Direct Final Rule Procedures

Guidance for FDA and Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Policy

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Comments and suggestions regarding this document should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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 the Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

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the purpose of issuing a proposed rule under usual notice-and-comment procedures in the event the direct final rule is withdrawn because the agency receives any significant adverse comment.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 non controversial 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 right sfor 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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