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Part IV

Department of Health and Human Services

Food and Drug Administration

**Guidance for FDA and Industry: Direct
Final Rule Procedures; Notice**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0439]

Guidance for FDA and Industry: Direct Final Rule Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures." This guidance explains when and how FDA will employ direct final rulemaking. FDA believes that direct final rulemaking will expedite the issuance of routine or otherwise noncontroversial rules and conserve limited Government resources for carrying out the agency's regulatory functions.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. A copy of this guidance will be made available on FDA's World Wide Web site at "<http://www.fda.gov/opacom/morechoices/industry/preguide.htm>".

FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Office of Policy (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION:

I. Background

In Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993), the President set forth the administration's regulatory philosophy and principles. The Executive Order contemplates an efficient and effective rulemaking process, including the conservation of limited Government resources for carrying out its regulatory functions. Furthermore, "Improving Regulatory Systems," an Accompanying Report of the National Performance Review, recognized the need to streamline the regulatory process and recommended the use of "direct final" rulemaking procedures to reduce needless double review of noncontroversial rules. Direct final rulemaking involves agency publication of a rule in the **Federal Register** with a statement that unless significant adverse comment, as defined

later in this document, is received on the rule within a specified time period, the rule will become effective as a final rule on a particular date. However, if a significant adverse comment is filed, the rule is withdrawn, and the agency may publish the rule as a proposed rule under the usual notice-and-comment procedures of the Administrative Procedure Act (APA).

From 1964 to 1995 the Administrative Conference of the United States (ACUS), established by the Administrative Conference Act (5 U.S.C. 591-596), studied the efficiency, adequacy, and fairness of the administrative procedures used by Federal agencies in carrying out administrative programs. When it was in existence, ACUS made recommendations for improvements to the agencies, collectively or individually, and to the President, Congress, and the Judicial Conference of the United States (5 U.S.C. 594(1)).

In the **Federal Register** of August 18, 1995 (60 FR 43108), ACUS issued a notice adopting five recommendations at its Fifty-Second Plenary Session held on June 15 to 18, 1995. Recommendation 95-4, "Procedures for Noncontroversial and Expedited Rulemaking," endorsed direct final rulemaking as a procedure that can expedite rules in appropriate cases (see 60 FR 43108, August 18, 1995). ACUS found direct final rulemaking appropriate where a rule is expected to generate no significant adverse comment. ACUS defined significant adverse comment as one where the comment explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change (60 FR 43108 at 43111). ACUS stated that, in determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, agencies should consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process (Id.). ACUS noted that the direct final rule process allows the agency to issue a rule without having to go through the review process twice (i.e., at the proposed and final rule stages) while at the same time offering the public the opportunity to challenge the agency's view that the rule has no significant opposition (60 FR 43108 at 43111 and 43112).

ACUS determined that direct final rulemaking is supported by two rationales under current law. First, it is justified by the APA's "good cause" exemption from notice-and-comment procedures where they are found to be "unnecessary." ACUS found that the

agency's solicitation of public comment does not undercut this argument, but rather validates the agency's initial determination. Second, ACUS stated that, alternatively, direct final rulemaking also complies with the basic notice-and-comment requirements in section 553 of the APA. ACUS stated that the agency provides the requisite notice and opportunity to comment on the rule through its **Federal Register** notice; the publication requirements are met, although the information has been published earlier in the process than normal; and, the requisite advance notice of the effective date required by the APA is provided (60 FR 43108 at 43111).

Because the process protects public comment and expedites routine rulemaking, ACUS recommended that agencies use direct final rulemaking in all cases where the "unnecessary" prong of the good cause exemption is available, unless the agency determines that the process would not expedite issuance of such rules (60 FR 43108 at 43111). ACUS further recommended that agencies explain when and how they will employ direct final rulemaking. Such a policy should be issued as a procedural rule or a policy statement (Id.).

Provided herein and on FDA's World Web site at "<http://www.fda.gov/opacom/morechoices/industry/preguide.htm>", FDA is making available a guidance document titled "Guidance for FDA and Industry: Direct Final Rule Procedures." This guidance explains when and how FDA will employ direct final rulemaking. FDA believes that direct final rulemaking will expedite the issuance of routine or otherwise noncontroversial rules.

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Requests and comments are to be identified with the docket number found in brackets in the heading of this document. Comments may be submitted at any time and will be used to determine whether to revise the guidance further.

Dated: November 12, 1997.

William B. Schultz,
Deputy Commissioner for Policy.

The text of the guidance is set forth below:

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Guidance for FDA and Industry: Direct Final Rule Procedures

U.S. Department of Health and Human Services

Food and Drug Administration

Office of Policy

November (*insert date of publication in the FEDERAL REGISTER*), 1997

Comments and suggestions regarding this document should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Requests and comments are to be identified with the docket number found in brackets in the heading of the notice of availability that published in the FEDERAL REGISTER. For questions regarding this document, contact Marquita B. Steadman, Office of Policy (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

I. Summary

This guidance will explain when and how the Food and Drug Administration (FDA) will employ direct final rulemaking. FDA believes that direct final rulemaking will expedite the issuance of routine or otherwise noncontroversial rules.

II. FDA's Direct Final Rulemaking Procedures

This guidance adopts many aspects of the former Administrative Conference of the United States' (1964 to 1995) recommendations concerning direct final rulemaking. FDA may use the direct final rule process when the agency does not anticipate receiving any significant adverse comment, or when a rule may qualify for exemption from notice-and-comment rulemaking. FDA will publish in the notice of direct final rulemaking the full text of the rule and the statement of basis and purpose, including all the material that would be required in the preamble to a final rule. FDA will also publish a companion proposed rule in the same issue of the **Federal Register**. That proposed rule will serve the purpose of issuing a proposed rule under usual notice-and-comment procedures in the event the direct final rule is withdrawn because the agency receives any significant adverse comment.

FDA ordinarily will allow at least 75 days for comment on the direct final rule after it is published in the **Federal Register**. If the agency receives any significant adverse comment, the agency will publish a notice of significant adverse comment and withdraw the direct final rule within 30 days after the comment period ends. In that circumstance, any comments received will be considered comments on the proposed rule and will be considered in developing a final rule using the usual APA notice-and-comment procedures. If the agency receives no significant adverse comment during the specified comment period, the direct final rule will go into effect no later than 60 days after the comment period ends. The agency will publish a document confirming the effective date within 30 days after the comment period ends, which ordinarily will state that the direct final rule will go into effect 30 days after the confirmation notice is published. This means that a direct final rule that receives no significant adverse comment will go into effect no later than 135 days after its publication in the **Federal Register**.

FDA will adopt ACUS's definition of significant adverse comment. Thus, significant adverse comment is defined as one where the comment explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. FDA notes that comments that are frivolous, insubstantial, or outside the scope of the rule would not be considered adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule (e.g., where a rule deletes several unrelated regulations), FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

As discussed previously, FDA will only use direct final rulemaking procedures when the agency expects that there will be no significant adverse comment. For example, FDA will consider direct final rulemaking for minor, substantive changes to regulations; incorporation by reference of the latest edition of technical or industry standards; extensions of compliance dates, direct incorporations of mandates from new legislation; and other noncontroversial rules where FDA determines that use of direct final rulemaking is in the public interest and that the rule is unlikely to result in any significant adverse comment.

III. Significance of Guidance

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance is issued as Level 1 guidance consistent with GGP's. The agency will not solicit public input prior to implementation because the guidance presents a less burdensome policy that is consistent with the public health. This guidance represents the agency's current thinking on direct final rules. It does not operate to create or confer any rights for or on any person and does not operate to

bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both.

IV. Request for Comments

Interested persons may, at any time, submit written comments on this guidance to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy.

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