

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 210

[Docket No. 2005N-0285]

Current Good Manufacturing Practice Regulation and Investigational New Drugs; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the direct final rule that published in the **Federal Register** of January 17, 2006, to amend its current good manufacturing practice (CGMP) regulations for human drugs, including biological products, to exempt most investigational “Phase 1” drugs from complying with the requirements in FDA’s regulations. FDA is withdrawing the rule because significant adverse comments were received.

DATES: The revision of 21 CFR part 210, published at 71 FR 2458 (January 17, 2006), is withdrawn as of *[insert date of publication in the **Federal Register]***.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA published a direct final rule on January 17, 2006 (71 FR 2458), that was intended to revise the current good manufacturing practice (CGMP) regulations for human drugs, including biological products, to exempt most investigational “Phase 1” drugs from complying with the requirements in FDA’s regulations. In response to the direct final rule, the agency received significant adverse comments about the proposed revisions to the rule.

Under FDA’s direct final rule procedures, the receipt of any significant adverse comment will result in the withdrawal of the direct final rule. Thus, this direct final rule is being withdrawn, effective immediately. Comments received by the agency regarding the withdrawn rule will be considered in developing a final rule using the usual Administrative Procedure Act notice-and-comment procedures.

For the reasons set forth in the preamble of this notice, and under the authority of the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the revision of 21 CFR part 210, published at 71 FR 2458 (January 17, 2006), is withdrawn.

Dated: April 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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