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This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Pratt & Whitney Canada, 1000 Marie-Victorin, Longueuil, Quebec, Canada J4G1A1. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in AD CF–98–41 in order to assure the airworthiness of these P&WC PT6A series turboprop engines in Canada.

Effective Date

(j) This amendment becomes effective on December 31, 2002.

Issued in Burlington, Massachusetts, on November 15, 2002.

Mark C. Fulmer,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 02–29671 Filed 11–25–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 90N–0056]

RIN 0910–AA74

Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition; Amendment; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying until January 26, 2004, the effective date of a final rule published in the **Federal Register** of January 26, 2000 (65 FR 4103) (aluminum final rule), and originally scheduled to become effective on January 26, 2001. In the **Federal Register** of January 26, 2001 (66 FR 7864), the agency delayed the effective date of the aluminum final rule until January 26, 2003. The aluminum final rule imposes certain requirements for aluminum-containing large volume parenterals (LVPs), small volume parenterals (SVPs), and pharmacy bulk packages (PBPs) used in total parenteral nutrition (TPN). FDA is delaying the effective date of the aluminum final rule to allow time for the agency to finalize an amendment to the aluminum final rule. The agency is also amending the aluminum final rule to change to January 26, 2004, the date that limits the use of historical levels to determine the maximum level of aluminum in SVPs and PBPs; this date corresponds to the effective date of the aluminum final rule, which is delayed until January 26, 2004, by this document.

DATES: This final rule is effective December 26, 2002. The effective date for § 201.323 (21 CFR 201.323), added at 65 FR 4103, January 26, 2000, is delayed until January 26, 2004.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: On January 26, 2000, FDA published final regulations at § 201.323 imposing certain requirements for aluminum-containing LVPs, SVPs, and PBPs used in TPN (65 FR 4103). The aluminum final rule was originally scheduled to become effective on January 26, 2001. In the **Federal Register** of January 26, 2001 (66 FR 7864), the agency published a notice delaying the effective date until January 26, 2003.

In the **Federal Register** of August 12, 2002 (67 FR 52429), FDA published a proposed rule to amend § 201.323. The proposed rule would permit SVPs and PBPs containing 25 micrograms per liter (µg/L) or less of aluminum to be labeled with the statement ''Contains no more than 25 µg/L of aluminum'', instead of stating the exact amount of aluminum they contain. Because there is insufficient time to finalize this proposed amendment before January 26, 2003, when § 201.323 is scheduled to become effective, the agency is delaying the effective date of § 201.323 until January 26, 2004.

The agency is also amending § 201.323(c)(3) of the aluminum final rule to reflect the fact that the effective date is now being extended to January 26, 2004. Section 201.323(c)(3) provides that a manufacturer may state the maximum level of aluminum in terms of historical levels, but only until completion of production of the first five batches after January 26, 2001, the date by which manufacturers were to have submitted supplements describing the validated assay method used to determine aluminum content. Because manufacturers now have until January 26, 2004, to submit supplements, this final rule is changing the date in § 201.323(c)(3) to reflect the fact that the effective date of the aluminum final rule has been extended to January 26, 2004.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C 553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to the public interest. The agency is delaying the effective date of § 201.323 because the agency has proposed to amend § 201.323. Given the imminence of the effective date of current § 201.323, seeking prior public comment on this delay is impracticable, as well as contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that the agency would be proposing to extend the effective date for § 201.323, those companies affected would have to be preparing to relabel to comply with the January 26, 2003, effective date. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on which this delay should be modified or revoked.

FDA has examined the impacts of this delay of effective date under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory

alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this action is consistent with the regulatory philosophy and principles identified in the Executive order. This action will ease the burden on industry of compliance with § 201.323 by giving manufacturers more time to relabel affected products. Thus, this action is not a significant action as defined by the Executive order.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.323(c)(3) is amended by removing the date ''2001'' and adding in its place the date ''2004''.

Dated: November 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–29924 Filed 11–25–02; 8:45 am]

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DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences under the United States and District of Columbia Codes

AGENCY: Parole Commission, Justice.

ACTION: Final rule.

SUMMARY: The U.S. Parole Commission is amending procedures governing parole proceedings for federal and District of Columbia offenders, and transfer treaty prisoners. Almost all the amendments are corrections and clarifications of the instructions for calculating the salient factor score, a component of the Commission's paroling policy guidelines. The Commission is also correcting a reference to the U.S. Sentencing Guidelines in a regulation regarding the imposition of release conditions for a transfer treaty prisoner released to a term of supervised release.

EFFECTIVE DATE: These rule amendments are effective December 30, 2002.

FOR FURTHER INFORMATION CONTACT: Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815, telephone (301) 492–5959. Questions about this publication are welcome, but inquiries concerning individual cases cannot be answered over the telephone.

SUPPLEMENTARY INFORMATION:

The salient factor score is an actuarial device used by the Commission to evaluate the risk of parole violation by a prisoner if released to supervision. The score is a component of the Commission's paroling policy guidelines for making parole release decisions for U.S. Code offenders (28 CFR 2.20), and is also employed in the guidelines for DC Code offenders (28 CFR 2.80). The score comprises six criminal history items, including items such as number of prior convictions and commitments, and age at the time of current offense. The total score ranges from 0–10, with the higher score indicating that the prisoner is a better parole risk.

The Commission is now updating the instructions in the salient factor scoring manual to give better guidance in the scoring of the individual items. Some of the changes are corrections of text that should have been amended in earlier revisions of the score, or editorial improvements to make the instructions easier to read. Other changes reflect the application of the score in determining terms of imprisonment for DC Code supervised release violators. Finally, several new instructions implement advice the Commission's Office of General Counsel has provided to Commissioners and staff in the use of DC juvenile consent decrees and juvenile commitments to the DC Department of Human Services for salient factor scoring.

Aside from the amendments to the salient factor scoring manual, the Commission is also correcting a reference to the U.S. Sentencing Guidelines in its regulation at 28 CFR 2.68(l) on the imposition of conditions of supervised release for a transfer treaty prisoner who is released to a term of supervised release.

Implementation

These amendments will be applied in any hearing or record review conducted after the effective date of the amendments.

Regulatory Assessment Requirements

The U.S. Parole Commission has determined that this final rule does not constitute a significant rule within the meaning of Executive Order 12866. The final rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b), and is deemed by the Commission to be a rule of agency practice that does not substantially affect the rights or obligations of non-agency parties pursuant to section 804(3)(c) of the Congressional Review Act.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Prisoners, Probation and parole.

The Final Rule

Accordingly, the U.S. Parole Commission is adopting the following amendments to 28 CFR part 2.

PART 2—[AMENDED]

1. The authority citation for 28 CFR part 2 continues to read as follows:

Authority: 18 U.S.C. 4203(a)(1) and 4204(a)(6).

Subpart A—United States Code Prisoners and Parolees

2. Section 2.20 is amended as follows:

a. In the table entitled ''Guidelines For Decisionmaking'' remove ''salient factor score 1981'' and substitute ''salient factor score 1998'';

b. Revise the Salient Factor Scoring Manual, Item A, paragraphs A.1, A.5, and add paragraph A.14;

c. Revise the Salient Factor Scoring Manual, Item B, paragraphs B.3(b)–(c), and add paragraph B.3(d);

d. Revise the Salient Factor Scoring Manual, Item C, paragraphs C.1–C.4, redesignate paragraph C.5 as C.10, and add paragraphs C.6–C.9;

e. Revise the Salient Factor Scoring Manual, Item E, paragraphs E.3(b)–(c);

f. Revise the Salient Factor Scoring Manual, Item F;

g. Revise the Salient Factor Scoring Manual, Special Instructions—Federal Probation Violators, by revising the title and the paragraphs for scoring Items A and E, remove the paragraph for scoring Item F, and redesignate the paragraph for scoring Item G as Item F;

h. Revise the Salient Factor Scoring Manual, Special Instructions—Federal Parole Violators, by revising the title and the paragraphs for scoring Items A–