Actions	Compliance	Procedures
(1) Inspect/check the rudder, aileron, and rudder-aileron interconnect rigging; correct any out-of-rig condition; and replace the attaching hardware for the rudder-aileron interconnect arm.	At whichever occurs first: (i) Within the next 25 hours time-in-service (TIS) after the effective date of this AD; or (ii) Within the next 3 months after the effective date of this AD.	Follow Cirrus Service Bulletin No. SB 2X–27–14 R3, Issued: May 9, 2007, Revised: October 10, 2007.
(2) *Only if you find an out-of-rig condition:* Report to the FAA any out-of-rig conditions discovered as a result of the inspection required by paragraph (e)(1) of this AD on the form in Figure 1 of this AD. The Office of Management and Budget (OMB) approved the information contained in this regulation under the provisions of the Paperwork Reduction Act and assigned OMB Control Number 2120–0056.	At whichever occurs later: (i) Within 10 days after the inspection required in paragraph (e)(1) of this AD; or (ii) Within 10 days after the effective date of this AD.	Send the form (Figure 1 of this AD) to FAA, Manufacturing Inspection District Office, 6020 28th Avenue South, Room 103, Minneapolis, Minnesota, 55450–2700; telephone (612) 713–4366; facsimile (612) 713–4365.

Note: Temporary revisions to the airplane maintenance manuals (AMM), SR20 AMM Temporary Revision No. 27–1 and SR22 AMM Temporary Revision No. 27–1, both dated October 10, 2007, contain information pertaining to this subject.

DOCKET NO. FAA–2007–28246 INSPECTION REPORT

[Report only if you find an out-of-rig condition]

1. Inspection Performed By:	2. Telephone:
3. Aircraft Model:	4. Airplane Serial Number:
5. Aircraft Total Hours Time-in-Service:	6. Date of inspection required in paragraph (e)(1) of this AD:
7a. Do any of the aircraft logs contain entries describing flight control system maintenance, preventative maintenance, or alteration: ____Yes ____No	7b. If Yes, copy the log book entry(s) and include the date of the entry.

8. Inspection Results: (Report only if an out-of-rig condition is found, and describe the out-of-rig condition as accurate and detailed as possible):

9. Corrective Action Taken:

Send to:

Federal Aviation Administration
Manufacturing Inspection District Office 6020 28th Avenue South, Room 103
Minneapolis, Minnesota 55450–2700

Telephone (612) 713–4366
Facsimile (612) 713–4365

Alternative Methods of Compliance (AMOCs)

(g) The Manager, Chicago Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Wess Rouse, Aerospace Engineer, 2300 East Devon Avenue, Room 107, Des Plaines, Illinois 60018; telephone: (847) 294–8113; fax: (847) 294–7834. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Related Information

(h) To get copies of the service information referenced in this AD, contact Cirrus Design Corporation, 4515 Taylor Circle, Duluth, Minnesota 55811; telephone: (218) 727–2737; Internet address: *http://www.cirrusdesign.com.* To view the AD docket, go to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or on the Internet at *http://dms.dot.gov.* The docket number is Docket No. FAA–2007–28246; Directorate Identifier 2007–CE–048–AD.

Issued in Kansas City, Missouri, on November 28, 2007.

Patrick R. Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–23456 Filed 12–3–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210 and 211

[Docket No. 1995N–0362]

Current Good Manufacturing Practice; Amendment of Certain Requirements For Finished Pharmaceuticals; Withdrawal

AGENCY: Food and Drug Administration, HHS

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

withdrawal of a proposed rule published in the **Federal Register** of May 3, 1996 (61 FR 20103) (the May 1996 proposed rule). The May 1996 proposed rule would have amended certain requirements of the current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. These proposed changes would have clarified certain manufacturing, quality control, and documentation requirements and would have updated the requirements for process and methods validation. In light of more recent scientific and technical advances and evolving quality systems and risk management concepts, FDA concludes that, at this time, it is appropriate to withdraw the May 1996 proposed rule and newly evaluate the issues raised in that proposal.

DATES: The proposed rule is withdrawn on December 4, 2007.

FOR FURTHER INFORMATION CONTACT:

Mary Malarkey, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, or

Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956, or

Frederick Blumenschein, Center for Drug Evaluation and Research (HFD–326), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9022.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 3, 1996 (61 FR 20103), FDA proposed to amend certain requirements of the CGMP regulations for finished pharmaceuticals in parts 210 and 211 (21 CFR parts 210 and 211) to clarify certain manufacturing, quality control, and documentation requirements so that the regulations would more accurately reflect the prevailing CGMP. FDA received approximately 1,500 comments on the proposed rule. (See section III of this document, Comments on the May 1996 Proposed Rule).

After publication of the May 1996 proposed rule, FDA began to reconsider its approach to regulation of CGMP, consistent with changes occurring in other industries and in other countries. This change in approach is summarized in the following paragraphs.

In August 2002, FDA announced a significant new initiative to enhance and modernize regulation of pharmaceutical manufacturing quality, the Pharmaceutical CGMPs for the 21st Century initiative (21st Century initiative). As a part of the 21st Century initiative, FDA created a CGMP Harmonization Analysis working group to analyze internal and external CGMP requirements, including those related to quality systems. The working group performed a formal analysis of parts 210 and 211 compared with other regulations, such as the FDA Medical Device Quality System Requirements, the FDA Food Hazard Analysis and Critical Control Points requirements, and the drug GMPs of the European Union, to identify the differences and consider the value of adding or changing the current regulations in light of these more recently developed and related product manufacturing standards.

Based on the working group's analysis, the agency decided that a different approach to revising the CGMP regulations was appropriate, and has decided to withdraw the proposed rule.

II. New Approach to Revising FDA's CGMP Regulations

The emphasis of the new approach to CGMP arising from the 21st Century Initiative will be to encourage timely detection of and response to emerging adverse trends or indications that product quality has been compromised, to provide further clarity and modernize the regulations, and to harmonize various aspects of parts 210 and 211 both internationally and with other agency regulations.[1]

The agency has determined that the current CGMP regulations (parts 210 and 211) provide a degree of flexibility that will permit the agency to continue to modernize its approach to regulation of CGMP. The agency has also concluded that, as stated in the final report on the 21st Century initiative, given this new approach to regulation of pharmaceutical CGMP, it would be preferable to revise the CGMP regulations in an incremental fashion, rather than using the comprehensive approach taken in the May 1996 proposed rule. After careful consideration, FDA concludes that at this time, it is appropriate to withdraw the May 1996 proposed rule and newly evaluate the issues raised in that proposal in the context of more recent scientific and technical advances and quality systems and risk management concepts.

[1]See Pharmaceutical CGMPs for the 21st Century—A Risk Based Approach; Final Report, September, 2004; available at *http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm.*

We plan to revise the CGMP regulations using a more incremental approach. As part of the FDA's incremental approach to revising our CGMP regulations, we are publishing a direct final rule (and a companion proposed rule) elsewhere in this issue of the **Federal Register** that will, when finalized, clarify and modernize certain provisions in parts 210 and 211. That direct final rule and proposed rule include some of the minor changes to CGMP that were originally proposed in 1996.

III. Comments on the May 1996 Proposed Rule

FDA received approximately 1,500 comments on the May 1996 proposed rule from 116 pharmaceutical companies, attorneys, consultants, trade associations, and generic companies. The most significant topics on which FDA received comments are summarized as follows:

- Approximately 298 comments addressed the proposed new section on process validation (§ 211.220). The volume and variety of comments and suggestions indicated to FDA that the new section, as proposed, did not provide the clarification intended.
- Approximately 102 comments were directed at the proposed changes to § 211.110 on sampling and testing of in-process materials and drug products, which would have added new in-process sampling and validation requirements with respect to blend uniformity. The bulk of these comments questioned the need for additional testing and sampling requirements in § 211.110, because other sections of the current rule already require scientifically sound sampling plans and representative samples.
- Approximately 112 comments discussed proposed revisions to § 211.192 on the production, control, and laboratory review, and investigation of discrepancies. The May 1996 proposed rule required written procedures to be established for the review of certain records and investigation of unexplained discrepancies. Many of these comments recommended that these investigations and reviews should be used to proactively prevent (potential) future problems rather than being used only to retroactively identify manufacturing discrepancies.
- A number of comments to the rule were submitted by the compressed medical gas industry, which communicated concerns regarding the applicability to the compressed medical gas industry of the proposed changes to CGMP.

• Approximately 70 comments were received regarding the proposed new § 211.240 on control of chemical and physical contaminants. Many of the comments stated that the rule should be revised to better describe how contaminants will be identified and to provide allowances for threshold levels or limits of contaminants.

Overall, the comments were constructive, informative, and addressed nearly every area of the May 1996 proposed rule. Although we do not plan to publish specific responses to each of these comments, we will take these comments into account as we proceed to make incremental changes to parts 210 and 211.

IV. Withdrawal of the Proposed Rule

For the reasons described in this document, FDA is withdrawing the proposed rule published on May 3, 1996 (61 FR 20103).

Dated: November 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–23271 Filed 12–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210 and 211

[Docket No. 2007N–0280]

Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals; Companion Document to the Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this companion proposed rule to the direct final rule, published elsewhere in this issue of the **Federal Register**, which is intended to amend certain sections of the regulations as the first phase of an incremental approach to modifying the current good manufacturing practice (CGMP) regulations for finished pharmaceuticals.

DATES: Submit written or electronic comments on or before February 19, 2008.

ADDRESSES: You may submit comments, identified by Docket No. 2007N–0280, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Mary Malarkey, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, or

Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956, or

Frederick Blumenschein, Center for Drug Evaluation and Research (HFD–326), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9022.

SUPPLEMENTARY INFORMATION:

I. Background

Since the development of the CGMP regulations in 1962, FDA has balanced the need for easily understood minimum standards with the need to encourage innovation and the development of improved manufacturing technologies. We strive to give manufacturers latitude to determine how to achieve the level of control necessary for CGMP compliance, recognizing that, in some instances, more direction from FDA is necessary to provide a uniform standard to the entire industry or because of the potential for harm or the narrow range of acceptable means to accomplish a particular CGMP objective. FDA periodically reassesses and revises the CGMP regulations to accommodate advances in technology that further safeguard the drug manufacturing process and the public health. As technology and scientific knowledge related to CGMP evolve, so does understanding of the material, equipment, and process variables, as well as the operational procedures and oversight methods that must be defined and controlled to achieve assurance of drug product quality.

In 1996, as part of this reassessment process, FDA proposed to amend certain requirements of the CGMP regulations for finished pharmaceuticals to clarify certain manufacturing, quality control, and documentation requirements, and to ensure that the regulations more accurately encompass current industry practice (61 FR 20103, May 3, 1996) (1996 proposed rule)). Subsequently, as a part of the risk-based pharmaceutical CGMPs for the 21st century initiative, FDA created a CGMP Harmonization Analysis Working Group (CGMP Working Group) to analyze related CGMP requirements in effect in the United States and internationally, including those related to quality systems. The CGMP Working Group compared parts 210 amd 211 (21 CFR parts 210 and 211) with the GMPs of the European Union (EU), as well as other FDA regulations (e.g., the Quality Systems Regulation, 21 CFR part 820) to identify the differences and consider the value of supplementing or changing the current regulations. Based on the CGMP Working Group's analysis, we decided to take an incremental approach to modifying parts 210 and 211 (see *http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm#_Toc84065744*).

Because of this change in approach, FDA decided not to finalize the 1996