depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. The SIAPs contained in this amendment are based on the criteria contained in the United States Standard for Terminal Instrument Approach Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports.

The FAA has determined through testing that current non-localizer type, non-precision instrument approaches developed using the TERPS criteria can be flown by aircraft equipped with Global Positioning System (GPS) equipment. In consideration of the above, the applicable Standard Instrument Approach Procedures (SIAPs) will be altered to include "or GPS" in the title without otherwise reviewing or modifying the procedure. (Once a stand alone GPS procedure is developed, the procedure title will be altered to remove "or GPS" from these non-localizer, non-precision instrument approach procedure titles.) Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public review of the procedures, before adopting these SIAPs are, impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this amendment only involves an established body of technical regulations for frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.
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 9002.00.80, 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.

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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, Packaging, 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: Effective 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.


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