Dated: April 21, 1995.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–10487 Filed 4–27–95; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210 and 211

[Docket No. 88N–0320]

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls; Partial Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA) is announcing a continuation of the partial extension of the compliance date for a provision of the final rule, which was published in the **Federal Register** of August 3, 1993 (58 FR 41348). The document revised the current good manufacturing practice (CGMP) regulations for certain labeling control provisions. In the **Federal Register** of August 2, 1994 (59 FR 39255), FDA partially extended the compliance date for a provision of the regulation to August 3, 1995, and requested comments on the scope of this provision. The agency is further extending the compliance date to August 2, 1996. FDA is taking this action in order to adequately assess comments received on the scope of a particular provision of that rule.

DATES: The final rule published at 58 FR 41348, August 3, 1993, is effective August 3, 1994. The date for compliance with § 211.122(g) for items of labeling (other than immediate container labels) is extended to August 2, 1996. The date of compliance for all other provisions of the final rule remains August 3, 1994.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046, or

Paul J. Motise, Center for Drug Evaluation and Research (HFD–323), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1089.

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of August 3, 1993 (58 FR 41348), FDA published a final rule that amended the CGMP regulations to require that certain special control procedures be instituted if cut labeling is used. One of these procedures requires the use of ''appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations'' (§ 211.122(g)(2)).

On May 4, 1994, FDA received a citizen petition from five trade associations requesting that the agency take a number of actions including, but not limited to, extending the August 3, 1994, effective date of this rule as it applies to labeling (other than the immediate container labels) as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(m)). The petition stated that additional time was needed because of the unavailability of bar code or machine readers as well as other equipment necessary to orient the labeling codes properly, and requested that FDA reopen its administrative record to reassess the scope of a certain provision of the regulation, as discussed below in this document.

On May 6, 1994, the agency received an additional petition from a trade association that requested, among other things, a 1-year stay of the effective date; the petitioner stated that additional time was needed to locate, install, and validate scanning equipment and other necessary equipment to orient items properly for bar code scanning.

Appropriate electronic or electromechanical equipment primarily consists of systems that scan identity codes printed on labeling. If an incorrect code is detected, the defective labeling is ejected from the labeling line. FDA contacted vendors of this equipment and determined that while there was not a general shortage of system hardware, there was a possible shortage of contract engineering firms employed by some drug manufacturers to evaluate, select, purchase, install, qualify, and validate labeling verification systems.

In response to this situation, FDA extended the compliance date of § 211.122(g) as it applied to items of labeling (other than the immediate container label) to assess further the availability of equipment necessary for compliance with the final rule and to evaluate adequately other issues raised by petitioners.

The first petition also requested that the agency reopen the administrative record to receive additional comments on the application of § 211.122(g) to items of labeling (other than that of the immediate container label) as defined in section 201(m) of the act. Both citizen petitions contended that § 211.122(g) expanded the proposed scope of the provision from immediate container labels to all drug product labeling.

In response to the issues raised, FDA agreed to receive comments on this issue and to evaluate those comments in light of the existing language of § 211.122(g). The comment period ended on October 4, 1994, and since that time FDA has had a number of meetings with representatives of the labeling industry and others to determine control options available through current technology and to evaluate this information in light of comments received during the extended comment period.

In order to adequately assess this information, determine whether any possible revision of the regulation should result, and provide industry adequate time to fully comply with a final regulation, FDA is extending the compliance date of § 211.122(g) as its applies to items of labeling other than the immediate container label to August 2, 1996. Should FDA determine, after completing its assessment of the comments, that § 211.122(g) should be retained in its current state or revised, FDA will provide notice of that decision in a future issue of the **Federal Register**. The compliance date for the remainder of § 211.122, including § 211.122(g) as it applies to immediate container labels, was August 3, 1994. The agency emphasizes, however, that § 211.125 makes a waiver of labeling reconciliation conditional on a 100-percent examination for correct labeling performed in accordance with § 211.122(g)(2).

Dated: April 24, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–10461 Filed 4–27–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 310

[Docket No. 77N–334S]

RIN 0905–AA06

Topical Drug Products for Over-the-Counter Human Use; Products for the Prevention of Swimmer's Ear and for the Drying of Water-Clogged Ears; Final Rule; Correction

AGENCY: Food and Drug Administration, HHS.