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Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives

February 1992

FDA REGULATIONS

Sustained Management Attention Needed to Improve Timely Issuance

GAO/HRD-92-35

GAO

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Human Resources Division

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February 21, 1992

The Honorable Henry A. Waxman
Chairman, Subcommittee on Health
and the Environment
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

Because of the wide range of products it regulates, the Food and Drug Administration (FDA) touches the day-to-day lives of virtually all Americans. Through an effective rulemaking process, FDA can address public health issues in an authoritative manner and establish the detailed rules that FDA-regulated industries must follow to comply with the law.

At your request, we prepared this report on problems FDA officials need to address in their efforts to improve the agency's rulemaking process. You asked us to report on the number of FDA regulations that are either

- under development and review or
- in pending status awaiting further action by the agency because they have been published in the Federal Register as proposed rules but not issued in final form.

In addition, we (1) determined general reasons for delays in issuing regulations, (2) identified actions planned by FDA to issue regulations in a more timely manner, and (3) identified areas for improvement in FDA's system for managing its regulations workload.

To prepare this report, we collected and analyzed data on FDA regulations in process as of April 1991. We also reviewed internal FDA documents, including prior agency studies initiated to identify weaknesses in regulation development and issuance. In addition, we interviewed FDA officials to determine reasons for delays in issuing regulations and FDA's plans to improve its system for developing and processing regulations and monitoring their status. (See app. I for additional details on our objectives, scope, and methodology.)

Results in Brief

Over the years, FDA has experienced major delays in the development of regulations and publication of its final regulations. As of April 1991, when FDA released agencywide data, 388 regulations were in process that the agency had begun to develop but had not completed or published in the Federal Register as final regulations. Of 301 regulations published as proposed rules to obtain public comment, 217 (72 percent) had been in pending status for more than 5 years. Some have been pending much longer; two have been pending for 29 years. Further, certain regulations required by federal statute had been in process an average of 4 years. At the time of our review, 45 such regulations were in process within FDA.

Because FDA's management of regulation development and issuance has been generally ineffective, we support the agency's August 1991 establishment of a Regulations Council to oversee and, when needed, direct the management of the rulemaking process. In addition, we believe a single automated tracking system that encompasses agencywide regulation activities is needed to improve management's oversight of the rulemaking process.

Background

FDA, an agency within the Department of Health and Human Services (HHS) and a component of the Public Health Service, is the nation's oldest consumer-protection agency. It regulates nearly $1 trillion worth of products.

To provide needed guidance to the food, drug, and cosmetic industries as well as the public on the products it regulates, FDA develops regulations and publishes them in proposed and final form in the Federal Register. In 1990, FDA published 56 proposed and 184 final regulations.

Primary responsibility for regulation development and issuance lies with FDA headquarters staff.[1] In recent years, nearly 98 percent of FDA documents (regulations and notices) published in the Federal Register have been signed by the FDA Commissioner and other FDA headquarters officials under authority delegated by the Secretary of HHS. The Secretary signed the remaining 2 percent.

[1]FDA is organizationally divided into a Commissioner's office, six centers, and field staff. FDA's headquarters staff (the Commissioner's office and five of the six centers) is located in the Washington, D.C., metropolitan area. The five centers are organized along product line and are responsible for developing regulations for products in their specialty areas. For example, the Center for Drug Evaluation and Research develops regulations dealing with prescription and nonprescription drugs and the Center for Food Safety and Applied Nutrition primarily develops regulations for safe food and food additives.

Backlog of Regulations Large, Some Decades-Old

Within the past 30 years, FDA has accumulated a large number of regulations that it (1) began to develop but never completed or (2) published in the Federal Register as proposed rules for public comment but never issued as final. As of April 1991,[2] 87 regulations were under development in the five FDA centers. An additional 301 proposed regulations (either advance notices of proposed rulemaking or notices of proposed rulemaking had been published in the Federal Register. Of the 388 proposed regulations, FDA considered 197 to be in an active work status category and the status of the rest to be inactive (164) or unknown (27) (see table 1).

Table 1: Work Status of FDA Regulations in Process (Apr. 1991)

	Number of regulations				
		Published as proposed rules			
Status	Under development	OTC[a]	Other	Total	Total in process
Active	69	38	90	**128**	197
Inactive	13	23	128	**151**	164
Unknown	5	0	22	**22**	27
Total	**87**	**61**	**240**	**301**	**388**

[a]FDA decided that regulations for drugs marketed over-the-counter (OTC) will be developed, monitored, and reported on as a separate project from all other regulations (see below).

Source: FDA Office of Regulatory Affairs, Division of Regulations Policy.

The 61 OTC proposed regulations are being developed and processed under a special FDA initiated drug review program. Of the 61 proposed regulations, 57 were developed to implement provisions of the Drug Amendments of 1962, which amended the Federal Food, Drug, and Cosmetic Act of 1938. The amendments required FDA to review for evidence of efficacy, those drugs introduced from 1938 to 1962 for marketing (including those marketed over-the-counter without a prescription). To complete the review of those OTC drugs covered under the amendments and others that were not included, FDA adopted rulemaking procedures that would allow reviewing categories of OTC drugs instead of each individual drug sold to the public. As of April 1991, 23 of the 61 OTC proposed regulations were categorized by FDA in an inactive work status.

[2]The month when agencywide information on FDA regulations was provided, as requested, to the House Subcommittee on Health and the Environment.

Nearly three-fourths (217) of the 301 proposed regulations that have been published in the Federal Register have been in pending status for more than 5 years, waiting for FDA to make changes before issuing them in final form.[3] The average length of time the 301 regulations were in pending status was 9 years. For over 10 percent of the 301 regulations, 15 years or more have elapsed. For over 30 percent of the 61 OTC regulations, 10 years or more have elapsed since they were published as proposed rules (see table II.1).

FDA has no policy regarding targets for how fast proposed regulations should move through the process or on when proposed actions should be terminated. But FDA officials acknowledge that the current time is too long.

Processing Time for High-Priority Regulations Often Long

Regulations that FDA considers very important and to which it gives high-priority status often take a long time to develop and issue. These include regulations that are

- considered "significant" by FDA and, therefore, are prepared for signature by the Secretary of HHS[4] and review by the Office of Management and Budget (OMB) before publication in the Federal Register and
- required by federal statute, some of which are also signed by the Secretary.

Although FDA, through HHS, is required to adopt a formal plan for issuing its major regulation initiatives,[5] including "significant" regulations, the pre-planning and high-priority status often have not expedited issuance.

[3]We did not measure elapsed time from when regulation development began to final issuance because sufficient data were not available. For 233 (60 percent) of the 388 regulations in process, neither actual nor estimated dates regulation development began were available because FDA centers do not routinely collect such information for each regulation. Thus, to measure delays in issuing final regulations, we analyzed only the 301 proposed regulations that had actual dates of initial publication in the Federal Register.

[4]The Secretary of HHS has reserved authority to approve certain FDA regulations that address highly significant public issues involving the quality, availability, marketability, or cost of foods, drugs, cosmetics, and medical devices.

[5]Under Executive Order 12498, executive departments and agencies must implement a planning process that includes setting goals and priorities for the development and issuance of regulations. For major regulation initiatives, FDA's plans are published annually in the Regulatory Program of the United States Government.

Considerable Time Taken to Issue "Significant" Regulations

From 1986 through 1990, FDA published 40 regulations that the agency considered important enough to be deemed "significant"[6] (see app. III). Despite their high-priority status, many of these regulations took several years to issue.

Because such regulations are signed by the Secretary of HHS and reviewed by OMB before both initial and final publication in the Federal Register, they need additional processing time before they are issued as final regulations. Of the 22 final regulations signed by the Secretary during the 5-year period, 14 took an average 5 years to develop and issue.[7] The time these 14 regulations were in process ranged from 15 months to about 9 years. The majority of the processing time for all of the regulations was FDA's. In only 5 of the 14 regulations, about 20 percent or more of the total time in process was spent obtaining HHS and OMB approvals, including time spent making changes based on their review (see app. IV).

Obtaining HHS and OMB approvals added at least 8 months to the overall process. From available data, we were unable to determine how much of the additional 8 months was time FDA spent responding to and making changes based on HHS and OMB comments.

Important regulations also can stay in pending status for several years. Our analysis of the time it took FDA to obtain public comments, revise, and issue all 22 final significant regulations after they were published as proposed rules indicated an average of 3 years (see table II.2). The 22 regulations were in pending status from less than 1 to 9 years. A large percentage of the pending regulations, however, fell into the 1- to 2-year range.

Of the 15 significant FDA regulations published as proposed regulations but not issued as final rules, 5 had been in pending status from 2 to 5 years as of April 1991. Two of the 15 had been pending for more than 5 years.

[6]These significant regulations dealt with such issues as current good manufacturing practices; food labeling requirements; irradiation in the production, processing, and handling of food; menstrual tampon labeling; and tamper-resistant packaging. As of April 1991, of the 40 significant regulations, 22 had been issued in final; 15 had been published as proposed rules (including 2 interim finals); 1 final rule was to be replaced by a new regulation; 1 proposed rule was withdrawn by FDA; and 1 interim final rule was outstanding because OMB suspended final review. Our analysis does not include the 3 regulations that were either replaced, withdrawn, or suspended.

[7]Our analysis of the total time to process and issue significant regulations in final form was limited to 14 regulations because FDA could not determine when development began for 8 of the 22 final regulations.

Pace in Issuing Statutorily Required Regulations Also Slow

FDA also has been slow in issuing many of the regulations required by federal statutes. According to information FDA provided as of April 1991, 37 regulations were being actively worked on to fulfill statutory requirements. The work status of an additional 8 was unknown (see table II.3). Further, although five laws set specific deadlines for issuing certain regulations, FDA had missed several of these deadlines as of December 1991.

The 45 regulations mentioned above have been in process, on average, for about 4 years. (See app. V for a list of the statutorily required regulations.) Of the 45, 10 were published in the Federal Register as proposed rules. To develop and issue the proposed rules after enactment of legislation took FDA from 1 to nearly 10 years. The majority of the regulations, 70 percent, took from 5 to nearly 10 years to publish as proposed rules (see table II.4).

Analysis of the five laws that established specific timeframes for issuing regulations showed that FDA missed deadlines contained in each law. As shown in table 2, FDA was unsuccessful in issuing regulations that had issuance deadlines required by three federal statutes enacted in the 1980s.

Table 2: Unsuccessful FDA Efforts to Issue Final Regulations Within Statutorily Established Timeframes (Dec. 1991)

	Implementing regulations	
Public law	**Issuance deadline**	**Status**
Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417)	09/23/85	Proposed regulation issued on 7/10/89. Two final regulations resulting from one proposed rule are still in process.
National Childhood Vaccine Injury Act of 1986 (P.L. 99-660), as amended by the Vaccine Compensation Amendments of 1987 (P.L. 100-203, title IV)	06/19/88	Review is underway to determine whether regulation is needed. FDA will decide whether to develop regulation in 1992.
Generic Animal Drug and Patent Term Restoration Act (1988) (P.L. 100-670)	11/15/89	Proposed regulation under development.

In addition, two other laws, enacted by the 101st Congress, had regulation issuance deadlines in 1991 that were not fully met. These are:

- The Nutrition Labeling and Education Act of 1990 (P.L. 101- 535). This act required the issuance of certain proposed and final regulations by November 8, 1991. In commenting on a draft of this report, FDA indicated that on November 27, 1991 (19 days after the deadline), 19 proposed regulations and 1 final regulation were published in the Federal Register.

- The Safe Medical Devices Act of 1990 (P.L. 101-629). This act required the issuance of proposed and final regulations within various timeframes. Of the 9 regulations that FDA developed to comply with the law, 8 had statutorily established deadlines for issuance. Of the 8 regulations,[8] 6 had deadlines for issuing either proposed or final rules in 1991. FDA missed the August 28, 1991 issue deadline for two proposed rules and the November 28, 1991 issue deadline for 3 of the remaining 4 regulations (1 final regulation was issued before the November 28th deadline).

Timely Issuance of Regulations Possible Despite Institutional Barriers

Despite institutional barriers to prompt regulation issuance, we observed that FDA can develop and issue regulations in a timely manner. High-priority status was given to some regulations because key decision-makers (including the FDA Commissioner) supported the development initiatives and monitored their progress during processing. High-level management involvement helped ensure that regulations were issued in a relatively short timeframe. Such management involvement is not typically the case.

In a July 1990 letter to the Chairman of the Advisory Committee on the Food and Drug Administration,[9] the Acting Commissioner of FDA identified the following as factors that may delay the issuance of regulations:

- Emergence of significant problems during the regulations development process that require reevaluation of previous agreements on regulation content.
- Competition among priorities within the agency with other regulatory and enforcement activities, such as the application process for premarket product approval.
- Required reviews within FDA, and by HHS and OMB.
- Need to coordinate with other agencies.
- Uncertainty as to the appropriate scope of review.
- Lack of resources.

The desire to reach consensus on pertinent issues during the development of regulations is another factor that delays the issuance of regulations, FDA officials said.

[8]of the 8 Regulations, 3 Have Issue Deadlines in 1992 (2 Finals by May 1992 and 1 of Unspecified Type No Later Than December 1, 1992) and 1 Final Issuance Deadline Is in 1995.

[9]The Advisory Committee on the Food and Drug Administration was established in May 1990 by the Secretary of HHS to examine FDA's mission, responsibilities, and structure.

With the support of key agency and department officials, the impact of many of these factors on timely regulation issuance can be overcome. For example, on July 19, 1990, FDA issued three proposed regulations to implement phase I of the Secretary's Food Labeling Reform Initiative that had been in process for a short time. Because these regulation initiatives had the support of the Secretary of HHS and the FDA Commissioner, FDA completed the drafting, review, and issuance of the proposed rules that involved complex scientific issues in less than 6 months. Agency officials thought it particularly noteworthy that no attempt was made to reduce the number of review levels in efforts to expedite regulation issuance.

At the time of our review, we became aware of other examples of atypical handling of regulation development concerning two major laws—the Nutrition Labeling and Education Act of 1990 and the Safe Medical Devices Act of 1990. In an effort to develop and issue proposed or final regulations within the 1-year limit permitted by the legislation, FDA was giving them priority treatment, with the strong support of key decisionmakers. The agency assigned specific staff the responsibility for developing and tracking the progress of the regulations. FDA staff also used a central automated tracking system and prepared biweekly status reports for the FDA Commissioner and other high-level managers for use in monitoring the development and processing of these regulations.

Lack of Comprehensive Automated Tracking System Inhibits Effective Management of Regulations Workload

At any point in time, FDA is processing hundreds of regulations. Yet top agency management has not been adequately informed about the scope of and delays in the overall regulations workload because FDA's centralized tracking system for monitoring rulemaking activities is incomplete. In addition, each of FDA's five centers has its own unique automated tracking system for regulations and these are not integrated with the centralized system. Consequently, FDA lacks an effective, agencywide system for regulations management.

Central Tracking System Inadequate to Perform Agencywide Assessments

FDA's Division of Regulations Policy (DRP), in the Office of Regulatory Affairs, is responsible for directing, managing, and coordinating the agency's rulemaking activities and regulations development system. But DRP's ability to fulfill its responsibilities is hindered because it has no mechanism in place to systematically analyze FDA's entire regulation workload and prepare reports to responsible agency officials.

In 1987, DRP developed a centralized automated system for tracking documents it receives from the FDA centers for publication in the Federal Register. Data in DRP's automated tracking system, however, are often incomplete and the system does not contain information on regulations under development in the various centers. Consequently, DRP is unable to provide top management with status reports on all rulemaking activities.

One disadvantage of not having an updated, comprehensive automated regulations tracking system was evident in March 1991 when FDA was unable to provide a timely response to the Subcommittee on Health and the Environment, House Committee on Energy and Commerce. The Subcommittee sought information on the extent of FDA regulations that had accumulated and that were waiting for further agency action. Uncertain about the extent of its regulations backlog, FDA could not compile the data without the assistance of each FDA center and an exhaustive search of both manual and automated records.

The data FDA finally provided to the Subcommittee were incomplete. An FDA official acknowledged this, saying one reason they had so much difficulty responding to the request was that no one had ever asked for such data and FDA did not systematically maintain the information.

FDA Center Tracking Systems Vary Widely

Each of the five FDA centers, using a different system, tracks regulations it is developing but usually stops when the regulation is forwarded to DRP for processing. Four of the five centers use automated tracking systems, but none tracks and produces status reports on its entire regulations workload. Three of the four centers reported that they use their automated systems to produce status reports on only certain selected regulations. Only one center regularly provides regulation development status reports to FDA management levels above the center director.

FDA Actions Planned to Improve Regulatory Process

In August 1991, the FDA Deputy Commissioner for Policy announced a new initiative to improve the management and flow of FDA's regulations. The primary objectives of this initiative are to (1) focus management attention on the rulemaking process, (2) streamline the process to the extent possible, and (3) develop information systems to effectively manage the process.

The agency has established a high-level Regulations Council to oversee, direct, and manage an agencywide rulemaking process. Chaired by the

Deputy Commissioner for Policy, the council is intended to play a central role in policy management, setting priorities, allocating resources, and proposing changes to the rulemaking process. The council, which first met in September 1991, plans to meet monthly.

In August 1991, FDA also announced plans to reduce its regulations backlog by withdrawing 115 pre-1986 proposed regulations that are not being worked on actively. In December 1991, FDA announced that 89 of these 115 proposed regulations were formally withdrawn. Further, FDA plans to review post-1985 proposed regulations to identify additional withdrawal candidates.

This approach is similar to actions FDA took in 1985 to reduce its regulations backlog. At that time, 142 pre-1980 proposed regulations were identified as possible regulations that could be withdrawn. Only 14 of the 142 regulations were eventually withdrawn.

Conclusions

While a number of factors contribute to delays in issuing FDA regulations, better management of the process is needed. This could not only reduce delays but also assure that top management will be able to better establish priorities for completing final regulations.

FDA's ability, through regulations, to effectively address public health problems and enforce compliance with federal law could be jeopardized unless the Regulations Council is able to improve the rulemaking process. Meaningful progress on improving the timeliness of regulation issuance will not be made if FDA continues to allow large regulation backlogs. Consequently, providing FDA's top management with the information needed to establish agencywide rulemaking priorities on a continuous basis is a key step in allowing management to focus on timeliness issues and the entire rulemaking process.

Recommendations to the Commissioner of Food and Drugs

To improve internal management oversight of the FDA regulation process, we recommend that the Commissioner of Food and Drugs develop a single automated regulation tracking system that (1) monitors the progress being made on all regulations under development within the five FDA centers; (2) generates recurring reports to top agency officials and center directors; and (3) serves as the primary basis for identifying delays in issuing regulations and initiating appropriate actions, when necessary, to overcome internal delays in the development of individual regulations.

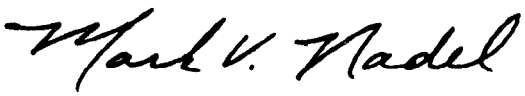
Agency Comments

In commenting on a draft copy of this report, HHS stated that it shared our concern that FDA should maintain an effective system to track the status of all regulations under consideration by the agency. In HHS's opinion, the need for such a tracking system is evident by our report findings and is consistent with FDA initiatives already underway to improve the management and flow of agency regulations. (See app. VI.) FDA also commented on information in our draft report which it believes warrants further clarification and explanation. These comments were considered and we made changes as appropriate.

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, copies will be sent to the appropriate congressional committees, the Secretary of Health and Human Services, the Commissioner of Food and Drugs, and other interested parties. It also will be made available to others on request.

If you have any questions regarding this report, please call me at (202) 512-7123. Other major contributors are listed in appendix VII.

Sincerely yours,



Mark V. Nadel
Associate Director, National and
Public Health Issues

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Abbreviations

DRP	Division of Regulations Policy
FDA	Food and Drug Administration
GAO	General Accounting Office
GRAS	generally recognized as safe
HHS	Department of Health and Human Services
OMB	Office of Management and Budget
OTC	over-the-counter

Objectives, Scope, and Methodology

As requested by the Chairman, Subcommittee on Health and the Environment, House Committee on Energy and Commerce, we reviewed the Food and Drug Administration's process for regulation development and issuance. More specifically, we (1) identified the number of FDA regulations under development and review and the time they were in process pending further action, (2) determined general reasons for delays in issuing regulations, and (3) ascertained FDA's plans to improve its regulation development and issuance process.

To determine the number of regulations in process, we obtained from FDA's Office of Regulatory Affairs, Division of Regulations Policy, a listing of regulations published, as of April 1991, in the Federal Register as notices of proposed rulemaking for which no final action had been taken and those under development in FDA centers but not yet published. We analyzed the information to determine how long the regulations had been in process and the current status of action being taken to complete processing.

To learn how long FDA took to develop and issue regulations the agency considered very important, we analyzed chronologies FDA officials provided on two categories of regulations—those processed by FDA between 1985 and 1991 that required the signature of the Secretary of Health and Human Services and approval by the Office of Management and Budget and those required by federal statute.

We reviewed the results of FDA's internal studies of its regulations issuance process and interviewed officials at FDA headquarters and its five centers to gather information on (1) FDA's ability to track the development and review of regulations (2) reasons for delays in processing regulations, and (3) FDA's plans for improving its regulations issuance process.

We did not independently verify the accuracy of data provided by FDA. While we requested complete lists of regulations, the extent to which the information reflects total numbers of regulations in various categories depends on the accuracy of agency officials' reporting. We checked the data for duplication and consistency.

Except where noted above, our review, which was done from February 1991 to September 1991, was conducted in accordance with generally accepted government auditing standards. We performed the review primarily at FDA headquarters in Rockville, Maryland.

FDA provided written comments on a draft of this report. (See app. VI.) Where appropriate, we made changes to the report.

Status of FDA Regulations Workload

Table II.1: Elapsed Time Since Proposed Regulations Were First Published in Federal Register (Apr. 1991)

	Number of proposed regulations			
Years	**OTC**	**Other**	**Total**	**Percent**
Less than 1	7	25	**32**	11
1 - 4	16	36	**52**	17
5 - 9	19	64	**83**	28
10 - 14	14	87	**101**	34
15 - 19	5	14	**19**	6
20 - 24	0	7	**7**	2
25 - 29	0	7	**7**	2
Total	**61**	**240**	**301**	**100**
Average number of years pending	8	10	**9**	

Table II.2: Elasped Time Between Initial Publication as Proposed Rules to Final Inssuance of 22 "Significant" Regulations (Apr. 1991)

Years	**Number of regulations**	**Percent**
Less than 1	4	18
1 - 2	9	41
3 - 4	4	18
5 - 6	3	14
7 - 8	2	9
Total	**22**	**100**
Average number of years - 3		

Table II.3: Work Status of FDA Regulations Required by Legislation (Apr. 1991)

Status	**Regulations under development**	**Number of proposed regulations**	**Total**
Active	30	7	37
Inactive	0	0	0
Unknown	5	3	8
Total	**35**	**10**	**45**

Source: FDA, Office of Regulatory Affairs, Division of Regulations Policy .

Table II.4: Elapsed Time From Enactment of Legislation to Date Proposed Regulations Were Published in Federal Register

Years pending	**Proposed regulations**	**Percent**
1 - 4	3	30
5 - 9	7	70
Total	**10**	**100**

Status of 40 "Significant" FDA Regulations in Process Between 1985 and 1991 That Required Signature of Secretary of HHS (Apr. 1991)

Regulation title	Date initiated	Published in Federal Register: Proposed	Published in Federal Register: Final
1. Adverse Drug Experience Reporting Requirement for Marketed Prescription Drugs Without Approved New Drug or Abbreviated New Drug Applications	06/27/84	03/21/85	07/03/86
2. Antidiarrheal Drug Products for OTC Use	02/10/75	03/21/75	Pending
3. Approval of Bulk New Animal Drug Substances for Use by Licensed Veterinarians	10/06/82	07/01/85 (Withdrawn)	N/A
4. Cardiac Pacemaker Registry	Unknown	05/05/86	07/23/87
5. Current Good Manufacturing Practice for Blood and Blood Components; Proficiency Testing Requirements	01/15/88	06/06/89	Pending
6. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food	08/15/77	06/08/79	06/19/86
7. Diluted Fruit or Vegetable Juice Beverages Other Than Diluted Orange Juice Beverages	Unknown	06/14/74	06/10/80[a]
8. Food Labeling; Declaration of Sulfiting Agent	11/15/83	04/03/85	07/09/86
9. Food Labeling; Advance Notice of Proposed Rule	06/15/89	08/08/89	Pending
10. Food Labeling; Definitions of Cholesterol Free, Low Cholesterol, and Reduced Cholesterol	04/08/85	11/25/86	Pending
11. Food Labeling; Health Messages and Label Statements	01/19/85	08/04/87	Pending
12. Food Labeling; Mandatory Status of Nutrition	03/07/90	07/19/90	Pending
13. Food Labeling; Reference Daily Intakes and Daily Reference Values	03/07/90	07/19/90	Pending
14. Food Labeling; Serving Size	07/03/90	07/19/90	Pending
15. General Biological Products Standards, Additional Standards for Human Blood and Blood Products; Test for Antibody to Human Immunodeficiency Virus (HIV)	01/15/85	02/21/86	01/05/88
16. Good Laboratory Practice Regulations	Unknown	10/29/84	09/04/87
17. Infant Formula Microbiological Testing, Consumer Complaints, and Record Retention Requirements	Unknown	01/26/89	Pending
18. Informed Consent for Human Drugs and Biologic Determination That Informed Consent Is Not Feasible	08/29/90	N/A	12/21/90[b]
19. Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale	Unknown	03/19/87	05/22/87
20. Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Procedures for Drugs Intended to Treat Life-Threatening and Severely Debilitating Illnesses	Unknown	N/A	10/21/88[b,c]
21. Irradiation in the Production, Processing, and Handling of Food	07/15/80	02/14/84	04/18/86
22. Labeling for Salicylate-Containing Drug Products	Unknown	12/28/82	03/07/86
23. Labeling of Drug Products for OTC Human Use	Unknown	07/02/82	05/01/86
24. Medical Devices: Labeling for Menstrual Tampon Ranges of Absorbency	01/15/85	09/23/88	10/26/89
25. National Institute on Drug Abuse; Methadone in Maintenance Treatment of Narcotic Addicts; Joint Proposed Revision of Conditions for Use	10/15/88	03/02/89	Pending

(continued)

Regulation title	Date initiated	Published in Federal Register: Proposed	Published in Federal Register: Final
26. New Animal Drugs for Use in Animal Feeds; Definitions and General Considerations; Revised Procedures Regarding Medicated Feed Applications	09/19/79	01/09/81	03/03/86
27. New Drug, Antibiotic, and Biologic Drug Product Regulations	11/15/79	06/09/83	03/19/87
28. Oral Mucosal Injury; Oral Wound- healing Drugs OTC Use	04/28/78	11/02/79	07/18/86
29. Patent Term Restoration Regulations	Unknown	07/11/86	03/07/88
30. Premarket Approval of Medical Devices	Unknown	12/12/80	07/22/86
31. Requirements Affecting Raw Milk For Human Consumption	12/31/81	06/11/87	08/10/87
32. Retention of Bioavailability and Bioequivalence Testing Samples	02/15/89	N/A	11/08/90[b]
33. Sponsored Compounds in Food Producing Animals; Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues; Animal Drug Safety Policy	Unknown	03/20/79	12/31/87
34. Sulfiting Agents in Standardized Foods; Labeling Requirements	Unknown	12/19/88	Pending
35. Sulfiting Agents: Proposal to Revoke Generally Recognized as Safe (GRAS) Status For Use on Fruits and Vegetables Intended to Be Served or Sold Raw to Consumers	03/30/85	08/14/85	07/09/86
36. Sulfiting Agents; Affirmation of GRAS Status	04/15/77	07/09/82	Pending
37. Sulfiting Agents; Labeling in Drugs for Human Use; Warning Statement	03/29/83	11/19/85	12/05/88
38. Sulfiting Agents; Requests for Data on Use of Sulfites on Frozen Potatoes	Unknown	03/15/90	Pending
39. Sulfiting Agents; Revocation of GRAS Status for Use on "Fresh" Potatoes Served or Sold Unpackaged and Unlabeled to Consumers	03/30/85	12/10/87	03/15/90
40. Tamper-Resistant Packaging Requirements for Certain OTC Human Drug Products	01/15/86	05/05/88	02/02/89

N/A = Not applicable because FDA did not issue a proposed or final rule.

[a]On June 27, 1984, FDA indefinitely postponed the effective date of the final rule published on June 10, 1980. FDA plans to issue a new regulation replacing this final rule by September 1992.

[b]FDA issued these rules as interim final regulations. According to FDA's Office of Regulatory Affairs, the Administrative Procedure Act allows the agency to issue interim final rules when there is good cause. FDA issued interim final rules because the agency was under pressure to issue final regulations immediately. Like proposed rules, interim final rules are subject to public comment and review.

[c]OMB suspended the final review of this regulation. The interim final is still in effect pending further action.

Source: FDA Office of Regulatory Affairs, Division of Regulatory Policy.

Calendar Days Spent Processing 14 Final "Significant" Regulations

Regulation	Total days in process	Obtaining HHS and OMB approval[a]	HHS and OMB approvals as a percent of total time
1. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food	3,230	235	7
2. Oral Mucosal Injury; Oral Wound-healing Drugs for OTC Use	3,003	267[b]	9[b]
3. New Drug, Antibiotic, and Biologic Drug Product Regulations	2,681	[c]	[c]
4. New Animal Drugs for Use in Animal Feeds; Definitions and General Considerations; Revised Procedures Regarding Medicated Feed Applications	2,357	[c]	[c]
5. Irradiation in the Production, Processing, and Handling of Food	2,103	331[b]	16[b]
6. Sulfiting Agents; Labeling in Drugs for Human Use; Warning Statement	2,078	81[b]	4[b]
7. Requirements affecting raw milk for human consumption	2,048	84	4
8. Sulfiting Agents; Revocation of GRAS status for use on "fresh" potatoes served or sold unpackaged and unlabeled to consumers	1,811	497	27
9. Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency	1,745	395	23
10. Tamper-Resistant Packaging Requirements for Certain OTC Human Drug Products	1,114	117	11
11. General Biological Products Standards, Additional Standards for Human Blood and Blood Products; Test for Antibody to Human Immunodeficiency Virus (HIV)	1,085	233	21
12. Food Labeling; Declaration of Sulfiting Agents	967	311[b]	32[b]
13. Adverse Drug Experience Reporting Requirements for Marketed Prescription Drugs Without Approved New Drug or Abbreviated New Drug Applications	736	147[b]	20[b]
14. Sulfiting Agents; Proposal to Revoke GRAS Status for Use on Fruits and Vegetables Intended to be Served or Sold Raw to Consumers	466	44[d]	9[d]
Average time in process (years)	5	0.626[e]	

[a]Includes time spent by FDA responding to HHS and OMB comments on proposed and final rules.

[b]Excludes OMB clearance time for proposed rule because of insufficient data.

[c]Insufficient data to calculate time to obtain HHS and OMB approvals for both proposed and final rules.

[d]Excludes HHS and OMB clearance time for proposed rule because of insufficient data.

[e]See notes b, c, and d.

Status of FDA Regulations in Process That Are Required by Legislation[a] (Apr. 1991)

Public Law/regulation	Under development	Published as proposed regulations
1. Safe Drinking Water Act (P.L. 93-523, Dec. 16, 1974)		
Bottled Water Standards; Establishment and Upgrade Bottled Water Standards for Seven Inorganic and 24 Organic Chemicals	X	
Bottled Water Standards; Subject Mineral Water to Quality Standards for Bottled Water	X	
2. Medical Device Amendments of 1976 (P.L. 94-295, May 28, 1976)		
Automated Differential Cell Counter		X
Hydrophilic Beads for Wound Exudate Absorption		X
Infant Radiant Warmer		X
Nonabsorbable Gauze, Surgical Sponge and Wound Dressing		X
Nonabsorbable Gauze for Internal Use		X
Porcine Burn Dressing		X
3. Orphan Drug Act (P.L. 97-414, Jan. 4, 1983)		
Orphan Drug Regulations		X
4. Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417, Sept. 24, 1984)		
Abbreviated New Drug Applications for Human Drugs		X
5. Alcohol and Drug Abuse Amendments of 1986 (P.L. 99-570, title IV, Oct. 27, 1986)		
Current Good Manufacturing Practice and Quality Control Procedures in Manufacturing, Packaging or Holding Infant Formula	X	
Infant Formula: Microbiological Testing and Consumer Complaints		X
6. National Childhood Vaccine Injury Act of 1986 (P.L. 99-660, title III, Nov. 14, 1986) as amended by the Vaccine Compensation Amendments of 1987 (P.L. 100-203, title IV)		
Review of Warnings, Use Instructions, and Precautionary Information Contained in Package Inserts for Certain Vaccines	X	
7. Generic Animal Drug and Patent Term Restoration Act (P.L. 100-670, Nov. 16, 1988)		
Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act	X	
Patent Term Restoration for Animal Drugs (Title II)		X
8. Nutrition Labeling and Education Act of 1990 (P.L. 101-535, Nov. 8, 1990)		
Food Labeling: Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision	X[bc]	
Food Labeling: Petitions Permitted by the Nutrition Labeling and Education Act of 1990	X[c]	
Adjectival Descriptors; General Principles; Petitions	X[c]	
Food Labeling: Nutrition Labeling of Raw Fruit, Vegetables and Fish; Guidelines for Voluntary Nutrition Labeling of Raw Fruit, Vegetables and Fish; Identification of the 20 Most Frequently Consumed Raw Fruit, Vegetables, and Fish; and Definition of Substantial Compliance	X[d]	
Food Labeling: Definitions of Terms Describing the Cholesterol, Fat, and Fatty Acid Content of Food	X[bc]	
Food Labeling: Health Messages and Label Statements; General Principles	X[bc]	
Food Labeling: Health Messages; Antioxidant Vitamins/Cancer	X[c]	

(continued)

Public Law/regulation	Under development	Published as proposed regulations
Food Labeling: Health Messages; Calcium/ Osteoporosis	X[c]	
Food Labeling: Health Messages; Fiber/Cancer	X[c]	
Food Labeling: Health Messages; Fiber/ Cardiovascular Disease (CHD)	X[c]	
Food Labeling: Health Messages; Folic Acid/ Neural Tube Defects	X[c]	
Food Labeling: Health Messages; Lipids/Cancer	X[c]	
Food Labeling: Health Messages; Lipids/CHD	X[c]	
Food Labeling: Health Messages; Omega-3/CHD	X[c]	
Food Labeling: Health Messages; Sodium/ Hypertension	X[c]	
Food Labeling: Health Messages; Zinc/ Immune Function	X[c]	
Food Labeling: Nutrition Label Format	X	
Food Labeling: Serving Sizes	X[bc]	
Food Labeling: Use of Descriptors with the Names of Standardized Foods	X[c]	
Butter: Nutrient Content Claims Use	X[c]	
9. Food, Agriculture, Conservation, and Trade Act of 1990 (P.L. 101-624, Nov. 28, 1990), title XIII subtitle B National Laboratory Accreditation		
Regulations related to standards and procedures for laboratories.	X	
10. Safe Medical Devices Act of 1990 (P.L. 101-629, Nov. 28, 1990)		
Classification of Transitional Devices	X	
Devices for Which Premarket Approvals Have Not Yet Been Required; Revision of Classification or Requirement to Remain in Class III	X	
Exemption of Humanitarian Devices	X	
Medical Device Reporting Regulations; Distributor Reporting Regulations	X[ce]	
Medical Device Reporting Regulations; User Reporting Regulations	X[ce]	
Medical Device Tracking Regulations	X	
Medical Devices; Reports of Removals and Corrections	X	
Premarket Review of Combination Products	X	
Requirements for Summaries of Safety and Effectiveness in Submissions for Premarket Notification	X	

[a]These laws required FDA to issue regulations but did not mandate in every case the specific categories of rules listed. FDA decided on the specific regulations.

[b]FDA had proposed five similar rules in the Federal Register under the agency's general rulemaking authority prior to enactment of the Nutrition Labeling and Education Act of 1990. FDA is revising the proposals developed under general rulemaking and plans to repropose four regulations implementing the new law (Two of five proposed regulations are combined and will be reproposed as one rule.).

[c]In commenting on a draft of this report FDA indicated that these proposed rules were issued in November 1991.

[d]In commenting on a draft of this report FDA indicated that these final rules were issued in November 1991.

[e]FDA combined these two rules and published them as one proposed regulation entitled Medical Devices: Medical Device; User Facility, Distributor, and Manufacturer Reporting, Certification, and Registration.

Comments From the Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
Rockville MD 20857

December 24, 1991

Janet L. Shikles
Director, Health Financing
and Policy Issues
U.S. General Accounting Office
Washington, D.C. 20548

Dear Ms. Shikles:

Enclosed are the Food and Drug Administration's comments on FDA's need to improve timely issuance of regulations. Thank you for the opportunity to comment on this draft.

Sincerely yours,

Kay Holcombe
Acting Associate Commissioner
for Legislative Affairs

Enclosure

COMMENTS ON THE DRAFT GENERAL ACCOUNTING OFFICE REPORT ENTITLED FDA REGULATIONS: SUSTAINED MANAGEMENT ATTENTION NEEDED TO IMPROVE TIMELY ISSUANCE

Thank you for the opportunity to comment on this report. The Department of Health and Human Services shares the concern of the GAO that the Food and Drug Administration (FDA) should maintain an effective system to track the status of all regulations under consideration by the agency. The need for such a tracking system has been well documented in the report and is in keeping with Commissioner Kessler's initiatives already underway to improve the management and flow of FDA regulations.

GAO RECOMMENDATION

GAO recommends that the Commissioner of FDA:

> Develop a single automated regulation tracking system that (1) monitors the progress being made on all regulations under development within the five FDA centers; (2) generates recurring reports to top agency officials and center directors; and (3) serves as the primary basis for identifying delays in issuing regulations and initiating appropriate actions, when necessary, to overcome internal delays in the development of individual regulations.

DEPARTMENT COMMENT

> We agree that a tracking system which monitors the progress of all regulations by generating periodic reports and identifying possible delays would be a desirable tool to improve the FDA's management of the regulatory process.

TECHNICAL COMMENTS

1. The last sentence in the second paragraph on page 12 is misleading and should be deleted. The sentence reads: "in addition, two of these laws, enacted by the 101st Congress, had deadlines for regulation issuance in November 1991 that had not been met as of October 31, 1991." Although the statement is factual, it is misleading when one considers the fact that FDA released to the public all of the proposed and final rules to implement the Nutrition Labeling and Education Act of 1990 on November 6, 1991, two days before the statutory deadline of November 8, 1991, and published them on November 27, 1991.

2. Concerning the agency's August 1991 action to withdraw 115 pre-1986 proposed rules (see page 20 of the GAO draft report), FDA issued a FEDERAL REGISTER notice on December 30, 1991 announcing that the agency is withdrawing 89 of these 115 proposed rules.

3. A footnote should be added to the title of Appendix V to denote that the appendix reflects the status of these

regulations as of April 1991. All 21 of the proposed regulations required by the Nutrition Labeling and Education Act of 1990 listed on page 41 of the draft report were published on November 27, 1991. In addition, the following FEDERAL REGISTER documents required to implement the Safe Medical Devices Act of 1990 have been issued:

Order for Transitional Class III Devices; Submission of Safety and Effectiveness Information Under Section 520(l)(5)(A) of the Federal Food, Drug, and Cosmetic Act; Notice - Issued on November 14, 1991

Assignment of Agency Component for Review of Premarket Applications; Final Rule - Issued on November 21, 1991

Medical Devices; Medical Device, User Facility, Distributor, and Manufacturer Reporting, Certification, and Registration; Proposed Rule - Issued on November 26, 1991

4. In Appendix II, in Table II.5., the following should appear next to the item on National Childhood Vaccine Injury Act (instead of "Regulation Development has not begun")?

FDA is planning a public meeting to identify and discuss the relevant issues on childhood vaccines.

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