

cycles until accomplishment of the requirements of paragraph (j) of this AD.

(i) Detailed Inspection for Cracks (No Leakage Found)

If no sign of fuel leakage is found during the most recent inspection required by paragraph (g) of this AD, within 450 flight cycles after accomplishing the inspection, repeat the general visual inspection required by paragraph (g) of this AD and do a detailed inspection for cracks on spar II, spar cap third, and main box lower skin of the wings, close to the rib 10, in accordance with Part II and Part III of the Accomplishment Instructions of EMBRAER Alert Service Bulletin 170-57-A053, dated February 13, 2012. Repeat both inspections thereafter at intervals not to exceed 450 flight cycles.

(j) Special Detailed Inspection (Leakage Found)

If any fuel leakage is found during any inspection required by paragraph (g) or (i) of this AD: Within 150 flight cycles after the most recent inspection, do an eddy current special detailed inspection for cracks on spar II of the wings, and a defueled tank leak check for fuel leakage, in accordance with Part IV and Part V, as applicable, of the Accomplishment Instructions of EMBRAER Alert Service Bulletin 170-57-A053, dated February 13, 2012.

(1) If any crack is found: Do the actions specified in paragraph (k) of this AD.

(2) If no crack is found: Repeat the general visual inspection specified in paragraph (g) of this AD and the detailed inspection specified in paragraph (i) of this AD at intervals not to exceed 450 flight cycles.

(k) Repair

If any cracking or fuel leakage is found during any inspection or check required by this AD: Before further flight, repair using a method approved by either the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the Agência Nacional de Aviação Civil (ANAC) (or its delegated agent). Repair of any crack terminates the repetitive inspection requirements required by this AD for that side of the wing.

Note 2 to paragraph (k) of this AD: Guidance on the classification of “fuel leakage” and the disposition of fuel leaks can be found in Task 28-11-00-790-801-A, Wing Tank—Fueled Tank Leakage Check, of the EMBRAER 170/175 Aircraft Maintenance Manual.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM-116, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, ANM-116, send it to ATTN: Cindy Ashforth, Aerospace Engineer, International Branch, ANM-116,

Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057-3356; telephone 425-227-2768; fax 425-227-1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(m) Special Flight Permits

Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), are not allowed.

(n) Related Information

Refer to MCAI Brazilian Airworthiness Directive 2012-02-01, dated February 22, 2012; and EMBRAER Alert Service Bulletin 170-57-A053, dated February 13, 2012; for related information.

(o) Material Incorporated by Reference

(1) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) of the following service information under 5 U.S.C. 552(a) and 1 CFR part 51:

(i) Embraer Alert Service Bulletin 170-57-A053, dated February 13, 2012.

(2) For service information identified in this AD, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170-Putim-12227-901 São Jose dos Campos—SP—BRASIL; telephone +55 12 3927-5852 or +55 12 3309-0732; fax +55 12 3927-7546; email distrib@embraer.com.br; Internet <http://www.flyembraer.com>.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Issued in Renton, Washington, on March 7, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

RIN 1205-AB58

Changes to the Labor Certification Process for the Temporary Non-Agricultural Employment of H-2B Aliens in the United States; Transition Period

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Guidance.

SUMMARY: On February 21, 2012, the Department of Labor (the Department or DOL) published a Final Rule amending H-2B regulations governing the certification of temporary employment of nonimmigrant workers in temporary or seasonal non-agricultural employment. The Department's H-2B Final Rule also created new regulations to provide for enhanced enforcement under the H-2B program requirements when employers fail to meet their obligations under the H-2B program. The Department also made changes to the *Application for Temporary Employment Certification*, ETA Form 9142.

The H-2B Final Rule becomes effective on April 23, 2012. All applications filed on or after that date will need to comply with all applicable program requirements. The purpose of this guidance is to provide transition procedures to ensure that employers filing H-2B applications on or after April 23, 2012, have sufficient information to file appropriately.

DATES: This guidance is effective March 20, 2012.

FOR FURTHER INFORMATION CONTACT:

William L. Carlson, Ph.D., Administrator, Office of Foreign Labor Certification, Employment and Training Administration, 200 Constitution Avenue NW., Room C-4312, Washington, DC 20210; Telephone: (202) 693-3010 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On February 21, 2012, the Department published a Final Rule amending the H-2B regulations at 20 CFR part 655, Subpart A. 76 FR 10038, Feb. 21, 2012. The rule becomes effective April 23, 2012 and applies to all applications filed on or after that date. Among other things, the H-2B Final Rule provides for a return to the compliance-based certification model, by which employers file before conducting recruitment. The

H-2B Final Rule also includes a new registration process, to precede the filing of applications.

Applications filed under Labor Certification Process and Enforcement for Temporary Employment in Occupations Other Than Agriculture or Registered Nursing in the United States (H-2B Workers), and Other Technical Changes, 73 FR 78020, Dec. 19, 2008 (the current regulation), must be sent to the Office of Foreign Labor Certification's (OFLC's) Chicago National Processing Center (CNPC) and postmarked no later than midnight April 22, 2012, the last day before the effective date of the H-2B Final Rule. An application filed up to the effective date of the H-2B Final Rule must still comply in full with the requirements of the current regulations. Applications postmarked on or after April 23, 2012 will be adjudicated in accordance with the requirements described in the H-2B Final Rule.

Any application filed under the current regulation that is postmarked on or after April 23, 2012 or later will be rejected, and the employer (and its agent or attorney) will be informed of the need to file a new application in accordance with the provisions of the new H-2B Final Rule.

To ensure a smooth transition from the current regulation and allow the OFLC to make the necessary changes to its program operations to accommodate the new planned registration process, the Department noted in the H-2B Final Rule, at 20 CFR 655.11(j), that it would announce in the **Federal Register** a separate transition period for the registration process. Employers who file H-2B applications with a start date of need before October 1, 2013 will not be required to obtain the pre-approved H-2B registration under 20 CFR 655.15, and the Department will continue to adjudicate temporary need during the processing of applications by reviewing the employer's statement of temporary need in Section B of the ETA Form 9142. Employers filing H-2B applications on or after April 23, 2012 with a start date of need on or after October 1, 2013, must comply with all the requirements contained in the registration process unless the OFLC publishes additional guidance in the **Federal Register**.

Employers with questions are encouraged to submit such questions to H-2B.Regulation@dol.gov. The Department will provide responses in the form of Frequently Asked Questions (FAQs) on its Web site.

Signed in Washington, this 14th day of March, 2012.

Jane Oates,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2012-6580 Filed 3-19-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. FDA-1997-N-0518] (formerly 97N-0300)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the packaging and labeling control provisions of the current good manufacturing practice (CGMP) regulations for human and veterinary drug products by limiting the application of special control procedures for the use of cut labeling to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. FDA is also permitting the use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment when cut labeling is used. This action is intended to protect consumers from labeling errors more likely to cause adverse health consequences, while eliminating the regulatory burden of applying the rule to labeling unlikely to reach or adversely affect consumers. This action is also intended to permit manufacturers to use a broader range of error prevention and labeling control techniques than permitted by current CGMPs.

DATES: This final rule is effective on March 20, 2013, except for the amendment adding § 211.122(g)(4), which is effective April 19, 2012.

FOR FURTHER INFORMATION CONTACT: Brian Hasselbalch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4364, Silver Spring, MD 20993-0002, 301-

796-3279, email: brian.hasselbalch@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 29, 1997 (62 FR 40489) (the proposed rule), FDA proposed to amend the packaging and labeling control provisions of the CGMP regulations for human and veterinary drug products by limiting the application of special control procedures for the use of cut labeling to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, and to permit the use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment when cut labeling—single labels for individual drug products that are “cut” from a sheet or roll of labels—is used.

Persistent problems with drug product mislabeling and subsequent recalls led FDA in 1987 and in 1990 to review labeling procedures and product recalls. The review identified gang-printed and cut labeling as a leading cause of labeling mixups. Gang-printed labeling is defined in § 210.3(b)(22) (21 CFR 210.3(b)(22)) as labeling derived from a sheet of material on which more than one item of labeling is printed. Each sheet includes labeling for a variety of products and, because of this, labeling for individual drug products must be separated from the labeling for other products. When labels are gang-printed, the labels for different drug products or different strengths for the same drug product are processed together, making them especially susceptible to mixups. Similarly, cut labeling is commonly placed in separate stacks before being transported to packaging and labeling lines for application to appropriate products. FDA found that stacks of labeling of similar size, shape, and color could easily be intermixed and, if the printer or manufacturer did not detect the error, incorrect labeling could be applied and a mislabeled drug product distributed. To reduce the frequency and likelihood of such mislabeling, FDA, in the **Federal Register** of August 3, 1993 (58 FR 41348), amended the packaging and labeling control provisions of the CGMP regulations in part 211 (21 CFR part 211) to provide specific conditions for the use of all gang-printed and cut labeling. Under § 211.122(f), use of gang-printed labeling for different drug products, or different strengths or net