

# Rules and Regulations

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## OFFICE OF PERSONNEL MANAGEMENT

### 5 CFR Part 731

RIN 3206-AC19

#### Suitability

**AGENCY:** U.S. Office of Personnel Management.

**ACTION:** Final rule, extension of effective date.

**SUMMARY:** The Office of Personnel Management (OPM) published a final rule on personnel suitability on December 28, 2000 in the **Federal Register** (65 FR 82239). Based on a memorandum received from the Assistant to the President and Chief of Staff outlining the President's plan for Regulatory Review, the implementation of these rules has been extended to allow adequate review. The effective date for implementation of these rules is being extended 60 days until March 30, 2001.

**DATES:** *Effective:* March 30, 2001.

**FOR FURTHER INFORMATION CONTACT:** Thomas DelPozzo, (724) 794-5612.

Office of Personnel Management.

**Steven R. Cohen,**  
*Acting Director.*

[FR Doc. 01-2476 Filed 1-24-01; 12:55 pm]

**BILLING CODE** 6325-40-P

## DEPARTMENT OF JUSTICE

### Immigration and Naturalization Service

#### 8 CFR Parts 103, 208, 210, 212, 235, 241, and 245a

[INS No. 2004-99; A.G. Order No. 2396-2001]

RIN 1115-AF53

#### Clarification of Parole Authority; Delay of Effective Date

**AGENCY:** Immigration and Naturalization Service, Department of Justice.

**ACTION:** Interim rule; delay of effective date.

**SUMMARY:** In accordance with the memorandum of January 20, 2001, from Andrew H. Card, Jr., the Assistant to the President and Chief of Staff, entitled "Regulatory Review Plan" (memorandum), this rule temporarily delays for 60 days the effective date of the interim rule entitled "Clarification of Parole Authority," published in the **Federal Register** on December 28, 2000, at 65 FR 82254. This temporary delay will allow the Department an opportunity for further consideration of this rule.

**EFFECTIVE DATE:** The effective date of the interim rule amending 8 CFR Parts 103, 208, 210, 212, 235, 241, and 245a published at 65 FR 82254, December 28, 2000, is delayed until March 30, 2001.

**FOR FURTHER INFORMATION CONTACT:** Kevin Jones, Deputy Assistant Attorney General, Office of Policy Development, U.S. Department of Justice, Washington, DC 20530, (202) 514-4604.

**SUPPLEMENTARY INFORMATION:** To the extent that 5 U.S.C. 553 applies, the Department's implementation of this rule effective upon publication in the **Federal Register** is based upon the "good cause" exception. This temporary delay in effective date will give Department officials the opportunity for further review and consideration of the earlier rule, consistent with the Memorandum of January 20, 2001, published in the **Federal Register** on January 24, 2001.

Dated: January 23, 2001.

**Eric H. Holder, Jr.,**  
*Acting Attorney General.*

[FR Doc. 01-2411 Filed 1-25-01; 8:45 am]

**BILLING CODE** 4410-10-M

## DEPARTMENT OF JUSTICE

### Immigration and Naturalization Service

#### 8 CFR Part 244

[INS No. 1972-99; A.G. Order No. 2397-2001]

RIN 1115-AF01

#### Temporary Protected Status: Amendments to the Requirements for Employment Authorization Fee, and Other Technical Amendments; Delay of Effective Date

**AGENCY:** Immigration and Naturalization Service, Department of Justice.

**ACTION:** Final rule; delay of effective date.

**SUMMARY:** In accordance with the memorandum of January 20, 2001, from Andrew H. Card, Jr., the Assistant to the President and Chief of Staff, entitled "Regulatory Review Plan" (memorandum), this rule temporarily delays for 60 days the effective date of the final rule entitled "Temporary Protected Status: Amendments to the Requirements for Employment Authorization Fee, and Other Technical Amendments," published in the **Federal Register** on December 28, 2000, at 65 FR 82256. This temporary delay will allow the Department an opportunity for further consideration of this rule.

**EFFECTIVE DATE:** The effective date of the final rule published at 65 FR 82256, December 28, 2000, adopting an interim rule that amended 8 CFR Part 244, is delayed until March 30, 2001.

**FOR FURTHER INFORMATION CONTACT:** Kevin Jones, Deputy Assistant Attorney General, Office of Policy Development, U.S. Department of Justice, Washington, DC 20530, (202) 514-4604.

**SUPPLEMENTARY INFORMATION:** To the extent that 5 U.S.C. 553 applies, the Department's implementation of this rule effective upon publication in the **Federal Register** is based upon the "good cause" exception. This temporary delay in effective date will give Department officials the opportunity for further review and consideration of the earlier rule, consistent with the Memorandum of January 20, 2001, published in the **Federal Register** on January 24, 2001.

Dated: January 23, 2001.

Eric H. Holder, Jr.,

Acting Attorney General.

[FR Doc. 01-2412 Filed 1-25-01; 8:45 am]

BILLING CODE 4410-10-M

## 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; 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 delaying until January 26, 2003, the effective date of a final rule published in the **Federal Register** of January 26, 2000 (65 FR 4103), and originally scheduled to become effective on January 26, 2001. The final rule amends FDA's regulations to add certain labeling requirements for aluminum content in large volume parenterals (LVP's), small volume parenterals (SVP's), and pharmacy bulk packages (PBP's) used in total parenteral nutrition (TPN). The rule also specifies an upper limit of aluminum permitted in LVP's and requires applicants to submit to FDA validated assay methods for determining aluminum content in parenteral drug products. FDA is delaying the effective date of this rule to address concerns raised by affected parties about the possible inability to meet the requirements of the rule by the current effective date.

**DATES:** The effective date for § 201.323 (21 CFR 201.323), added at 65 FR 4103, January 26, 2000, is delayed until January 26, 2003. Submit written comments by April 26, 2001.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. 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:

##### I. Background

On January 26, 2000, the agency published final regulations at § 201.323 (21 CFR 201.323) enacting certain requirements regarding aluminum levels in SVP's, LVP's, and PBP's used in TPN. The new regulations added to part 201 (21 CFR part 201) at § 201.323(a) limit the aluminum content for all LVP's used in TPN therapy to 25 micrograms per liter ( $\mu\text{g/L}$ ). This requirement applies to all LVP's used in TPN therapy, including, but not limited to, parenteral amino acid solutions, highly concentrated dextrose solutions, parenteral lipid emulsions, saline and electrolyte solutions, and sterile water for injection.

New § 201.323(b) requires the package insert for all LVP's used in TPN therapy to state that the drug product contains no more than 25  $\mu\text{g/L}$  of aluminum. This statement must be included in the "Precautions" section of the labeling.

New § 201.323(c) requires the product's maximum level of aluminum at expiry to be stated on the immediate container label of SVP's and PBP's used in the preparation of TPN solutions. The statement on the immediate container label must read as follows: "Contains more than \_\_\_  $\mu\text{g/L}$  of aluminum." For those SVP's and PBP's that are lyophilized powders used in the preparation of TPN solutions, the maximum level of aluminum at expiry must be printed on the immediate container label as follows: "When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than \_\_\_  $\mu\text{g/L}$ ." The maximum level of aluminum must be stated as the highest of: (1) The highest level for the batches produced during the last 3 years; (2) the highest level for the latest five batches, or (3) the maximum historical level, but only until completion of production of the first five batches after the effective date of the rule. The labeling requirement applies to all SVP's and PBP's used in the preparation of TPN solutions, including, but not limited to: Parenteral electrolyte solutions, such as calcium chloride, calcium gluceptate, calcium gluconate, magnesium sulfate, potassium acetate, potassium chloride, potassium phosphate, sodium acetate, sodium lactate, and sodium phosphate; multiple electrolyte additive solutions; parenteral multivitamin solutions; single-entity parenteral vitamin solutions, such as vitamin K injection, folic acid, cyanocobalamin, and thiamine; and trace mineral solutions,

such as chromium, copper, iron, manganese, selenium, and zinc.

New § 201.323(d) requires the package insert for all LVP's, SVP's, and PBP's used in TPN to contain a warning statement. The warning statement must be included in the "Warnings" section of the labeling. The warning must contain the following language:

**WARNING:** This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5  $\mu\text{g/kg/day}$  accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

New § 201.323(e) requires applicants and manufacturers to use validated assay methods to determine the aluminum content in parenteral drug products used in TPN therapy. The assay methods must comply with current good manufacturing practice regulations under part 211 (21 CFR part 211) (see § 211.194(a)). Holders of approved applications for LVP's, SVP's, and PBP's used in TPN therapy are required to submit a supplement to FDA under 21 CFR 314.70(c); see also 21 U.S.C. 356a(b) describing the assay method used for determining the aluminum content. Applicants must submit the validation method used and the release data for several batches. In addition, manufacturers of parenteral drug products not subject to an approved application must make assay methodology available to FDA during inspections (see §§ 211.160 and 211.180(c)).

New § 201.323 applies to all human drug LVP's, SVP's, and PBP's used in TPN. Licensed biological products are not covered by this rule.

##### II. Description and Rationale for a Delay of the Effective Date of the Final Rule

Since publication of the final rule, the agency has received letters and has had other communications with industry and industry trade associations in which industry has stated the need for additional time to meet the requirements of the rule. In early June 2000, the agency met with representatives from industry and an industry association. The meeting participants discussed their concerns with the following issues: (1) Inadequate