Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 02N–0241]

Amendment of Regulations on Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend its regulations to change the labeling requirements concerning aluminum in small volume parenterals (SVPs) and pharmacy bulk packages (PBPs) used in total parenteral nutrition (TPN). FDA proposes that the immediate container labels of SVPs and PBPs containing 25 micrograms per liter (µg/L) or less of aluminum may state: ''Contains no more than 25 µg/L of aluminum'' instead of stating the exact amount of aluminum they contain. FDA is taking this action in response to a request from industry.

DATES: Submit written or electronic comments by October 28, 2002.

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 at 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:

I. Background

In the **Federal Register** of January 26, 2000 (65 FR 4103), FDA published a final rule amending its regulations in § 201.323 (21 CFR 201.323) to enact certain requirements regarding aluminum levels in large volume parenterals (LVPs), SVPs, and PBPs used in TPN. The 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 document extending the effective date to January 26, 2003.

Current § 201.323(c) requires the product's maximum level of aluminum at expiry to be stated on the immediate container label of SVPs and PBPs used in the preparation of TPN solutions. The statement on the immediate container label currently must read as follows: ''Contains no more than __ µg/L of aluminum.'' For those SVPs and PBPs 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__ µg/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 SVPs and PBPs 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.

On June 1, 2000, the agency met with the Health Industry Manufacturers Association (HIMA, now called AdvaMed). HIMA requested that FDA permit SVPs and PBPs containing less than 25 µg/L to be labeled ''Contains no more than 25 µg/L of aluminum'' rather than requiring such products to be labeled with the exact amount of aluminum as required by § 201.323© (Ref. 1). In support of this proposal, participants made the following points: (1) 25 µg/L of aluminum is a safe level of aluminum for SVPs because the agency has already determined that amount of aluminum to be safe for LVPs; (2) it would make no clinical difference to know the precise amount less than 25 µg/L that an SVP contained; and (3) permitting the label to state ''Contains no more than 25 µg/L'' rather than the exact amount of aluminum would avoid the need for labels to be reprinted in the future with the exact amounts of aluminum at expiry.

One comment to the proposed rule had asked FDA to set a minimum level below which the amount of aluminum in SVPs and PBPs would not have to be declared. In the final rule, the agency responded that it was important for health care practitioners to know as much as possible about aluminum levels so that practitioners could calculate the total aluminum exposure from multiple sources and would be able to prepare low-aluminum parenteral solutions for patients in high risk groups.

HIMA's request has caused the agency to reconsider its position on whether it is appropriate to set a minimum level of aluminum in SVPs and PBPs that would not have to be declared. While the comment to the proposed rule did not suggest a particular minimum level, HIMA has now proposed a specific level, 25 µg/L of aluminum. FDA has already determined that 25 µg/L is a safe upper limit for manufacturers to include in LVPs and believes that it is similarly appropriate for SVPs and PBPs.

An important factor for the agency when reconsidering its position was that if an SVP or PBP that contains 25 µg/L of aluminum is added to a TPN solution that contains 25 µg/L of aluminum, the concentration of aluminum in the mixture will still be 25 µg/L. Consistent with its approach to LVPs (to which SVPs and PBPs are added) that are permitted to contain 25 µg/L, FDA believes health care practitioners will be provided with sufficient information on the aluminum

content of SVPs and PBPs if the label states that the product contains no more than 25 µg/L of aluminum. For this reason, the agency does not believe it is necessary for SVPs and PBPs that contain 25 µg/L or less of aluminum to be labeled with the precise concentration of aluminum. Therefore, the agency proposes to modify the required labeling as requested.

II. Description of the Proposed Rule

The proposed rule would add new § 201.323(d) to permit SVPs and PBPs that contain 25 µg/L or less of aluminum to be labeled ''Contains no more than 25 µg/L'' rather than requiring such products to state the exact amount of aluminum.

III. Proposed Implementation Plan

FDA proposes that the effective date of any final rule that may issue based on this proposed rule coincide with the effective date of the aluminum final rule that published in the **Federal Register** of January 26, 2000 (66 FR 7864). As discussed in section I of this document, the agency has extended this effective date to January 26, 2003. The agency intends to further extend this effective date as necessary to provide time for this proposed rule to be finalized.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order.

The proposed rule would relax the requirements of the final rule for labeling aluminum content in SVPs and PBPs used in TPN. Specifically, manufacturers would be allowed to use a standard statement of quantity of aluminum content in place of the exact amount for affected products that contain no more than 25 µg/L of aluminum. Thus, the proposed rule is not a significant action as defined by the Executive order.

In the Analysis of Impacts section of the final rule published on January 26, 2000, the agency relied on the Eastern Research Group (ERG) report entitled ''Addendum to Compliance Cost Analysis for a Regulation for Parenteral Drug Products Containing Aluminum.'' In that report, ERG calculated the total relabeling costs for SVPs and PBPs to be about $523,000, or about $3,500 per product (equivalent to annualized costs totaling $128,000, or about $850 per product, discounted at 7 percent over 5 years). To the extent that manufacturers of SVPs and PBPs containing no more than 25 µg/L of aluminum use the added flexibility in labeling this proposal provides, the compliance burden cited above could be reduced.

Because this proposed rule could slightly decrease current compliance costs for the affected industry without imposing any additional costs, FDA has determined that the proposed rule is not a significant action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant impact on a substantial number of small entities. FDA made the determination for the final rule published January 26, 2000, that very few small firms, if any, would be significantly impacted. Thus, the agency certified that the final rule would not have a significant impact on a substantial number of small entities. This proposed rule could slightly lessen the economic impact of the final rule published on January 26, 2000. Accordingly, FDA certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (as amended).

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted annually for inflation).

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule because the rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Request for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IX. Reference

The following reference has been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Minutes of June 1, 2000, HIMA meeting, slide 10.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

PART 201—LABELING

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

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 is amended by revising the first two sentences of the introductory text of paragraph (c); by redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively; and by adding new paragraph (d) to read as follows:

§ 201.323 Aluminum in large and small volume parenterals used in total parenteral nutrition.

* * * * *

(c) The maximum level of aluminum present at expiry must be stated on the immediate container label of all small volume parenteral (SVP) drug products and pharmacy bulk packages (PBPs) used in the preparation of TPN solutions. Except as provided in paragraph (d) of this section, the aluminum content must be stated as follows: ''Contains no more than __ µg/L of aluminum.'' * * *

(d) If the maximum level of aluminum is 25 µg/L or less, instead of stating the exact amount of aluminum as required in paragraph (c) of this section, the immediate container label may state: ''Contains no more than 25 µg/L of aluminum.'' If the SVP or PBP is a lyophilized powder, the immediate container label may state: ''When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than 25 µg/L.''

* * * * *

Dated: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–20300 Filed 8–9–02; 8:45 am]

BILLING CODE 4160–01–S

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1626

RIN 3046–AA54

Procedures—Age Discrimination in Employment Act

AGENCY: Equal Employment Opportunity Commission (EEOC).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission proposes to amend its regulations on the processing of age discrimination charges to provide that it will issue a notice, when it has dismissed or otherwise terminated the processing of an age discrimination charge, that the right to file a lawsuit on the charge under the ADEA will expire in 90 days. These amendments also delete references to the previously applicable two-or three-year limitations period for filing a civil action. Finally, EEOC is deleting its list of ADEA referral states because the list is obsolete and unnecessary. These changes will conform the Commission's regulations to the procedures adopted by the Commission to implement section 115 of the Civil Rights Act of 1991.

DATES: Comments must be received by October 11, 2002.

ADDRESSES: Written comments should be submitted to Frances M. Hart, Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 1801 L Street, NW., Washington, DC 20507. As a convenience to commenters, the Executive Secretariat will accept comments of six pages or less transmitted by facsimile (''FAX'') machine. The telephone number of the FAX receiver is (202) 663–4114. This is not a toll free number. The six-page limitation is necessary to assure access to the equipment. Receipt of FAX transmissions will not be acknowledged although a sender may request confirmation by calling the Executive Secretariat at (202) 663–4078 (voice) or (202) 663–4077 (TTY). These are not toll free numbers. Copies of comments submitted by the public will be available for review at the Commission's library, Room 6502, 1801 L Street NW., Washington, DC, between the hours of 9:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Thomas J. Schlageter, Assistant Legal Counsel at (202) 663–4669 (voice) or (202) 663–7026 (TTY). This proposed rule is also available in the following formats: large print, braille, audiotape and electronic file on computer disk. Requests for this proposed rule in an alternative format should be made to EEOC's Publication Center at 1–800–669–3362.

SUPPLEMENTARY INFORMATION: This notice of proposed rulemaking contains EEOC's proposed revisions to part 1626 of its regulations. These changes are proposed in order to conform the Commission's regulations to the procedures it adopted for the processing of charges under the Age Discrimination in Employment Act (ADEA) following passage of section 115 of the Civil Rights Act of 1991. Section 7(e) of the ADEA no longer incorporates the two-or three-year statute of limitations on civil actions in section 6 of the Portal to Portal Act nor does it incorporate the exemption to the Portal to Portal Act's limitations period during EEOC's conciliation efforts. Instead, upon dismissal or termination of proceedings, the Commission must notify the aggrieved person that his or her right to file a civil action under the ADEA will expire 90 days after receipt of the notice. This notice is denominated a ''Notice of Dismissal or Termination.'' The Commission is also taking this opportunity to delete an obsolete and unnecessary list of State Fair Employment Practices Agencies to which EEOC will send copies of ADEA charges.

The current § 1626.7(a) provides that charges will not be rejected as untimely provided that they are not barred by the statute of limitations contained in section 6 of the Portal to Portal Act. This provision recognized the Commission's authority to file suit within the Portal to Portal Act's limitation period even if the charging party did not have a private right of action because the charge was filed more than 180 days (or 300 days in a referral jurisdictions) after the discriminatory event took place. Following passage of the Civil Rights Act of 1991, the statute of limitations contained in the Portal to Portal Act is no longer applicable to ADEA lawsuits filed by either the charging party or the Commission. We therefore propose to delete the current § 1626.7(a). The Commission will dismiss ADEA charges filed more than 180 days (or 300 days in a referral jurisdiction) after the discriminatory act, absent waiver, estoppel or equitable tolling.

The current § 1626.9(b) and (c) contain a list of states to which the Commission refers charges under section 14(b) of the ADEA. These lists were created when there were relatively few such agencies. Since almost all states now have laws prohibiting age discrimination, the lists are being deleted as obsolete and unnecessary. The regulation continues to provide that the Commission will refer age charges to appropriate state agencies.

Section 7(d) of the ADEA requires that, upon receipt of a charge, the Commission shall promptly attempt to eliminate any alleged unlawful practice by informal methods of conciliation, conference and persuasion. Under current § 1626.12, EEOC issues a notice if this attempt at conciliation fails. To eliminate any possible confusion between this failure of conciliation notice and the new Notice of Dismissal or Termination (NDT), we propose to add a sentence to § 1626.12 stating that notice under this section is not a Notice of Dismissal or Termination under § 1626.20.

The second sentence and last two sentences of the current § 1626.15(b) concern the tolling of the ADEA's statute of limitations during EEOC