activity, and "customer satisfaction" measures of performance; and the proposer's plan must include documentation, analysis of the results, and must show how the results can be used in improving the resource center.

(7) Management experience and Plans. Applicants should specify Plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications and experience of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; and appropriateness of the organizational approach for carrying out the proposed activity.

(8) Financial plan. Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the cooperative agreement has expired. Factors that may be considered include: Reasonableness of the budget, both in income and expenses; strength of commitment and amount of the proposer's cost share; effectiveness of management plans for control of the budget; and appropriateness of matching contributions.

# §291.5 Proposal selection process.

The proposal evaluation and selection process will consist of three principal phases: Proposal qualification; proposal review and selection of finalists; and award determination.

(a) Proposal qualification. All proposals will be reviewed by NIST to assure compliance with the proposal content and other basic provisions of this notice. Proposals which satisfy these requirements will be designated qualified proposals; all others will be disqualified at this phase of the evaluation and selection process.

(b) Proposal review and selection of finalists. NIST will appoint an evaluation panel composed of NIST and in some cases other federal employees to review and evaluate all qualified proposals in accordance with the evaluation criteria and values set forth in this notice. A site visit may be required to make full evaluation of a proposal. From the qualified proposals, a group of finalists will be numerically ranked and recommended for award based on this review.

(c) Award determination. The Director FOR FURTHER INFORMATION CONTACT: of the NIST, or her/his designee, shall select awardees based on total evaluation scores, geographic distribution, and the availability of funds. All three factors will be considered in making an award. Upon the final award decision, a notification will be made to each of the proposing organizations.

# §291.6 Additional requirements; federal policies and procedures.

Recipients and subrecipients are subject to all Federal laws and Federal and Department of Commerce policies, regulations, and procedures applicable to Federal financial assistance awards.

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# DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 90N-0376]

RIN 0905-AA73

### **Current Good Manufacturing Practice** in Manufacturing, Processing, Packing, or Holding of Drugs; Amendment of **Certain Requirements for Finished** Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising certain requirements of the current good manufacturing practice (CGMP) regulations for finished human and veterinary pharmaceuticals. The changes include clarifying the degree of discretion provided to manufacturers to determine whether separate or defined areas of production and storage are necessary, clarifying the standard used to determine the degree of scrutiny necessary to check the accuracy of the input to and output from computer systems, exempting investigational new drug products from bearing an expiration date, permitting the use of a representative sampling plan for the examination of reserve samples, and clarifying the manufacturer's responsibilities regarding batch records during the annual evaluation of drug product quality standards. These revisions will reduce regulatory burdens.

EFFECTIVE DATE: February 21, 1995.

- Howard P. Muller, Jr., Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1046.
- Paul J. Motise, Center for Drug Evaluation and Research (HFD-323), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1089, or
- William G. Marnane, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville MD 20855, 301-594-0678.

#### SUPPLEMENTARY INFORMATION:

## I. Background

In the Federal Register of July 14, 1981 (46 FR 36332), FDA announced that it was undertaking a review of existing regulations with the goal of minimizing regulatory burdens while maintaining an acceptable level of consumer protection. The public was invited to submit information to assist the agency in deciding the priority of review. FDA invited data that would enable the agency to identify specific existing regulations or groups of regulations perceived to be unnecessarily costly, burdensome, or without public benefit, and on the potential savings to be derived from revising or removing regulations.

In the Federal Register of July 2, 1982 (47 FR 29004), FDA announced its review priorities based on comments from 125 individuals and organizations. One area selected for regulatory review was part 211 (21 CFR part 211), the regulations that govern CGMP for finished pharmaceuticals.

This, in turn, led to an internal retrospective review that resulted in recommendations to the agency. As a result of the agency review, in the Federal Register of February 12, 1991 (56 FR 5671), FDA issued a proposed rule incorporating the recommendations resulting from the review (hereinafter referred to as the proposed rule). Consideration of these comments and any resulting revisions have been incorporated into this final rule and are discussed in detail below.

The agency's review of CGMP regulations is ongoing and FDA anticipates further revisions based on the agency's experience with the regulations, enforcement efforts, and communications with industry and the general public.