See Headquarters Ruling Letter (HRL) 087271 dated January 17, 1991, (the expressions ''Made in China, Assembled in Hong Kong'' or ''Knit in China, Assembled in Hong Kong'' were acceptable under 19 U.S.C. 1304 and 19 CFR 134.46 indicating that the country of origin of sweaters was China). But see HRL 733564 dated August 10, 1990 (the marking ''Made in Canada'' needed to be removed from hoses manufactured in Canada, after assembly with brass fittings in Mexico, as the country of origin of the assembled article was Mexico pursuant to 19 CFR 10.22 and the article could be marked ''Assembled in Mexico'').

Due to the confusion generated by 19 CFR 10.22 concerning when it is acceptable to use the words ''Assembled in,'' in country of origin marking, this section, effective August 5, 1996, will be removed from the Customs Regulations as part of a final document which principally implemented Annex 311 of the North American Free Trade Agreement (T.D. 96–48, 61 FR 28932, 28955, June 6, 1996). That final rule document also included an amendment to 19 CFR 134.43(e) to provide for the use of the phrases, ''Assembled in (country of final assembly),'' ''Assembled in (country of final assembly) from components of (name of country or countries of origin of all components),'' or ''Made in, or product of, (country of final assembly),'' as methods of marking an imported article when the country of origin of such article is determined to be the country in which it was finally assembled.

Accordingly, for all goods entered, or withdrawn from warehouse, for consumption on or after August 5, 1996, the country of origin indicator, ''Assembled in,'' may be used for the marking of imported articles only when the country of origin of that article is determined to be the country in which the article was finally assembled. Whether or not the article is eligible for entry under subheading 9802.00.80, HTSUS, will not be relevant to the use of this marking.

Furthermore, as a result of the amendment of 19 CFR 134.43(e), the terms ''Made in'' and ''Assembled in'' are always words of similar meaning, and it will no longer be acceptable to use ''Made in,'' ''Product of,'' or words of similar meaning, along with the words ''Assembled in'' in a single country of origin marking statement on articles of foreign origin imported into the United States.

However, the marking statute and regulations allow for exceptions to the marking requirements under certain circumstances. One of these exceptions concerns articles which cannot be marked prior to, or after, importation except at an expense that would be economically prohibitive. See 19 U.S.C. 1304(a)(3) (C) and (K), and 19 CFR 134.32 (c) and (o).

In consideration of: (1) the fact that the use of ''Made in,'' ''Product of,'' or words of similar meaning, along with the use of the words ''Assembled in'' in a single country of origin marking statement has been acceptable until the amendment of 19 CFR 134.43(e), and many articles or labels containing such statements may have already been made; (2) the expectation that many individual requests will be received for marking exceptions on the ground of economic prohibitiveness; and (3) the importance of providing uniform Customs treatment, Headquarters has made a general finding under these circumstances that it would be economically prohibitive to require the marking of imported foreign articles (either before or after importation) in compliance with 19 CFR 134.43(e), as amended, as of the effective date of the new regulations. This general marking exception shall be granted for all imported foreign articles marked ''Made in,'' ''Product of,'' or words of similar meaning, such as ''Knit in,'' along with the use of the words ''Assembled in'' in a single country of origin marking statement, for a period not to exceed three (3) months from the effective date of 19 CFR 134.43(e), as amended, (i.e., no later than November 5, 1996), which Customs views as a reasonable period of time for the exhaustion of existing inventory. Please note that, if information is obtained that the above articles or labels were made after August 5, 1996, this general marking exception will not apply.

Dated: July 11, 1996.

Stuart P. Seidel,

Assistant Commissioner, Office of Regulations and Rulings.

[FR Doc. 96–18135 Filed 7–18–96; 8:45 am]

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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 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 April 28, 1995 (60 FR 20897), FDA partially extended the compliance date to August 2, 1996, for that part of the final rule pertaining to items of cut labeling other than immediate container labels. This document extends the compliance date to August 1, 1997. FDA is taking this action to afford the industry sufficient time to purchase necessary equipment or to take other steps necessary to comply with certain provisions of the final rule, and to provide additional time for the agency to consider any revisions to the final rule.

DATES: Efffective July 19, 1996, the date for compliance with § 211.122(g) (21 CFR 211.122(g)) for items of labeling (other than immediate container labels) is now extended to August 1, 1997. The date of compliance for all other provisions of the final rule published August 3, 1993 (58 FR 41348) remains August 3, 1994.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046, or

Paul J. Motise, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0098.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 3, 1993 (58

FR 41348), FDA published a final rule that amended the labeling control provisions in the CGMP regulations. The final rule defined the term ''gang-printed labeling,'' specified conditions for the use of gang-printed or cut labeling, exempted manufacturers that employ certain automated inspection systems from labeling reconciliation requirements, and made other revisions intended to reduce the frequency of drug product mislabeling and associated drug product recalls. One of the three special control options for cut labeling is 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)).

In response to two citizen petitions requesting certain amendments to § 211.122(g) as it applies to cut labeling, a stay of the effective date, and reopening of the administrative record, FDA, in the Federal Register of August 2, 1994 (59 FR 39255), granted a partial extension of the compliance date for certain provisions of § 211.122(g) to August 3, 1995, and a limited reopening of the administrative record. In the Federal Register of April 28, 1995 (60 FR 20897), FDA granted a further partial extension of the compliance date to August 2, 1996.

FDA extended the compliance date to provide industry with additional time to comply with certain provisions of the final rule. FDA found that additional time was needed to locate, install, and validate scanning equipment and other necessary equipment to orient items properly for bar code scanning because there was a shortage of contract engineering personnel employed by some drug manufacturers to evaluate, select, purchase, install, qualify, and validate labeling verification systems.

FDA reopened the administrative record to receive additional comments on the application of § 211.122(g) to items of labeling (other than the immediate container label) as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m)), and whether § 211.122(g) expanded the proposed scope of the provision from immediate container labels to all drug product labeling.

FDA has held 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. To assess this information adequately, provide industry with adequate time to comply fully with a final regulation, and provide additional time for FDA to consider any revisions to the final rule, the agency is extending to August 1, 1997, the compliance date for § 211.122(g) as it applies to items of labeling other than the immediate container label.

FDA's determination as to whether § 211.122(g) will be retained as currently codified or whether it will be revised will be published 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 that, under 21 CFR 211.125, a waiver of labeling reconciliation is conditioned on a 100-percent examination for correct labeling performed in accordance with § 211.122(g)(2).

Dated: July 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–18285 Filed 7–18–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 500, 505, 507, 508, 510, and 570

[Docket No. 95N–310V]

Revocation of Certain Animal Food and Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking certain regulations regarding animal food and animal drugs that are obsolete or no longer necessary to achieve public health goals. These regulations have been identified for revocation as the result of a page-by-page review of the agency's regulations. This regulatory review is in response to the administration's ''Reinventing Government'' initiative which seeks to streamline Government to ease the burden on regulated industry and consumers. These regulations are being consolidated in order to respond to ''Reinventing Government.''

EFFECTIVE DATE: August 19, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kristi O. Smedley, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1995, President Clinton announced plans for the reform of the Federal regulatory system as part of the administration's ''Reinventing Government'' initiative. In his March 4 directive, the President ordered all Federal agencies to conduct a page-by-page review of all of their regulations and to ''eliminate or revise those that are outdated or otherwise in need of reform.'' In the Federal Register of October 13, 1995 (60 FR 53480), FDA provided its initial efforts in implementing the President's plan. The proposed rule announced regulations that FDA intended to eliminate based on the page-by-page review.

The agency received no comments regarding their intention to eliminate any of the regulations that cover animal food or animal drug regulations. Therefore the agency is removing the following regulations:

1. Section 500.49 *Chlorofluorocarbon propellants* (21 CFR 500.49). This section prohibits the use of chlorofluorocarbons as propellants in self-pressurized containers in animal drugs. Chlorofluorocarbons are prohibited by the Clean Air Act Amendments of 1990 (42 U.S.C. 7671) and can no longer be marketed for this use. This section is unnecessary because coverage in § 2.125 (21 CFR 2.125) of this prohibition is sufficient.

2. Section 505.3 *Warnings on animal drugs intended for administration to diseased animals* (21 CFR 505.3). This section states that no warning or caution statements recommended for use in the labeling of animal drugs intended for administration to diseased animals shall be construed to suggest or imply that a product of diseased animals is suitable for food use. This provision cautions against misuse of language in § 505.20 (21 CFR 505.20) which is now being withdrawn and is, therefore, unnecessary.

3. Section 505.20 *Recommended animal drug warning and caution statements*. This section provides recommended animal drug warning and caution statements for specific drugs. The statements provided are voluntary label statements that do not contain requirements and need not appear in the CFR.

4. Part 507—Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR part 507). This part contains the criteria that apply in determining whether the facilities, methods, practices, and