

recently updated by a final rule published in the **Federal Register** (65 FR 31263) on May 17, 2000.

This document amends § 122.15(b) to reflect that the name of the user fee airport located in Ocala, Florida, has been changed from Ocala Regional Airport to Ocala International Airport.

Inapplicability of Public Notice and Delayed Effective Date Requirements

Because this amendment merely reflects the changed name of a user fee airport that has already been designated by the Commissioner of Customs in accordance with 19 U.S.C. 58b and neither imposes additional burdens on, nor takes away any existing rights or privileges from, the public, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary, and for the same reasons, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. This amendment does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

Drafting Information

The principal author of this document was Janet L. Johnson, Regulations Branch, Office of Regulations and Ruling, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 122

Air carriers, Aircraft, Airports, Customs duties and inspection, Freight.

Amendment to the Regulations

Part 122, Customs Regulations (19 CFR part 122) is amended as set forth below.

PART 122—AIR COMMERCE REGULATIONS

1. The authority citation for part 122 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a.

2. Section 122.15(b) is amended by removing the name "Ocala Regional Airport" in the "Name" column adjacent to "Ocala, Florida" in the

"Location" column and adding in its place "Ocala International Airport".

Charles W. Winwood,

Acting Commissioner of Customs.

Approved: September 20, 2001.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

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DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

RIN 1205-AB30

Labor Certification and Petition Process for the Temporary Employment of Nonimmigrant Aliens in Agriculture in the United States; Delegation of Authority To Adjudicate Petitions; Deferral of Effective Date

AGENCY: Employment and Training Administration, Labor.

ACTION: Interim final rule with request for comments; deferral of effective date of final rule.

SUMMARY: The Department of Labor (DOL or Department) is deferring the effective date of its final rule implementing the delegation of authority to adjudicate petitions for the temporary employment of nonimmigrant aliens in agriculture in the United States. The Immigration and Naturalization Service (INS) is also delaying the delegation of INS' authority to the Department to adjudicate petitions for the temporary employment of nonimmigrant aliens in agriculture in the United States. The Department has the need for additional time to effectively implement the delegation of authority, develop new systems and procedures, and to train and brief members of the affected public and the employment and training community in the new systems and procedures. Therefore the Department has determined to defer the effective date of the Final Rule promulgated at 65 FR 43538 (July 13, 2000). Comments are being requested on this action. The rule being deferred amends the Employment and Training Administration (ETA) regulations to implement the delegation of authority to adjudicate petitions for temporary nonimmigrant agricultural workers (H-2A's) from the INS to the Department.

DATES: The effective date of the final rule in FR Doc. 00-17641, published at

65 FR 43538 (July 13, 2000), was deferred from November 13, 2000, until October 1, 2001, by an interim final rule published in FR Doc. 00-28897, published at 65 FR 67628 (November 13, 2000). This interim final rule defers the effective date of the final rule until September 27, 2002.

Comments: Comments are invited on the deferral of the effective date. Submit comments on or before October 29, 2001.

ADDRESSES: Send comments to Assistant Secretary of Labor for Employment and Training, Attention: Division of Foreign Labor Certifications, Employment and Training Administration, 200 Constitution Avenue, NW., Room N-4456, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Denis M. Gruskin, Senior Specialist, Division of Foreign Labor Certifications, Employment and Training Administration, 200 Constitution Avenue, NW., Room N-4456, Washington, DC 20210. Telephone (202) 693-2953 (this is not a toll-free number)

SUPPLEMENTARY INFORMATION: The Department of Labor (DOL or Department) published a final rule in this rulemaking in the **Federal Register** at 65 FR 43538 (July 13, 2000), with an effective date of November 13, 2000, implementing a delegation of authority from the INS to the Department to adjudicate petitions for the temporary employment of nonimmigrant aliens in agriculture in the United States. Concurrently, the INS published a Final Rule at 65 FR 43528 (July 13, 2000) with an effective date of November 13, 2000, transferring to the Secretary of Labor the authority to adjudicate petitions for temporary agricultural workers and the authority to decide appeals on these decisions and to make determinations for revocation of petition approvals.

Subsequently, the INS at 65 FR 67616 (November 13, 2000) published a final rule and DOL at 65 FR 67628 (November 13, 2000) published an interim final rule (IFR) deferring the effective dates of their final rules. The Department in its IFR invited comments on the deferral of the effective date. No comments were received by DOL on the deferral of the effective date.

The Department also reopened and extended the comment period at 65 FR 50170 (August 17, 2000) on a companion notice of proposed rulemaking (NPRM) published at 65 FR 43545 (July 13, 2000) setting forth implementation measures necessary to the successful implementation of the delegation of authority to adjudicate petitions. Among the implementation measures was a new Form ETA 9079,

Application for Alien Employment Certification and H-2A Petition, which consolidated two current forms, ETA 750 Application for Alien Employment Certification) and INS I-129 (Petition for Nonimmigrant Workers). The NPRM also set forth the implementation of a new fee schedule to collect a combined fee for processing the petition and labor certification application. It is contemplated that under the administrative procedures arrived at by INS and the Employment and Training Administration to implement the delegation of the petition authority from INS to the Department, DOL will collect the petition fee on behalf of INS and will be reimbursed by INS for the costs involved in processing the H-2A petition.

The INS reopened and extended the comment period at 65 FR 50166 (August 17, 2000) on a proposed rule published concurrently at 65 FR 43535 (July 13, 2000) with its final rule delegating the authority to adjudicate petitions to DOL. The INS proposed rule provided, among other things, that all petition requests and extensions of stay and change of status petitions must be filed with DOL and the current INS petition fee will be collected by DOL as part of a combined fee.

Commenters raised a number of issues about the proposed rules. The comments received by the Department as a result of the August 17, 2000, reopening and extension of the proposed rule did not provide sufficient information to permit the Department to draft a final rule concerning a number of issues, such as the design of the new form and the fee structure. Consequently, the Department intends in the near future to again reopen and extend the comment period on the July 13, 2000, NPRM. In a document published elsewhere in this issue of the **Federal Register**, the Department is reopening and extending the comment period on the NPRM. In another document, the Department is announcing informal briefings to allow agricultural workers and employers and other interested parties to communicate directly with the Department regarding the proposed rule changes which would require employers to submit fees for temporary labor certification and the associated H-2A petition with a consolidated application form at the time of filing, and as indicated above, sets forth a new fee structure for the labor certification.

Finalizing the proposed rules is essential to the effective implementation of any delegation of authority to DOL to adjudicate petitions for temporary employment of nonimmigrant aliens in

the United States. Allowing the Final Rule to become effective without finalizing action on the proposed rule published by the Department would lead to administrative uncertainty and result in confusion on the part of employers, agricultural workers, and other interested parties. Accordingly, the Department has concluded good causes exist to defer the effective date of the July 13, 2000, Final Rule until the rulemaking on the companion proposal is completed. At this time we are extending the effective date of the final rule published at 65 FR 43538 for one year, until October 27, 2002. The regulatory certifications set forth in the July 13, 2000, Final Rule apply to this deferral as well.

Signed at Washington, DC, this 24th day of September 2001.

Emily Stover DeRocco,

Assistant Secretary for Employment and Training.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration.

21 CFR Part 341

[Docket No. 76N-052G]

RIN 0910-AA01

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Partial Final Rule for Combination Drug Products Containing a Bronchodilator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing that cough-cold combination drug products containing any oral bronchodilator active ingredient in combination with any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient are not generally recognized as safe and effective and are misbranded for over-the-counter (OTC) use. FDA is issuing this final rule after receiving no public comments on the agency's proposed nonmonograph status of these specific combination drug products, which was issued in the form of a tentative final monograph for OTC cough-cold combination drug products. This final rule is part of the ongoing

review of OTC drug products conducted by FDA.

DATES: This regulation is effective October 29, 2001.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 9, 1976 (41 FR 38312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic (cough-cold) drug products, together with the recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. The Panel placed the combination of an oral bronchodilator with either an analgesic-antipyretic, anticholinergic, antihistamine, or antitussive (when the product is labeled only for cough associated with asthma) ingredient in Category II (not generally recognized as safe and/or effective) (41 FR 38312 at 38326).

The agency concurred with the Panel in the tentative final monograph for cough-cold combination drug products (53 FR 30522 at 30556, August 12, 1988). The agency also classified the combination of caffeine and ephedrine or pseudoephedrine in Category II (53 FR 30522 at 30557). No comments on these specific combinations were submitted in response to the tentative final monograph.

The current monograph oral bronchodilator active ingredients are ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racedephedrine hydrochloride (21 CFR 341.16(a), (b), (c), and (f)). The agency is not aware of any OTC drug products currently marketed containing an oral bronchodilator active ingredient in combination with any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient.

II. The Agency's Conclusion

The OTC drug review program establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded.