of a proposed rule on organic labeling, in order to address certain issues pertaining to the RFA. During this meeting, the Office of Advocacy reviewed size definitions, explained the requirements of an IRFA, and explained outreach options.

By working closely with the staff of the Organic Program prior to publication of the rule, the Office of Advocacy has been able to make regulatory flexibility analysis a primary consideration of this AMS office, rather than a secondary one.

9 *Glickman v. Wileman Brothers & Elliott, Inc.*, docket no. 95-1184 (Dec. 2, 1996).

The only challenge thus far has been to dispel the notion within the AMS as a whole that the Office of Advocacy is unreasonable and uncompromising. The Organic Program staff and the Office of Advocacy now have a cooperative working relationship, and the proposed rule on organic labeling is due to be published in 1997.

Food and Drug Administration

Medical Device Reclassification

On September 3, 1996, Advocacy submitted comments to the Food and Drug Administration registering its strong concern about the impact of a proposed rule to, among other things, reclassify blood reagents into three types of medical devices. The reagents — called "immunohistochemistry reagents" —are blood derivatives manufactured for the purpose of aiding the diagnosis of disease. They may be purchased only by licensed doctors and are not available to the general public.

In June 1996, the FDA proposed a rule that would certainly have a serious economic impact on those businesses that sell the products, and would hamper manufacturers in their efforts to make new advances in research.[10]

In its proposed rule, the FDA outlined procedures for reclassifying certain reagents into Class III medical devices (requiring premarket approval to provide reasonable assurance of a product's safety and effectiveness—the most stringent level of regulation). The FDA's reclassification system failed to account for the fact that some reagents/antibodies have uses in both research and the clinical laboratory, while others have utility only in the area of basic research. Lumping both groups together means that useful research tools will be eliminated.

In the Sept. 3 comments, the Office of Advocacy recommended relabeling the reagents "For In Vitro Experimental Use Only." According to Advocacy's comment letter, "this would keep the market for dual-use products open, while accomplishing FDA's objective of assuring appropriate use of the product."

The Office of Advocacy's comments also argued that pre-market notification procedures should not be required for Class I (that is, low-risk) devices because of the tremendous cost involved in recordkeeping. (The problems that generally arise from such products come from a pathologist's inaccurate interpretation of results rather

10 61 FR 30197 (June 14, 1996).

than from a defect in the product.) The letter urged the FDA to focus on good manufacturing standards.

Finally, Advocacy discussed the inadequacy of the FDA's regulatory flexibility analysis. The agency certified that its rule would not have a significant economic impact on a substantial number of small entities, but the Office of Advocacy cited hundreds of U.S. companies that would be affected. The final rule has not yet been published, but this situation is an example of how a careless regulatory analysis can severely affect an industry.

Over-the-Counter Availability of Ephedrine

The FDA issued a proposed rule on July 27, 1995, to prohibit the continued over-the-counter availability of combination ephedrine drugs (asthma medication, generally) and single-ingredient ephedrine drugs. The FDA's goal was to curb the use of these drugs for non-intended purposes (for example, as weight-loss pills).

The Office of Advocacy's comment letter to the FDA on Sept. 27, 1995, asserted that the rule was contrary to case law and failed to address fundamental differences between ephedrine drugs that are generally recognized as safe and effective for their intended use, and those products containing ephedrine that are marketed and sold for purposes not approved by the FDA.

In support of its position, the Office of Advocacy cited the federal court of appeals decision in *American Pharmaceutical Assn. v. Weinberger* (1976), which stated that the FDA does not have the statutory authority to restrict distribution of a drug that is not deemed solely investigational.[11] In its decision, the court concluded that only the Justice Department (under the Comprehensive Drug Abuse Prevention and Control Act of 1970) has authority over permissible distribution of drugs that are controlled substances.

Advocacy further asserted that "the proposed regulation would have an adverse effect on legitimate ephedrine manufacturers and distributors." The FDA failed to cite evidence that combination products marketed only for the treatment of asthma were being abused.

Without conceding its case, the FDA took no further action on this regulation in 1996. It is interesting to note, however, that the Drug Enforcement Administration (DEA) took similar action to place restrictions on the over-the-counter availability of pseudoephedrine products (such as cold medications), citing the use of

11 *American Pharmaceutical Assn. v. Weinberger,* 377 F.Supp. 824; aff'd *American Pharmaceutical Assn. v. Mathews,* 503 F.2d 1054 (D.C. App., 1976).

pseudoephedrine in the manufacture of illicit methamphetamine, a controlled substance. (See the section on the DEA, below.)

Drug Enforcement Administration

Pseudoephedrine Regulation

In comments to the Drug Enforcement Administration (DEA) dated March 5, 1996, the Office of Advocacy addressed a proposed rule that sought to regulate over-the-counter availability of pseudoephedrine-containing drugs. The intent of this rule was to curb the use of these products by drug traffickers, since they can be used for the manufacture of illicit methamphetamine. The Office of Advocacy stated that the proposed rule did not target the source of the problem (primarily mail order businesses and large wholesalers) and instead "casts a wide net affecting small businesses" without justifying the need for the broad measures proposed by the DEA.

The rule would have required retailers of the products to keep records, and report to the DEA on any quantities of pseudoephedrine sold in excess of 24 grams (the equivalent of a 120-day supply for a single person). The threshold amount would have included multiple sales to a single customer over a period of time. Drug stores, grocery stores, convenience stores, newsstands, gas stations — most of which are small businesses — potentially would have been affected.

According to Advocacy, the DEA did not provide sufficient evidence to explain the need for the regulation. The comments noted that the agency did not cite a single case of diversion by the retail establishments targeted in the proposal. Moreover, the DEA did not demonstrate that the scope, duration, and significance of the alleged diversion warranted the corrective action sought (as required by the Domestic Chemical Diversion Control Act of 1993).

The final rule reflected a number of significant changes to reduce the burden on small entities. The threshold amount was doubled, multiple transaction requirements were removed, and the DEA registration requirements were removed for small retailers who did not sell threshold amounts.

Congress later intervened, passing a law lowering the threshold amount back to the level contained in the original DEA proposal — 24 grams.

Department of Transportation

Applicability of the RFA

The Department of Transportation's (DOT) agencies inconsistently apply the Regulatory Flexibility Act. At least one agency, the Federal Aviation Administration (FAA) established a policy for the RFA in 1986 in order to inform the public of its assumptions about "significant costs." However, this policy is likely to be revised, and the Office Advocacy plans to be involved in that activity in 1997. The DOT general counsel, and several officials from the Federal Railroad Administration (FRA), participated in Advocacy-sponsored briefings during 1996. Advocacy has worked with individual agencies to help bring the DOT's policies into conformance with the RFA, but a comprehensive effort is being made in 1997 for the entire department, beginning with a series of meetings with staff from the general counsel's office in January 1997.

Office of the Secretary

In response to a proposal requiring passenger manifests for international flights, the Office of Advocacy made suggestions to the DOT for ensuring compliance with the RFA in a Nov. 13, 1996, letter. The agency's certification that the rule will not have a significant impact on a substantial number of small entities was inadequate and an analysis of industry-specific estimates is needed.

Coast Guard

The Office of Advocacy submitted comments on Aug. 19, 1996, to the Coast Guard regarding a proposal to incorporate voluntary consensus standards into electrical engineering requirements for merchant vessels. Advocacy charged the agency with ensuring that the costs of complying with these standards would not be overly burdensome to small operations that often are not involved in standards development.

Federal Highway Administration

A Federal Highway Administration (FHWA) proposed rule would revise procedures for employers to collect the safety performance history of new drivers. The Office of Advocacy submitted comments on May 13, 1996, recommending that reporting requirements be fact-based, a phase-in period be considered, an explanation be provided on how to collect a driver's violations of alcohol or controlled substance rules, and duplicative recordkeeping of out-of-service orders be eliminated. The Office of Advocacy recommended alternatives to minimize the cost to small businesses, while the FHWA asserted that its rule would not have a significant economic impact on small business.

The agency also is planning to promulgate a rule that would require employers to provide entry-level driver training for commer-

cial motor vehicles. In an Oct. 22, 1996, letter to the FHWA, Advocacy urged the agency to involve small businesses in the process and to thoroughly assess the costs in its deliberations.

Federal Railroad Administration

The Office of Advocacy began working with the Federal Railroad Administration (FRA) to help the agency define small railroads, to provide more specific information on the economic impact on small firms, and to perform more outreach to small entities, especially tourist and excursion railroads and contractors. Advocacy commented on a proposed roadway worker protection standard (May 13, 1996) and an advance notice of proposed rulemaking for passenger equipment safety (July 8, 1996), and worked with the agency on its regulatory flexibility analysis for the end-of-train device rulemaking for freight operations.

Federal Aviation Administration

On November 14, 1996, the Office of Advocacy submitted comments to the Federal Aviation Administration (FAA) on its plans to limit air tour operations in the Grand Canyon National Park. Specifically, the agency seemed to underestimate the impact of the regulation on the industry for a rule that would reduce the air space available to tour operators by 50 percent. Advocacy argued that the FAA must investigate the effect of similar restrictions in the Hawaii air tour industry and assess the likelihood that costs could be passed on to customers when the elasticity of prices is limited. Further, the agency failed to offer viable alternatives that would minimize the impact on small businesses.

Research and Special Programs Administration

The Office of Advocacy convened a roundtable meeting on July 12, 1996, with interested small business organizations to discuss the Research and Special Programs Administration's rulemaking for small quantity hazardous materials and intrastate transportation. Based on recommendations collected during the roundtable, Advocacy submitted comments on Aug. 16, 1996. The rule provides some exemptions for materials of trade and supersedes state regulations for hazardous material transport for intrastate commerce. Some small business sectors are provided new relief under this rulemaking. However, the Office of Advocacy raised concerns about new burdens on previously exempt sectors under the intrastate commerce provisions (for example, in agriculture) and suggested that the agency consider regulating transportation based on actual hazard content versus the current system that counts the non-hazardous volume or weight of solvents or containers.

Internal Revenue Service

The Small Business Regulatory Enforcement Fairness Act specifically included certain interpretative regulations of the Internal Revenue service (IRS) under the RFA. IRS rules have long escaped the requirements of the RFA because they were considered "interpretative," that is, simply carrying out the intent of Congress without elaboration. Under the Administrative Procedures Act, interpretative rules have always been exempt from the RFA.

Since the passage of the SBREFA, the IRS has been working with the Office of Advocacy to learn more about complying with the requirements of the RFA.

Most IRS regulations published in 1996 were not affected by the SBREFA. This is true even though the SBREFA amendments extended application of the RFA to certain IRS interpretative rules under the following circumstances:

1. Under the provisions of the SBREFA amendments, the RFA applies only to those interpretative IRS regulations to the extent that they impose a "collection of information" requirement on small entities. Under this test, most IRS regulations fall outside the jurisdiction of the RFA. "Collection of information" is defined to include recordkeeping requirements.

2. Under the SBREFA, even where there is a "collection of information" requirement, only the portion of the proposed regulation that contains that requirement (and not the entire regulation) needs to be analyzed for its impact on small business and flexible regulatory alternatives offered to what has been proposed.

3. Finally, by a specific provision contained in the SBREFA amendments, the RFA provisions do not apply to any IRS interpretative rules proposed prior to the date of the law's enactment on March 29, 1996. By the end of 1996, there were still a number of regulations being finalized that had been proposed prior to that date.

One result of the above restrictions is that no initial or final regulatory flexibility analyses were done by the IRS on regulations promulgated in 1996. The Office of Advocacy has continued to work with the IRS, through both formal comments and informal discussions, to ensure that the views of small business are represented.

De Facto Recordkeeping

On Nov. 11, 1996, the Office of Advocacy commented on the IRS' proposed interpretative rules describing the type of evidence needed by a business to establish that it had a "reasonable basis" on which to base tax decisions. The Office of Advocacy argued that the stronger evidentiary standard was a *de facto* "collection of information requirement" since the only way for a business to have "evi-

dence" was to maintain records. Advocacy urged the IRS to analyze the impact of the proposal on small business, as required by the RFA.

Electronic Payment Systems

During 1996, the Office of Advocacy commented on regulations or worked closely with the IRS to bring to its attention small business concerns about regulations and other initiatives that, although not subject to the RFA, nevertheless had an impact on small business.

For example, when the IRS announced that firms would have to pay federal withholding electronically or face financial penalties, the Office of Advocacy contacted the IRS to inform them of the serious hardship such a rule could cause more than one million small businesses unless businesses had adequate notice.

The IRS commissioner postponed the effective date of the requirement. Since then, Advocacy has worked with the IRS to alert and educate affected small businesses.

Medical Savings Accounts

The Treasury Department contacted the Office of Advocacy in November 1996 to consult on the notice they were drafting for publication providing guidance for establishing and using high-deductible health care plans and medical savings accounts (MSAs). The Office of Advocacy provided suggestions about interpretations that could help small businesses, most of which were accepted. One of Advocacy's major concerns was the scope of coverage for uninsured employees of "small employers." The IRS notice made it appear that an employee of a "small employer" that does not maintain an individual or family "high deductible health plan" is ineligible to participate in an MSA. It seemed in keeping with congressional intent and small business interests that an interested employee could pay for the plan, through payroll deductions, as long as the employer handled the paperwork and made the plan available to all employees on equal terms. Such a statutory interpretation was consistent with the stated purpose of the law.

Simplified Forms and Publications

During 1996, the IRS conducted an active review of all its forms and publications, soliciting comments from the Office of Advocacy. For example, the IRS solicited Advocacy's comments on its proposal to reduce significantly the content of IRS Publication 334, *Tax Guide for Small Business*. Advocacy commented that the guide was very helpful to small business since it provided, in one place, all the tax information and guidance needed by a small business.

The Office of Advocacy has also been pro-active in urging regulations to make reporting easier for small business. For example, the chief counsel for advocacy recommended the single model enroll-

ment form for the Savings Incentive Match Plans for Employees (SIMPLE) retirement plan for small business. The IRS recently unveiled this form for public comment. Also, the Office of Advocacy has been promoting the development of a single form to report both state and federal quarterly small business information (for companies with 10 or fewer employees). The IRS has moved forward with a demonstration plan as part of its Simplified Tax and Wage Reporting System (STAWRS) program to test the form's feasibility.

Targeted Capital Gains

Rules for the Small Business Capital Gains Program (section 1202 of the Internal Revenue Code) would be made more useful by amendments recommended by the Chief Counsel for Advocacy. The amendments, which have been published in a Notice of Proposed Rulemaking, would allow the stock of a small business company to remain "qualified" for a 50-percent reduction in the capital gains tax, when certain redemptions of the stock occur. (Currently, any redemption disqualifies the stock for the favorable tax treatment.) The amendments would give investors confidence that the tax benefits that make their investment more attractive will not be lost by accident. If the amendments are adopted, the 50-percent reduction in the capital gains tax would be allowed for redemptions in the case of the death, incapacity, or departure from the business of a principal.

Unfair Competition from Non-Profits

The Office of Advocacy has a long history of advocating fair treatment for taxpaying small businesses that are forced to compete against government-sponsored or non-profit (tax-favored) businesses. Studies performed by the Office of Advocacy show that such unequal competition is becoming more pervasive. The Office of Advocacy asked the Department of the Treasury to review the impact of the unrelated business income tax (UBIT) provisions, which are supposed to prevent tax-exempt businesses from gaining a competitive advantage as the result of tax benefits. The Treasury Department had been considering issuing an expansive letter ruling on the issue. The Office of Advocacy maintains that the only way small business can get a fair hearing on this issue is by means of a regulatory proceeding, and it has urged the Department to conduct one instead of issuing a letter ruling.

The Treasury Department, in its proposed 1997 business plan, will focus on several issues affecting non-profits. The Office of Advocacy has urged the Department to include the need for regulatory guidance under the UBIT "substantially related" test — already identified as a major concern to small businesses — as one of the priority issues under that plan.

Federal Communications Commission

The Federal Communications Commission (FCC) oversees virtually all aspects of the telecommunications marketplace, including telephones, cellular telephones, cable television, television and radio broadcasting, satellite communications, spectrum auctions, telecommunications equipment manufacturing, and others. In 1996, the FCC was primarily involved in implementing the complex and far-reaching provisions of the Telecommunications Act of 1996.

The passage of the SBREFA amendments to the RFA in March 1996 inaugurated a series of efforts by the Office of Advocacy to improve the FCC's compliance with the Act. These efforts included Advocacy's leadership of two panel discussions held at the FCC and attended by approximately 120 FCC staff members. The Office of Advocacy also hosted a Telecommunications Roundtable discussion of the SBREFA amendments to the RFA for nearly 30 representatives of small telecommunications entities. These efforts were in part responsible for a marked increase in the quality and quantity of the FCC's compliance efforts.

Universal Service

One of the cornerstones of the Telecommunications Act of 1996 was its mandate to revolutionize the so-called "universal service" support systems. These systems channel subsidies from low-cost urban areas to higher-cost rural areas to keep rates reasonable so that all Americans have affordable access to the national telephone network.

In March 1996 the FCC proposed rules to implement these changes, and the Federal/State Joint Board issued its proposed decision in November 1996. Both proposals raised a number of issues of concern for small businesses. Both recommended cutting off from universal support all small businesses in rural areas that had more than one telephone line. In practice this would mean enormous rate increases for these small businesses, on the order of two to 10 times their current rates. The Office of Advocacy filed in opposition to both proposals and helped coordinate the efforts of other concerned small business groups. The final decision on these cuts must be made by May 1997.

Interconnection

The Telecommunications Act of 1996 mandated the fundamental restructuring of all local telephone networks in order to open the local telephone monopoly to competition. The FCC released its monumental order in August 1996, which was soon challenged in court, chiefly by incumbent monopoly telephone companies and state commissions. The FCC's order implemented many of the Of-

fice of Advocacy's recommendations that will help maximize small competitors' ability to access these new markets, including:

- unbundling local telephone networks into at least eight distinct elements for repurchase by competitors;
- ensuring fair discounts for competitors that purchase network capacity for resale to customers; and
- establishing national guidelines that clarify incumbent telephone companies' duty to negotiate with new competitors in good faith.

Furthermore, the FCC agreed for the first time to recognize that the RFA applies to the 1,300 existing small telephone companies, a policy that Advocacy had attempted to change for many years. This ensured that these companies would not be deprived of the benefits of this law.

Market Entry Barriers

A vital provision for small businesses in the Telecommunications Act of 1996 requires the FCC to identify and eliminate market entry barriers to small businesses in the telecommunications industry. The Office of Advocacy recommended a number of changes that would open both markets and the FCC's processes up to small businesses, including: (1) making all FCC orders and filings available electronically, and (2) revising and streamlining FCC complaint procedures to facilitate the processing of small companies' complaints, which are currently all but ignored. The Office of Advocacy will continue to work with the FCC to ensure that this proceeding results in the removal of significant barriers as Congress intended.

Cable Television Rules

The Telecommunications Act of 1996 contained a number of provisions that further deregulated the cable television industry. One of these provisions, however, would have inadvertently excluded many small cable operators from the relaxed regulation from which they already benefit. This provision would also threaten their ability to raise capital at a time of rapidly increasing competition from other technologies. The Office of Advocacy filed comments on November 12, 1996, with the FCC clarifying this issue, urging it to expand its small cable affiliation rules to ensure that small cable operators continue to fall under the FCC's small system rules. Advocacy specifically urged the FCC to adopt rules that parallel the SBA's affiliation rules that have worked effectively for many years in determining what businesses should be considered small. The FCC is expected to issue its decision in this proceeding early in 1997.

Occupational Safety and Health Administration

The Office of Advocacy worked closely with the Occupational Safety and Health Administration (OSHA) to assist the agency with RFA compliance. OSHA attended several RFA briefings held by Advocacy. Further, Advocacy staff met throughout the year with agency officials to critique specific economic analyses for rulemakings, including those pertaining to occupational exposure to tuberculosis for general industry and steel erection and scaffolding in construction.

To emphasize the importance of the RFA, Advocacy staff made presentations before OSHA's three public advisory committees on the SBREFA amendments and OSHA's obligations under the law. The Office of Advocacy initiated extensive outreach to industry representatives in 1996 to gauge their major concerns about occupational safety and health issues, and to determine if they were prepared to use the newly amended RFA in an effective manner. Outreach included roundtables, regulatory updates, and issue-specific notices. Industry-specific outreach was done to identify special concerns. For instance, staff of the Office of Advocacy met with industry officials from the maritime sector at job sites to talk about the complex concerns of small employers.

The Office of Advocacy spent much of 1996 assessing the level of compliance by OSHA and discerning the most effective ways to help small business. Advocacy continues to be concerned about the agency's compliance with the RFA, including its preparation for the final methylene chloride rule and the proposed recordkeeping rule. The agency should consistently use the SBA's definitions of small business, provide a breakdown of cost estimates by industry sector (even when certifying a rulemaking), make a conscious effort to invite small business to the table early in the rulemaking process, and develop feasible regulatory alternatives for small business when appropriate. A key to ensuring full agency compliance is involvement and education of the small business sector on its rights under the RFA.

Recordkeeping Proposed Rule

Following a roundtable meeting with small business interests in April 1996, the Office of Advocacy presented testimony at a public meeting on May 31, and submitted comments on July 1, on OSHA's proposed rule for revising recordkeeping requirements. The agency certified that the rule would not have a significant impact on a substantial number of small entities. However, Advocacy's review revealed that the agency did not use the appropriate definitions of

small business or provide a sufficient analysis of the impact on small businesses in various industry sectors. The Office of Advocacy provided substantive comments on the proposed rule, raising questions about (1) the expansion of recordable incidents and conditions; (2) provisions allowing for public access to employers' OSHA Injury and Illness Incident Record; and (3) expanded paperwork collection by construction contractors and subcontractors.

Tuberculosis

Under new requirements of the RFA, OSHA was required to notify the Chief Counsel for Advocacy regarding plans to publish a proposed rule for regulating occupational exposure to tuberculosis. Advocacy identified parties from a variety of industries — including nursing homes, emergency medical services, in-home care services, and homeless services — that should be consulted in the process. As required by the SBREFA amendments, an interagency Small Business Advocacy Review Panel was convened on September 10, 1996, and the group solicited comments and recommendations about the draft proposed rulemaking from small businesses and nonprofit organizations. A final report was issued on November 12, 1996, detailing the concerns raised, including questions about the need for the rule, its feasibility, and the costs associated with it. (The proposed rule had not been published by the close of 1996.)

Methylene Chloride Exposure

Concerns were raised by the manufacturing sector about OSHA's anticipated final rule for lowering the occupational exposure limit for methylene chloride. The Office of Advocacy reviewed the draft final regulatory flexibility analysis and submitted its concerns to OSHA and the Office of Management and Budget (OMB) on August 27, 1996. Advocacy raised several issues.

First, OSHA failed to use the correct definition of small business for all industries in its analysis and therefore minimized the characterization of the rule's impact on small business.

Second, the agency did not offer significant, viable alternatives to the rule for consideration by the public. In the original proposed rule published in 1991, the agency relied on substitute products for relieving the effects of lowering the exposure limit. However, data presented later showed that the alternatives could create new workplace hazards, leaving the affected industries struggling with the feasibility of the rule.

Third, there was an inconsistent interpretation of the hazards of methylene chloride between OSHA and the Environmental Protection Agency.

Following a meeting with staff from the Office of Advocacy, representatives from the manufacturing sector, and OMB, OSHA re-

turned to develop more extensive data on the manufacturing sector most affected and to consider alternatives to be included in the final rule. While the Office of Advocacy is of the view that OSHA did not thoroughly examine all of the feasible alternatives to its proposed rule, it recognizes that the agency has been forced to provide some relief to the affected small businesses, including a phase-in period for manufacturing firms with fewer than 100 employees. Advocacy will review the final regulatory flexibility analysis and OSHA's response to the Office of Advocacy's concerns.

Fire Protection for Shipyards

The Office of Advocacy submitted comments on July 8, 1996, in response to an OSHA notice that a negotiated rulemaking committee was being formed for developing a rule for fire protection for shipyards. Advocacy recommended that an analysis be performed to determine the size of the firms being regulated and to ensure that small firms are well represented on the committee. The agency has responded by placing a special emphasis on small business during the rulemaking process.

Metalworking Fluids

The Office of Advocacy organized a coalition of manufacturing associations to meet with OSHA officials about a priority rulemaking that may lower the exposure limit for airborne metalworking fluids and place new requirements on employers, such as exposure testing and engineering controls. While the American Automobile Manufacturers' Association had been heavily involved in this issue, Advocacy was concerned that small businesses were not aware of this rule development and would be significantly affected. Advocacy convened more than 20 trade associations to talk with agency officials and review documentation from the National Institute of Occupational Safety and Health (NIOSH) on the issue. Scientific assessment and economic modeling were discussed as well. NIOSH agreed to hold a seminar about its findings for the affected parties in December 1996. In addition, the Office of Advocacy is urging OSHA to include representatives of small business on a soon-to-be announced standards advisory committee.

Hazard Communication Standard

OSHA, as required by the Paperwork Reduction Act (PRA), issued a request for public comment on the paperwork requirements of the hazard communication standard. The PRA requires OSHA to ask the public to comment on regulatory paperwork requirements every three years. The Office of Advocacy submitted comments on May 13, 1996, indicating that this rule significantly affects small businesses. Advocacy suggested that a complete overhaul of this regulation was needed, and submitted recommendations that were

developed in 1992 by Reps. Norman Sisisky and Larry Combest in cooperation with small businesses.

The National Advisory Committee on Occupational Safety and Health completed a review of the standard in October. The committee recommended that OSHA retain the current standard but make changes to the rule, making it easier for small firms to comply. OSHA has received numerous extensions from the Office of Management and Budget in its consideration of this rule. The agency must decide if the hazard communication standard will be rescinded, revised, or retained.

Workplace Violence

In April 1996, OSHA issued a draft version of *Guidelines for Workplace Violence Prevention Programs for Night Retail Establishments*. The Office of Advocacy, along with small business organizations, asked OSHA to extend the deadline for comment and to hold public meetings on the *Guidelines*. OSHA met both of these requests. In comments to the agency submitted on Sept. 30, 1996, Advocacy recommended that the agency work more closely with the affected industries. The letter also expressed concern that the guidance contained in the *Guidelines* could be misused for regulatory enforcement and as "standards of care" in third-party litigation. While guidance documents are not covered technically by the RFA, the Office of Advocacy wanted to ensure that the guidance is beneficial to small businesses and does not create regulatory or liability problems.

Mine Safety and Health Administration

The Mine Safety and Health Administration (MSHA) worked with the Office of Advocacy on improving its RFA compliance. Specifically, Advocacy recommended using the appropriate SBA definition of small mine and providing analysis for different industry sectors.

In 1997, MSHA will be assessing the feasibility of establishing an alternative small mine size standard after doing a thorough economic analysis, as requested by Advocacy, and seeking public comment, as required by the RFA.

Noise Exposure

Advocacy reviewed the regulatory flexibility analysis in the pre-proposal stage for a major rulemaking for a noise exposure standard. Public comments were submitted on Sept. 17 and Nov. 19, 1996. The MSHA agreed to use the SBA's definition of small mines, and it analyzed costs for different industry sectors before concluding that the standard would not have a significant economic impact on

small business. Advocacy pointed out that the threshold for determining a "significant" impact must be assessed by the industry during the public comment period when the proposed rule is published.

Federal Energy Regulatory Commission

In 1995, the Office of Advocacy participated in a landmark ruling at the Federal Energy Regulatory Commission (FERC) involving the open access transmission of electrical power. The ruling proposed to deregulate the power industry and to provide increased competition in the industry. It also raised the possibility of price discrimination against small business commercial customers. At the time of the proposed rulemaking, the Office of Advocacy submitted comments that endorsed mandating open access while expressing concerns about stranded cost recovery and suggesting methods for ensuring that the savings derived from competition were passed on to commercial customers.

The Commission issued a final ruling on open access transmission in May 1996. Order 888 allows for the recovery of stranded costs that were the direct result of deregulation; develops a formula for determining the amount of costs to be recovered; and allows for recovery through negotiations of the parties. Although the Office of Advocacy agreed with most of the ruling, it had reservations about some aspects of the order.

The Office of Advocacy supported the Commission's decision to limit the recovery of stranded costs to fees directly related to deregulation. However, Advocacy expressed concerns about the equitable distribution of stranded costs among a utility's customer base, since cost recovery might not occur in a manner that provided for an equal assessment of the costs to all customers.

Advocacy contended that the direct assignment of stranded costs was a potential barrier to the competitive marketplace that could impede the growth of small businesses. If the amount of stranded cost assessment to a departing customer were too high, customers might be unwilling to leave their current supplier to obtain a more competitive rate. As a consequence, competitors entering the market might not be able to obtain the necessary customer base to become a viable contender in the industry. Similarly, if the recovery amount were too low, the remaining customers might have to bear an undue burden from the inequitable distribution of the stranded costs.

Advocacy recognized that the FERC would be monitoring the process, and that the Commission would make the final determination

on the proper amount of stranded costs recovery. The Office of Advocacy nevertheless expressed concerns about the potential abuse of the stranded costs recovery process. For this reason, Advocacy requested that the FERC solicit its input, as well as the input of the small business community and small business organizations, when determining whether a proposed stranded costs recovery amount is fundamentally fair in terms of maintaining a viable environment for small businesses. By providing comments to the FERC, the Office of Advocacy, the small business community, and small business organizations may be able to assist in ensuring that benefits do not accrue to one class of customers at the expense of others.

Finally, in Order 888, the FERC stated that a regulatory flexibility analysis was not necessary because the regulation would not affect a significant number of small entities. The basis of its conclusion was that, currently, small entities make up approximately 11 percent of the electric utility industry. The FERC contended that although 50 of the 166 public utilities dispose of less than 4 million megawatt/hours per year, only 19 of these 50 are unaffiliated with larger utilities.

The Office of Advocacy maintains that the Commission's conclusion was erroneous. By any mode of reasoning, the percentage of small businesses in the electrical industry is 30 percent, which amounts to a significant portion of the industry. Moreover, Advocacy asserted that given the circumstances of deregulation, 11 percent was also significant.

Advocacy asserted that the Commission erred in concluding that it need only consider the small businesses that were already in the power industry in deciding whether to perform a regulatory flexibility analysis. The Commission's failure to perform a regulatory flexibility analysis was particularly disturbing, not only because of the number of small businesses that are in the power industry, but because of the anticipated number of small business entrants into the industry.

National Marine Fisheries Service

The Office of Advocacy's 1996 comments to the National Marine Fisheries Service (NMFS), a part of the National Oceanic and Atmospheric Administration (NOAA), ranged from comments on NOAA's failure to provide proper RFA information to comments questioning the selection of a particular alternative or action. In general, the comments on improper regulatory flexibility activity focused on issues such as the failure to describe properly a particular

industry or the failure to quantify adequately the anticipated impact on small businesses.[12] Since the businesses in the fishery industry tend to be small, a proper, fully inclusive regulatory flexibility analysis is meaningful for determining whether a particular action is disproportionately burdensome.

In addition to writing comments on proposed regulations, the Office of Advocacy worked along with NOAA' s Office of General Counsel and regional fishery councils to address the RFA deficiencies found in the proposed regulations. Through joint effort and cooperation, Advocacy believes that NOAA will be able to achieve a higher level of compliance with the RFA in 1997.

Environmental Protection Agency

Nineteen ninety-six was a very significant year for the EPA and small businesses. It marked the one-year anniversary of the 1995 White House Conference on Small Business. The ensuing time period saw the EPA make considerable progress in implementing many of the important environmental recommendations that were made by delegates to the conference. Furthermore, it was the first year of implementation of the new SBREFA amendments to the RFA, which created a special new set of rules governing relations between the EPA and small business in the rulemaking process.

During 1996, the EPA initiated four rulemakings that potentially would require the use of the Small Business Advocacy Panels required by section 609(b) of the Regulatory Flexibility Act, as amended by the SBREFA amendments. These panels of federal officials are required by this provision to receive comments on draft proposals by representatives of small entities, and address them in a panel report before the agency can issue a proposed rule. This procedure can have a dramatically salutary effect on the agency's issuance of proposed regulations that affect small businesses.

Clean Air Act Compliance Monitoring

As part of its enforcement of the Clean Air Act, the EPA circulated a draft proposal that would require facilities to adopt certain monitoring and recordkeeping requirements in order to ensure compliance with applicable clean air standards. These rules could substantially affect many major sources of air pollution, including many small

12 See, for example, the comments submitted to NMFS on April 15, 1996; April 24, 1996; and July 19, 1996.

businesses. The Office of Advocacy was concerned that the EPA's requirements were both unnecessarily broad and too expensive to achieve the statutory purpose. Advocacy drafted a memorandum outlining regulatory alternatives to the EPA's draft proposal, which was submitted for consideration for a public hearing on Sept. 10, 1996.

While the EPA had not finalized its proposal by the end of the year, the agency is seriously considering Advocacy's recommendations in drafting the proposed rule for publication. The alternatives proposed by the Office of Advocacy will lower the cost of the proposed rule by adding exemptions for smaller air pollution sources, and will reduce the regulatory complexity of a portion of the rule.

Expansion of Toxic Release Inventory

The Office of Advocacy submitted comments in September in response to the EPA's June 1996 proposal to expand the Toxic Release Inventory (TRI) reporting requirements to seven classes of additional industrial facilities.[13] These industry groups are coal mining, metal mining, electric utilities, commercial hazardous waste treatment, chemicals and allied products (wholesale), petroleum bulk stations (wholesale), and solvent recovery services. This rule is a major expansion of the current community-right-to-know regulations.

Because the proposed rule would impose a significant economic impact on a substantial number of small businesses, the EPA prepared an initial regulatory flexibility analysis, as required by the RFA. According to the EPA's economic analysis, small businesses in both the chemical wholesale (SIC 5169) and waste treatment (SIC 4953) industries will bear particularly heavy annual costs, exceeding 1 to 5 percent of annual sales.

Although the regulatory analysis is, in many respects, a model analysis, the agency made several very important errors. The economic analysis made no serious effort to quantify the expected size of the chemical releases to be reported for SIC 5169 (chemicals and allied products), 4953 (refuse systems), and other industries, despite the availability of hundreds of TRI reports. Thus, the EPA appears to be choosing industries for reporting without consideration of whether the volume of releases and transfer warrant reporting. In addition to its failure to comply with the Regulatory Flexibility Act, the EPA also needed to improve its compliance with the Paperwork Reduction Act.

13 61 FR 33588 (June 27, 1996).

The Office of Advocacy will continue to work with the EPA to look for ways to preserve the right to know, while saving substantial compliance costs. Among the regulatory alternatives under exploration are exemption from the reporting requirements of those industries with inadequate right-to-know data, or adoption of methods for reduction of compliance costs, including substitution of reporting under other statutes for the TRI data.

Regulation of VOCs in Architectural Coatings

In June 1996, the EPA proposed to lower the limit on the amount of volatile organic compound (VOC) emissions from architectural and industrial maintenance coatings. The Office of Advocacy was concerned that small regional and local paint manufacturers would not be able to reformulate their coatings to meet the lower VOC limits, particularly for their smaller product lines, in a cost-effective manner.

As a result of this concern, the Office of Advocacy worked with small business representatives in presenting recommendations to the EPA to revise the draft proposal. Advocacy suggested two significant changes to the EPA's proposal, which the EPA eventually included in the preamble to its request for comments on the proposal.

First, the Office of Advocacy asked that the EPA reduce its threshold for proposed emissions fees (that is, the fee paid to the EPA by a manufacturer for coatings with a VOC content in excess of the standards) from $5,000 per ton to $2,500 per ton. Second, Advocacy requested that the EPA include a small-volume exemption for product lines below a certain size (for example, 5,000 gallons per year). In this manner, a paint manufacturer would not need to spend $25,000 to reformulate a small product line, while the increased emissions resulting from this exemption would be insignificant. Advocacy is working with small business trade associations to acquire data to determine if further small business relief is needed in the final rule, which is expected to be issued in early 1997.

Hazardous Waste Identification Rule

The proposed hazardous waste identification rule, issued in December 1995,[14] marked a major effort by the EPA to reduce the cost of regulations for generators of hazardous wastes. The agency proposed a rule that would eliminate certain wastes from the expensive hazardous waste regulations that are now in effect.

The EPA admitted that few hazardous waste generators, including almost all smaller generators (mostly representing smaller busi-

14 60 FR 66344 (December 21, 1995).

nesses), would benefit from this deregulatory proposal. The EPA's analysis estimated that, as a practical matter, only 3 percent of the facilities would benefit from this new proposal. This occurred because the cost of implementation under the proposed regulation, even as estimated by the EPA, would exceed the cost of full compliance with the current hazardous waste regulations. In other words, the cost of proving that wastes are low-risk (and thus exempt from the rules) would be higher than the cost of treating the wastes as hazardous under the old rules. Only the top 3 percent of covered facilities, or 167 facilities, would be the beneficiaries of this deregulatory proposal.

Considering the extraordinary resources that the EPA, trade associations, companies, and public-sector organizations have invested over many years in this rulemaking, this was a very disappointing outcome. The Office of Advocacy agreed with the large number of commentaries that the risk-based methodology suffered from many technical flaws, and needed substantial revision. Subsequently, the EPA acknowledged many of these problems and is still in the process of determining whether it can address these concerns in a final rule, or whether it needs to propose a new set of standards.

Ozone and Particulate Matter

Late in 1996, the EPA proposed a rule that poses great burdens to small businesses — a revision of the National Ambient Air Quality Standard (NAAQS) for ozone and particulate matter. In the draft proposal, the EPA avoided preparing a regulatory flexibility analysis by making a certification under the RFA that the revision of the ozone NAAQS would not have a "significant economic impact on a substantial number of small entities." Considering the large economic impacts that would unquestionably fall on tens of thousands, if not hundreds of thousands, of small businesses, the Office of Advocacy urged the EPA to rethink its position, and convene a Small Business Advocacy Review Panel before the issuance of the proposal, as required by the new Small Business Regulatory Enforcement Fairness Act. The EPA included some preliminary small business analysis within its draft economic analysis, but additional work needs to be done to conform with the initial regulatory flexibility analysis requirements of the RFA.

In a Nov. 4, 1996, draft preamble, the EPA indicated that the revision of the ozone NAAQS would not require the preparation of a regulatory flexibility analysis because the regulation does not directly regulate small businesses, and, therefore, has no impact on small entities as the terms are used in the RFA. Instead, the small businesses are only regulated as a result of additional federal and state regulatory actions in order to bring non-attainment regions

into compliance with the revised, more stringent standard. The EPA relied on two court cases to support its position that the SBREFA amendments to the RFA do not apply to this rulemaking.[15] The Office of Advocacy contended that the holdings of those cases do not apply to this regulation.

In this case, Advocacy applauded the EPA's partial fulfillment of the analytic requirements in its draft economic analysis under Executive Order 12866,[16] and asked the EPA to add some additional detail on the small business impacts in the analysis, including the baseline costs of the current ozone standard and the affected small business industry impacts. The EPA's analyses revealed extremely high impacts. This regulation is certainly one of the most expensive regulations — if not the most expensive regulations — faced by small businesses in 10 or more years.

Within a week of receiving the Office of Advocacy's letter requesting the application of the SBREFA procedures, the agency reversed course and instead pledged to convene a panel of federal officials to receive comments from small business groups on both the ozone and particulate matter standards immediately following the proposal of the two rules. The EPA felt compelled to move forward quickly because of a court order mandating that the agency propose the particulate standards rule by a date certain, and the belief that the ozone rule was closely related to it and needed to be co-proposed.

Federal Trade Commission

In August 1996, the Office of Advocacy submitted a letter to the Federal Trade Commission (FTC) expressing its concerns about the widely publicized merger between Turner Broadcasting and Time Warner. In the letter, Advocacy questioned whether the proposed merger would violate section 7 of the Clayton Act,[17] which prohibits anti-competitive activities. The Office of Advocacy based its concern on documented incidents of Time Warner's prior discriminatory behavior toward small cable operators. The Office of Advocacy also

15 *Mid-Tex Electric Cooperative, Inc. v. Federal Energy Regulatory Commission (FERC),* 773 F.2d 327 (D.C. Cir. 1985); *United Distribution Companies v. FERC,* 88 F.3d 1105 (D.C. Cir. 1996).

16 E.O. 12866, "Regulatory Planning and Review," Sept. 30, 1993, at 58 FR 51735 (Oct. 4, 1993).

17 15 U.S.C. 12.

questioned whether the new entity would use its market dominance to bundle programming, practice price discrimination in wholesale cable programming rates, and adversely affect competition from direct-to-home satellite services.

On Sept. 12, 1996, the FTC released its proposed decision approving the proposed Turner – Time Warner merger. To overcome anti-competitive concerns, the Commission proposed an agreement containing a consent order which required the parties to agree to certain conditions.

The Office of Advocacy's intervention in the Time Warner proceedings did not focus on regulatory flexibility issues, but on the impact of the merger on small entities. As a result of Advocacy's intervention, the Commission's order bars price discrimination and program bundling. It also ensures that the additional market power of the merger will not result in higher prices for new entrants and that cable operators will not be forced to purchase unwanted programming. In addition, the agreement provides for conduct and reporting requirements to ensure that Time Warner Cable does not discriminatorily deny program access to unaffiliated programmers.

Conclusion

The enactment of the Small Business Regulatory Enforcement Act was a major accomplishment for the small business community. Because of the judicial review provisions in the amendments to the Regulatory Flexibility Act contained in the SBREFA, many federal regulatory agencies have expressed a new willingness to comply with the requirements of the RFA.

However, to conclude that the SBREFA amendments solved all of the problems small businesses encounter when dealing with regulatory agencies would be naive. Many agencies appear to be making good-faith efforts to comply with the reformulated RFA. Complete integration of regulatory flexibility analyses into agency decision-making processes is, however, far from complete. There is still a need for ongoing education and interaction with agencies in order to ensure full compliance. The Office of Advocacy will continue to work with federal agencies and provide the necessary information and guidance to advance their understanding of regulatory flexibility compliance. These efforts are important elements of the Office's larger mission — to help agencies devise public policy solutions that do not disproportionately burden small businesses.

Appendix A: Regulatory Comments Filed by the Office of Advocacy in 1996

Date	*Agency*	*Comment Subject*
01/05/96	DOD/GSA/NASA	Proposed rule published in the *Federal Register* on Nov. 6, 1995, entitled "Federal Acquisition Regulation; Competitive Range," and giving contracting officers greater flexibility in limiting the number of offerors that qualify in the "competitive range" (Case 95-008; 60 FR 56035).
02/14/96	OFPP	Letter requesting that the full intent and due process required by the Regulatory Flexibility Act be exercised in the development of implementing rules for the Federal Acquisition Reform Act of 1996.
02/20/96	PWBA	Proposed rule published in the *Federal Register* on Dec. 20, 1995, concerning the definition of plan assets; participant contributions (60 FR 66036).
03/05/96	DEA	Proposed rule published in the *Federal Register* on Oct. 31, 1995, concerning the removal of exemption for certain pseudoephedrine products marketed under the Food, Drug, and Cosmetics Act (60 FR 55348).
04/11/96	MMS	Draft proposed rule concerning flexibility in keeping leases in force beyond their primary term. The proposed rule was subsequently published in the *Federal Register* on April 25, 1996 (61 FR 18309).
04/12/96	FCC	Brief concerning amendment of Part 36 of the commission's rules and establishment of a joint board, published in the *Federal Register* on March 14, 1996 (CC Docket no. 96-45; 61 FR 10499).

Appendix A: Regulatory Comments Filed by the Office of Advocacy in 1996

Date	*Agency*	*Comment Subject*
4/12/96	MMS	Proposed rule for specifying how to continue drilling leases for outer continental shelf. Memorandum concerning advance revised economic analysis of impacted industries affected by proposed rule change (30 CFR Part 250 § 250.13).
04/12/96	NLRB	Proposed rule published in the *Federal Register* on Sept. 28, 1995, regarding the appropriateness of requested single location bargaining units in representation cases (60 FR 50146).
04/15/96	NMFS	Advance proposed rule published in the *Federal Register* on April 8, 1996, western Pacific crustacean fisheries (61 FR 15452).
04/22/96	EPA	Proposed rule published in the *Federal Register* on Dec. 21, 1995, concerning hazardous waste identification (60 FR 66344).
04/22/96	MMS	Comment on proposed rule published in the *Federal Register* on March 25, 1996, concerning the interim rule for deepwater royalty relief for new leases (61 FR 12022).
04/24/96	NMFS	Proposed rule published in the *Federal Register* on March 28, 1996, concerning "North Pacific Fisheries Research Plan: Fee Refund" (61 FR 13782).
04/24/96	FCC	Application of Mobile Communications Holdings, Inc., for authority to construct, launch, and operate a low-earth orbit satellite in the 1610 – 1626.5 MHz / 2483.5 – 2500 MHz bands (File nos. 11-DSS-P-91; 18-DSS-P-91; 11-SAT-LA-95; and 12-SAT-AMEND-95).

04/24/96	NMFS	Proposed rule published in the *Federal Register* on April 2, 1996, concerning limited access management of federal fisheries in and off of Alaska; allowing processing of non-individual fishing quota species (61 FR 14547).
04/28/96	IRS	Comments requested by IRS Commissioner Margaret Richardson, concerning revised service worker classification training manual, entitled *Employee or Independent Contractor?*
05/01/96	OSHA	Testimony at public hearing on proposed rule published in the *Federal Register* on Feb. 2, 1996, concerning occupational injury and illness recording and reporting requirements (60 FR 4030).
05/13/96	OSHA	Request for comments published in the *Federal Register* on March 13, 1996, concerning paperwork collection; Hazard Communication Standard (61 FR 10384).
05/13/96	FHWA	Proposed rule published in the *Federal Register* on March 14, 1996, concerning "Safety Performance History of New Drivers" (49 CFR Parts 382, 390, and 391; 61 FR 10548).
05/13/96	FRA	Proposed rule published in the *Federal Register* on March 14, 1996, concerning "Railroad Worker Protection" (49 CFR Parts 214; 61 FR 10528).
05/16/96	FCC	Brief concerning proposed rule published in the *Federal Register* on April 25, 1996, on implementation of the local competition provisions in the Telecommunications Act of 1996 (61 FR 18311).
05/16/96	FCC	Brief concerning IRFA prepared on local competition provisions of the Telecommunications Act of 1996.
05/20/96	FS	Proposed rule published in the *Federal Register* on April 3, 1996, concerning disposal of national forest system timber; modification of timber sale contracts in extraordinary conditions (61 FR 14618).

Appendix A: Regulatory Comments Filed by the Office of Advocacy in 1996

Date	*Agency*	*Comment Subject*
05/22/96	FCC	Brief concerning the application of Mobile Communications Holdings, Inc., for authority to construct, launch, and operate a low-earth orbit satellite system in the 1610 – 1626.5 MHz / 2483.5 – 2500 MHz bands (File nos. 11-DSS-P-91; 18-DSS-P-91; 11-SAT-LA-95; and 12-SAT-AMEND-95).
05/31/96	FCC	Brief on final rule published in the *Federal Register* on March 12, 1996, concerning amendment of the "Commission's Regulatory Policies Governing Domestic Fixed Satellites and Separate International Satellite Systems" (61 FR 9946).
06/10/96	FERC	Final rule published in the *Federal Register* on May 10, 1996, concerning promotion of wholesale competition through open access non-discriminatory transmission services by public utilities, and recovery of stranded costs by public utilities and transmitting utilities (61 FR 21540).
06/12/96	FSIS	Draft final rule concerning "Hazard Analysis Critical Control Points for Meat and Poultry" (Docket no. 93-016P).
06/13/96	USTR	Proposed imposition of retaliatory duties on certain bicycles imported from China (Docket no. 301-02).
06/24/96	DEA	Letter to the OMB in reference to letter of March 5, 1996, to DEA, concerning proposed rule published in the *Federal Register* on Oct. 31, 1995, concerning the removal of exemption for certain pseudoephedrine products marketed under the Food, Drug, and Cosmetic Act (60 FR 55346).
06/26/96	DOD/GSA/NASA	Advance NPRM published in the *Federal Register* on May 13, 1996, concerning the "Federal Acquisition Regulation; Implementation of

		Commercially Available Off-the-Shelf Item Acquisition Provisions of the Federal Acquisition Reform Act" (FAR Case 96-308; 61 FR 22010).
06/27/96	OSHA	Comments on OSHA's outreach to small business on proposed *Guidelines for Workplace Violence Prevention Programs for Night Retail Establishments* (OSHA draft posted on Internet, April 1996).
07/01/96	OSHA	Proposed rule published in the *Federal Register* on Feb. 2, 1996, concerning occupational injury and illness recording and reporting requirements (61 FR 4030). (Public meeting testimony given May 1, 1996.)
07/08/96	OSHA	Confirmation of deadline extension (to September 30, 1996) for comments concerning OSHA's proposed *Guidelines for Workplace Violence Prevention Programs for Night Retail Establishments*. (The extension had been requested on June 27, 1996.)
07/08/96	OSHA	Notice of intent to form a negotiated rulemaking advisory committee for developing a proposed rule on fire protection in shipyard employment, published in the *Federal Register* on June 6, 1996 (61 FR 28824).
07/09/96	FRA	Advance notice of proposed rulemaking published in the *Federal Register* on June 17, 1996, concerning passenger equipment safety standards (FRA Docket no. PCSS-1; 61 FR 30672).
07/17/96	DOJ	Comments submitted in response to a public notice and invitation for reactions and views published in the *Federal Register* on May 23, 1996, concerning proposed reforms to affirmative action in federal procurement (61 FR 26042).
07/18/96	APHIS	Proposed rules published in the *Federal Register* on July 2, 1996, concerning humane treatment of dogs and cats in regard to: wire flooring in cages and pens (Docket no. 95-100-1; 61 FR 34389) and tethering and temperature requirements (Docket no. 95-078-1; 61 FR 34386).

Appendix A: Regulatory Comments Filed by the Office of Advocacy in 1996

Date	*Agency*	*Comment Subject*
07/19/96	NMFS	Proposed rule published in the *Federal Register* on June 3, 1996, concerning summer flounder and scup fisheries (Amendment 8; 61 FR 27851).
07/25/96	FRA	Intent for rulemaking on passenger equipment safety standards. Follow-up to July 9, 1996, letter to the FRA concerning the tourist railways that were not represented in the working group developing this rule (FRA Docket no. PCSS-1).
08/14/96	FTC	Draft consent order for the proposed merger of Time Warner, Inc., and Turner Broadcasting, Inc.
08/16/96	OSHA	Letter to OSHA asking agency to include small businesses on OSHA's standards advisory committee for occupational exposure to metalworking fluids.
08/19/96	Coast Guard	Proposed rule published in the *Federal Register* on June 4, 1996, concerning electrical engineering requirements for merchant vessels (61 FR 28260).
08/19/96	RSPA	Supplemental notice published in the *Federal Register* on March 20, 1996, concerning proposed rulemaking on hazardous materials in intrastate transportation (61 FR 11484).
08/22/96	FCC	Brief concerning rule published in the *Federal Register* on July 29, 1996, to amend Parts 1, 2, 21, and 25 of the commission's rules to redesignate the 27.5 – 29.5 GHz frequency bank, to Reallocate the 29.5 – 30.0 GHz frequency bank, and to establish rules and policies for local multi-point distribution service and for fixed satellite services (CC Docket no. 92-297; 61 FR 39425).

08/23/96	OSHA	Letter to Advisory Committee on Construction Safety and Health commenting on its revised draft of a standard that would require firms to establish workplace safety and health programs.
08/27/96	OSHA	Draft final rule for occupational exposure to methylene chloride; sent to OMB on Aug. 27, 1996 (29 CFR Part 1910; Docket No. H-71; RIN 1218-AA98.)
08/27/96	DOD/GSA/NASA	Proposed rule published in the *Federal Register* on July 31, 1996, concerning competitive range determinations (FAR Case 96-303; 61 FR 40116).
08/29/96	FMC	Letter outlining size standards, in reference to a proposed rule published in the *Federal Register* on June 26, 1996, concerning financial responsibility requirements for non-performance of transportation (61 FR 33059).
08/29/96	OSHA	Letter providing a list of small entities to consult and recommended outreach procedures, pursuant to the Small Business Regulatory Enforcement Act. A Small Business Advocacy Review Panel was required because OSHA developed a proposed rule to protect workers from occupational exposure to tuberculosis and the IRFA indicated that the rule may have a significant economic impact on a substantial number of small entities. (Response to letter of Aug. 16, 1996, requesting a panel.)
09/03/96	BIA	Comment letter concerning 12 proposed rules that were not in compliance with the Regulatory Flexibility Act: 61 FR 30560 (June 17, 1996); 61 FR 31470 (June 20, 1996); 61 FR 31875 (June 21, 1996; 61 FR 33876 (July 1, 1996); 61 FR 34400 (July 2, 1996); 61 FR 35167 (July 5, 1996); 61 FR 35158 (July 5, 1996); 61 FR 35163 (July 5, 1996); 61 FR 36671 (July 12, 1996); 61 FR 36829 (July 15, 1996); 61 FR 37417 (July 18, 1996); 61 FR 41365 (Aug. 8, 1996).

Appendix A: Regulatory Comments Filed by the Office of Advocacy in 1996

Date	*Agency*	*Comment Subject*
09/03/96	FDA	Proposed rule published in the *Federal Register* on June 14, 1996, concerning the classification/reclassification of immunohistochemistry reagents and kits (Docket no. 94P-0341; 61 FR 30197).
09/04/96	DOD/GSA/NASA	Final rule published in *Federal Register* on July 26, 1996, on simplified acquisition threshold/Federal Acquisition Computer Network (FACNET); and micro-purchase procedures (FAR Case nos. 94-770 and 94-771; 61 FR 39189).
09/04/96	IRS	Comment letter in regard to proposed rule published in the *Federal Register* on June 6, 1996, that would amend regulations related to the tax treatment of qualified small business stock (IRS no. IA-26-94; 61 FR 28821).
09/06/94	DOD/GSA/NASA	Final rule published in the *Federal Register* on July 26, 1996, concerning task and delivery order contracts (FAR Case no. 94-711; 61 FR 39186).
09/09/96	EPA	Memorandum containing a list of regulatory alternatives for consideration by the EPA in regard to its Compliance Assurance Monitoring (CAM) draft proposal.
09/10/96	OSHA	Letter encouraging revisions to OSHA's Nationally Recognized Testing Laboratories (NRTL) program that would increase small firm participation.
09/11/96	DOD/GSA/NASA	Comment letter regarding competitive range determinations (FAR Case no. 96-303; 61 FR 40116, July 31, 1996).
09/17/96	MSHA	Preliminary comments regarding draft proposed rule and initial regulatory flexibility analysis for occupational noise exposure in mines (30 CFR Part 62; RIN 1219-AA53).

09/23/96	EPA	Comments on the peer review reports on technical aspects of the proposed hazardous waste combustor rule.
09/23/96	DOD/GSA/NASA	Request for an extension of the public comment period for two proposed regulations: competitive range determinations and FAR Part 15 Rewrite — Phase I.
09/24/96	IRS	Comments on proposed changes to IRS publication no. 334, *Tax Guide for Small Business*.
09/25/96	EPA	Comments in response to a proposal published in the *Federal Register* on June 27, 1996, that would expand the Toxic Release Inventory (TRI) reporting requirements to seven additional industries (Docket no. OPPTS-400104; 61 FR 33588).
09/27/96	EPA	Request for expanded use of TRI Form A, the alternative threshold form, provided as a substitute for the longer nine-page Form R (OMB no. 2070-0143; EPA ICR no. 1704.03; 61 FR 41407, Aug. 8, 1996).
09/30/96	FCC	Brief on proposed rule published in the *Federal Register* on June 26, 1996, concerning Section 257, the commission's proceeding to identify and eliminate market entry barriers for small businesses in various telecommunications markets (GN Docket no. 96-113; 61 FR 33066).
09/30/96	OSHA	Comments on the draft *Guidelines for Workplace Violence Prevention Programs for Night Retail Establishments*.
10/03/96	IRS	Testimony before the IRS concerning amendments to regulations governing the tax treatment of qualified small business stocks (26 U.S.C. § 1202; 26 CFR Part I, §§ 1.1202-0 and 1.1202-2; proposed IRS regulation no. IA-26-94).

Appendix A: Regulatory Comments Filed by the Office of Advocacy in 1996

Date	*Agency*	*Comment Subject*
10/17/96	FRA	Roadway worker protection (49 CFR Part 214; FRA Docket no. RSOR 13, Notice no. 6).
10/17/96	EPA	Advocacy's response to an EPA SBREFA notification regarding a proposed rule: "Amendments to Parts 51, 52, 63, 70, and 71 Regarding Potential to Emit; SBREFA Small Business Advocacy Review Panel."
10/22/96	FHWA	Comment on plans to promulgate a rulemaking that would require employers to provide adequate entry-level driving training for commercial motor vehicles (FHWA Docket no. MC-93-12).
10/28/96	EPA	Renewal request on TRI Form R, which is used to provide information about chemical releases and transfers under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (OMB no. 2070-0143; EPA ICR no. 1363.05; 61 FR 45964, Aug. 30, 1996).
10/28/96	BLM	Comment letter concerning 10 proposed rules that were not in compliance with the Regulatory Flexibility Act: 61 FR 42579 (Aug. 16, 1996); 61 FR 45385 (Aug. 29, 1996); 61 FR 47853 (Sept. 11, 1996); 61 FR 47855 (Sept. 11, 1996); 61 FR 48455 (Sept. 13, 1996); 61 FR 48454 (Sept. 13, 1996); 61 FR 53887 (Oct. 16, 1996); 61 FR 54120 (Oct. 17, 1996); 61 FR 54384 (Oct. 18, 1996); 61 FR 54977 (Oct. 23, 1996).
10/29/96	FAA	Requesting information from the FAA on the agency's current policy concerning the Regulatory Flexibility Act.
10/30/96	NPS	Proposed rule published in the *Federal Register* on Sept. 17, 1996, concerning transportation and utility systems in and across Alaska; access into conservation system units in Alaska (61 FR 48873).

11/01/96	FCC	Brief concerning pleading cycle established for waivers of down-payment rules in the Broadbank Personal Communications Services C-Block, 900 MHz specialized mobile radio, and multi-point distribution service auctions (Public Notice no. DA 96-1692).
11/05/96	GSA	Proposed rule published in the *Federal Register* on Sept. 6, 1996, concerning application of special simplified procedures to the procurement of certain commercial items under the FAR (FAR Case no. 96-307; 61 FR 47384).
11/05/96	EPA	Advocacy response to an EPA SBREFA notification regarding a proposed rulemaking: "Amendments to the Definition of Solid Waste, 40 CFR Parts 260, 261, 266, and 267 (Regulation of Recycling under RCRA); SBREFA Small Business Advocacy Review Panel."
11/08/96	DOD/GSA/NASA	Testimony before FAR Council meeting on regulatory proposals concerning competitive range determinations (FAR Case no. 96-303) and FAR Part 15 Rewrite — Phase I (FAR Case no. 96-029).
11/11/96	DOD/GSA/NASA	Letter to FAR Secretariat concerning proposed rules on competitive range determinations (FAR Case no. 96-303) and FAR Part 15 Rewrite — Phase I (FAR Case no. 96-029).
11/12/96	FCC	Comments on proposed rules published in the *Federal Register* on April 30, 1996, implementing provisions of the Telecommunications Act of 1996. The commission was urged to adopt affiliation rules similar to the SBA's for determining which small cable operators qualify for deregulation (CS Docket no. 96-85; 61 FR 18968).
11/12/96	OSHA	Report prepared by the Small Business Advocacy Review Panel on OSHA's draft proposed rule for occupational exposure to tuberculosis. Panel included the SBA's chief counsel for advocacy, administrator of the OMB's Office of Information and Regulatory Affairs, and staff from OSHA.

Appendix A: Regulatory Comments Filed by the Office of Advocacy in 1996

Date	*Agency*	*Comment Subject*
11/13/96	DOT	Proposed rule published in the *Federal Register* on Sept. 10, 1996, concerning passenger manifest information for domestic airline flights (Docket no. OST-95-950; 61 FR 47692).
11/14/96	FAA	NPRM published in the *Federal Register* on July 31, 1996, concerning special flight rules in the vicinity of Grand Canyon National Park (Docket no. 28537; Notice no. 96-11; 61 FR 40120).
11/18/96	EPA	Letter commenting on the draft of the EPA's review of the National Ambient Air Quality Standards (NAAQS) for ozone, and calling for the convening of a Small Business Advocacy Review Panel.
11/18/96	FBI	Draft final rule concerning cost recovery regulations for the Communications Assistance for Law Enforcement Act; proposed rule published in the *Federal Register* on May 10, 1996 (61 FR 21396).
11/19/96	IRS	Proposed rule published in the *Federal Register* on Nov. 12, 1996, concerning amendments to the income tax regulations related to the definition of "reasonable basis" for the purpose of accuracy-related penalty regulation under Chapter 1 of the Internal Revenue Code (61 FR 58020).
11/19/96	MSHA	Follow-up to letter of Sept. 17, 1996, concerning draft proposed rule for occupational noise exposure and the accompanying regulatory flexibility analysis (30 CFR Part 62; RIN 1219-AA53).
11/25/96	FTC	Regarding proposed acquisition of Turner Broadcasting, Inc., by Time Warner, Inc. (File no. 961-0004).

11/26/96	EPA	Advocacy's response to the EPA's request for SBREFA Small Business Advocacy Review Panel regarding control of air pollution from non-road diesel engines.
11/26/96	DOD/GSA/NASA	Comments regarding two proposed rules published in the *Federal Register* on July 31, 1996, concerning competitive range determinations (FAR Case no. 96-303) and "Part 15 Rewrite — Phase I" (FAR Case no. 96-029) (61 FR 40116).
12/05/96	OTP	Comments on advance copy of Notice 96-53, which provides answers to commonly asked questions about medical savings accounts.
12/13/96	FCC	Letter to Hon. Reed E. Hundt, chairman of the FCC, on the Federal-State Joint Board on Universal Service's proposal on telephone universal service (CC Docket no. 96-45).
12/19/96	FCC	Comments on the Federal-State Joint Board's proposal on telephone universal service (CC Docket no. 96-45).
12/24/96	EPA	Letter regarding the expansion of TRI reporting requirements to chemical wholesalers, advising the EPA of new data that demonstrates that facilities in SIC code 5169 (chemical and allied products) do not belong in the proposed expansion (Docket no. OPPTS-400104).

Note: The full text of these regulatory comment letters is available on the Office of Advocacy's site on the World Wide Web at *http://www.sba.gov/ADVO/laws/comments/rfr96.html.*

Appendix B: The Regulatory Flexibility Act

The following text of the Regulatory Flexibility Act of 1980, as amended, is taken from Title 5 of the United States Code, sections 601–612

§ 601. Definitions

For purposes of this chapter—

(1) the term "agency" means an agency as defined in section 551(1) of this title;

(2) the term "rule" means any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title, or any other law, including any rule of general applicability governing Federal grants to State and local governments for which the agency provides an opportunity for notice and public comment, except that the term "rule" does not include a rule of particular applicability relating to rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services, or allowances therefor or to valuations, costs or accounting, or practices relating to such rates, wages, structures, prices, appliances, services, or allowances;

(3) the term "small business" has the same meaning as the term "small business concern" under section 3 of the Small Business Act, unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(4) the term "small organization" means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(5) the term "small governmental jurisdiction" means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and which are based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction, and publishes such definition(s) in the Federal Register;

(6) the term "small entity" shall have the same meaning as the terms "small business", "small organization" and "small governmental jurisdiction" defined in

paragraphs (3), (4) and (5) of this section; and

(7) the term "collection of information"—

(A) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either—

(i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, 10 or more persons, other than agencies, instrumentalities, or employees of the United States; or

(ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes; and

(B) shall not include a collection of information described under section 3518(c)(1) of title 44, United States Code.

(8) Recordkeeping requirement.—The term "recordkeeping requirement" means a requirement imposed by an agency on persons to maintain specified records.

§ 602. Regulatory agenda

(a) During the months of October and April of each year, each agency shall publish in the Federal Register a regulatory flexibility agenda which shall contain—

(1) a brief description of the subject area of any rule which the agency expects to propose or promulgate which is likely to have a significant economic impact on a substantial number of small entities;

(2) a summary of the nature of any such rule under consideration for each subject area listed in the agenda pursuant to paragraph (1), the objectives and legal basis for the issuance of the rule, and an approximate schedule for completing action on any rule for which the agency has issued a general notice of proposed rulemaking, and

(3) the name and telephone number of an agency official knowledgeable concerning the items listed in paragraph (1).

(b) Each regulatory flexibility agenda shall be transmitted to the Chief Counsel for Advocacy of the Small Business Administration for comment, if any.

(c) Each agency shall endeavor to provide notice of each regulatory flexibility agenda to small entities or their representatives through direct notification or publication of the agenda in publications likely to be obtained by such small entities and shall invite comments upon each subject area on the agenda.

(d) Nothing in this section precludes an agency from considering or acting on any matter not included in a regulatory flexibility agenda, or requires an agency to consider or act on any matter listed in such agenda.

§ 603. Initial regulatory flexibility analysis

(a) Whenever an agency is required by section 553 of this title, or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretative rule involving the

internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities. The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule. The agency shall transmit a copy of the initial regulatory flexibility analysis to the Chief Counsel for Advocacy of the Small Business Administration. In the case of an interpretative rule involving the internal revenue laws of the United States, this chapter applies to interpretative rules published in the Federal Register for codification in the Code of Federal Regulations, but only to the extent that such interpretative rules impose on small entities a collection of information requirement.

(b) Each initial regulatory flexibility analysis required under this section shall contain—

(1) a description of the reasons why action by the agency is being considered;

(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;

(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

(c) Each initial regulatory flexibility analysis shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as—

(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

(3) the use of performance rather than design standards; and

(4) an exemption from coverage of the rule, or any part thereof, for such small entities.

§ 604. Final regulatory flexibility analysis

(a) When an agency promulgates a final rule under section 553 of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking, or promulgates a final interpretative rule involving the internal revenue laws of the United States as described in section 603(a), the agency shall prepare a final regulatory flexibility analysis. Each final regulatory flexibility analysis shall contain—

(1) a succinct statement of the need for, and objectives of, the rule;

(2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

(3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

(4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

(b) The agency shall make copies of the final regulatory flexibility analysis available to members of the public and shall publish in the Federal Register such analysis or a summary thereof.

§ 605. Avoidance of duplicative or unnecessary analyses

(a) Any Federal agency may perform the analyses required by sections 602, 603, and 604 of this title in conjunction with or as a part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of such sections.

(b) Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration.

(c) In order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.

§ 606. Effect on other law

The requirements of sections 603 and 604 of this title do not alter in any manner standards otherwise applicable by law to agency action.

§ 607. Preparation of analyses

In complying with the provisions of sections 603 and 604 of this title, an agency may provide either a quantifiable or numerical description of the effects of a proposed rule or alternatives to the proposed rule, or more general descriptive statements if quantification is not practicable or reliable.

§ 608. Procedure for waiver or delay of completion

(a) An agency head may waive or delay the completion of some or all of the requirements of section 603 of this title by publishing in the Federal Register, not later than the date of publication of the final rule, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes compliance or timely compliance with the provisions of section 603 of this title impracticable.

(b) Except as provided in section 605(b), an agency head may not waive the requirements of section 604 of this title. An agency head may delay the completion of the requirements of section 604 of this title for a period of not more than one hundred and eighty days after the date of publication in the Federal Register of a final rule by publishing in the Federal Register, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 of this title impracticable. If the agency has not prepared a final regulatory analysis pursuant to section 604 of this title within one hundred and eighty days from the date of publication of the final rule, such rule shall lapse and have no effect. Such rule shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency.

§ 609. Procedures for gathering comments

(a) When any rule is promulgated which will have a significant economic impact on a substantial number of small entities, the head of the agency promulgating the rule or the official of the agency with statutory responsibility for the promulgation of the rule shall assure that small entities have been given an opportunity to participate in the rulemaking for the rule through the reasonable use of techniques such as—

(1) the inclusion in an advanced notice of proposed rulemaking, if issued, of a statement that the proposed rule may have a significant economic effect on a substantial number of small entities;

(2) the publication of general notice of proposed rulemaking in publications likely to be obtained by small entities;

(3) the direct notification of interested small entities;

(4) the conduct of open conferences or public hearings concerning the rule for small entities including soliciting and receiving comments over computer networks; and

(5) the adoption or modification of agency procedural rules to reduce the cost or complexity of participation in the rulemaking by small entities.

(b) Prior to publication of an initial regulatory flexibility analysis which a covered agency is required to conduct by this chapter—

(1) a covered agency shall notify the Chief Counsel for Advocacy of the Small Business Administration and provide the Chief Counsel with information on the potential impacts of the proposed rule on small entities and the type of small entities that might be affected;

(2) not later than 15 days after the date of receipt of the materials described in paragraph (1), the Chief Counsel shall identify individuals representative of af-

fected small entities for the purpose of obtaining advice and recommendations from those individuals about the potential impacts of the proposed rule;

(3) the agency shall convene a review panel for such rule consisting wholly of full time Federal employees of the office within the agency responsible for carrying out the proposed rule, the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel;

(4) the panel shall review any material the agency has prepared in connection with this chapter, including any draft proposed rule, collect advice and recommendations of each individual small entity representative identified by the agency after consultation with the Chief Counsel, on issues related to subsections 603(b), paragraphs (3), (4) and (5) and 603(c);

(5) not later than 60 days after the date a covered agency convenes a review panel pursuant to paragraph (3), the review panel shall report on the comments of the small entity representatives and its findings as to issues related to subsections 603(b), paragraphs (3), (4) and (5) and 603(c), provided that such report shall be made public as part of the rulemaking record; and

(6) where appropriate, the agency shall modify the proposed rule, the initial regulatory flexibility analysis or the decision on whether an initial regulatory flexibility analysis is required.

(c) An agency may in its discretion apply subsection (b) to rules that the agency intends to certify under subsection 605(b), but the agency believes may have a greater than de minimis impact on a substantial number of small entities.

(d) For purposes of this section, the term "covered agency" means the Environmental Protection Agency and the Occupational Safety and Health Administration of the Department of Labor.

(e) The Chief Counsel for Advocacy, in consultation with the individuals identified in subsection (b)(2), and with the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, may waive the requirements of subsections (b)(3), (b)(4), and (b)(5) by including in the rulemaking record a written finding, with reasons therefor, that those requirements would not advance the effective participation of small entities in the rulemaking process. For purposes of this subsection, the factors to be considered in making such a finding are as follows:

(1) In developing a proposed rule, the extent to which the covered agency consulted with individuals representative of affected small entities with respect to the potential impacts of the rule and took such concerns into consideration.

(2) Special circumstances requiring prompt issuance of the rule.

(3) Whether the requirements of subsection (b) would provide the individuals identified in subsection (b)(2) with a competitive advantage relative to other small entities.

§ 610. Periodic review of rules

(a) Within one hundred and eighty days after the effective date of this chapter, each agency shall publish in the Federal Register a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities. Such plan may be amended by the agency at any time by publishing the revision in the Federal Register. The

purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities. The plan shall provide for the review of all such agency rules existing on the effective date of this chapter within ten years of that date and for the review of such rules adopted after the effective date of this chapter within ten years of the publication of such rules as the final rule. If the head of the agency determines that completion of the review of existing rules is not feasible by the established date, he shall so certify in a statement published in the Federal Register and may extend the completion date by one year at a time for a total of not more than five years.

(b) In reviewing rules to minimize any significant economic impact of the rule on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the agency shall consider the following factors—

(1) the continued need for the rule;

(2) the nature of complaints or comments received concerning the rule from the public;

(3) the complexity of the rule;

(4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and

(5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

(c) Each year, each agency shall publish in the Federal Register a list of the rules which have a significant economic impact on a substantial number of small entities, which are to be reviewed pursuant to this section during the succeeding twelve months. The list shall include a brief description of each rule and the need for and legal basis of such rule and shall invite public comment upon the rule.

§ 611. Judicial review

(a)(1) For any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7. Agency compliance with sections 607 and 609(a) shall be judicially reviewable in connection with judicial review of section 604.

(2) Each court having jurisdiction to review such rule for compliance with section 553, or under any other provision of law, shall have jurisdiction to review any claims of noncompliance with sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7. Agency compliance with sections 607 and 609(a) shall be judicially reviewable in connection with judicial review of section 604.

(3)(A) A small entity may seek such review during the period beginning on the date of final agency action and ending one year later, except that where a provision of law requires that an action challenging a final agency action be commenced before the expiration of one year, such lesser period shall apply to an action for judicial review under this section.

(B) In the case where an agency delays the issuance of a final regulatory flexibility analysis pursuant to section 608(b) of this chapter, an action for judicial review under this section shall be filed not later than—

(i) one year after the date the analysis is made available to the public, or

(ii) where a provision of law requires that an action challenging a final agency regulation be commenced before the expiration of the 1-year period, the number of days specified in such provision of law that is after the date the analysis is made available to the public.

(4) In granting any relief in an action under this section, the court shall order the agency to take corrective action consistent with this chapter and chapter 7, including, but not limited to—

(A) remanding the rule to the agency, and

(B) deferring the enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest.

(5) Nothing in this subsection shall be construed to limit the authority of any court to stay the effective date of any rule or provision thereof under any other provision of law or to grant any other relief in addition to the requirements of this section.

(b) In an action for the judicial review of a rule, the regulatory flexibility analysis for such rule, including an analysis prepared or corrected pursuant to paragraph (a)(4), shall constitute part of the entire record of agency action in connection with such review.

(c) Compliance or noncompliance by an agency with the provisions of this chapter shall be subject to judicial review only in accordance with this section.

(d) Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise permitted by law.

§ 612. Reports and intervention rights

(a) The Chief Counsel for Advocacy of the Small Business Administration shall monitor agency compliance with this chapter and shall report at least annually thereon to the President and to the Committees on the Judiciary and Small Business of the Senate and House of Representatives.

(b) The Chief Counsel for Advocacy of the Small Business Administration is authorized to appear as amicus curiae in any action brought in a court of the United States to review a rule. In any such action, the Chief Counsel is authorized to present his or her views with respect to compliance with this chapter, the adequacy of the rulemaking record with respect to small entities and the effect of the rule on small entities.

(c) A court of the United States shall grant the application of the Chief Counsel for Advocacy of the Small Business Administration to appear in any such action for the purposes described in subsection (b).

(*The Regulatory Flexibility Act was originally passed in 1980 (P. L. 96-354). The Act was amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121).*)