adding, in their place, the words ''FAA Order 7400.9H''.

§ 71.79 [Amended]

10. Section 71.79 is amended by removing the words ''FAA Order 7400.9G'' and adding, in their place, the words ''FAA Order 7400.9H''.

§ 71.901 [Amended]

11. Paragraph (a) of § 71.901 is amended by removing the words ''FAA Order 7400.9G'' and adding, in their place, the words ''FAA Order 7400.9H''.

Issued in Washington, DC, September 8, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 00–23673 Filed 9–18–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ACE–13]

Amendment to Class E Airspace; Fairfield, IA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Fairfield, IA.

DATES: The direct final rule published at 65 FR 40991 is effective on 0901 UTC, November 30, 2000.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (861) 329–2525.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on July 3, 2000 (65 FR 40991). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on November 30, 2000. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Dated: Issued in Kansas City, MO on September 6, 2000.

Richard L. Day,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 00–2394 Filed 9–18–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 7, 10, 14, 19, 25, 101, 107, 110, 114, 170, 310, 312, 314, 316, 500, 514, 601, 803, 814, and 860

[Docket No. 99N–4783]

Administrative Practices and Procedures; Good Guidance Practices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its administrative regulations to codify its policies and procedures for the development, issuance, and use of guidance documents. This action is necessary to comply with requirements of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The Modernization Act codified certain parts of the agency's current ''Good Guidance Practices'' (GGP's) and directed the agency to issue a regulation consistent with the act that specifies FDA's policies and procedures for the development, issuance, and use of guidance documents. The intended effect of this regulation is to make the agency's procedures for development, issuance, and use of guidance documents clear to the public.

DATES: This rule is effective October 19, 2000.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 405 of the Modernization Act (Public Law 105–115), statutory provisions on guidance documents were added to the Federal Food, Drug, and Cosmetic Act (the act) in section 701(h) (21 U.S.C. 371(h)). In the **Federal Register** of February 14, 2000 (65 FR 7321), we (FDA) proposed changes to our existing part 10 (21 CFR part 10) regulations to clarify our procedures for the development, issuance, and use of guidance documents. Interested parties were given until May 1, 2000, to comment on the proposal.

II. Description of the Final Rule

A. Comments and Agency Response

We received 18 comments on the proposed rule, largely from trade organizations. The comments we received generally supported the policies and procedures described in the GGP's.

1. General Comment

(Comment 1) One comment recommended that we include in this preamble a list of generally accepted principles of a good guidance document. The comment nominated several principles for inclusion on the list.

We decline to develop a list of generally accepted principles of a ''good'' guidance document because we believe that the procedures described in § 10.115 reflect generally accepted principles for developing, issuing, and using guidance documents. For example, a good guidance document represents our current thinking on a matter and clearly states that it does not establish legally enforceable requirements. We expect each guidance document developed, issued, and used under the rule to have the characteristics of a good guidance document.

2. Definition of Guidance Documents

(Comment 2) One comment suggested that we include in the definition of guidance documents those documents that describe our current policies regarding labeling and promotion.

In our proposal, we defined guidance documents to include, among other kinds of documents, those that relate to the design, production, manufacturing, and testing of regulated products and those that relate to inspection or enforcement policies. We interpret our definition to include guidance documents about product labeling and promotion. We are amending the definition in § 10.115(b)(2) to clarify our intent to include such topics as subjects for guidance documents.

3. Comprehensive List of Guidance Documents and Guidance Document Agenda

(Comment 3) Several comments discussed the annual publication of the comprehensive list of guidance documents and the guidance document