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October 28, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane (HFA-305)
Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0241: Proposed Rule: Amendment of Regulations on Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition Published August 12, 2002 (and amended August 21, 2002)

Dear Sir or Madam:

AdvaMed, the Advanced Medical Technology Association (formerly known as HIMA), represents more than 1100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the \$68 billion health care technology products consumed annually in the United States, and nearly 50 percent of the \$159 billion of those purchased around the world annually. AdvaMed is pleased to comment on the August 12, 2002 proposed rule: "Amendment of Regulations on Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition." We recognize that this proposal is an amendment to the existing rule published in the *Federal Register* on January 26, 2000 (65 FR 4103). Our comments are as follows:

1. AdvaMed concurs with the proposal that the immediate container labels of Small Volume Parenterals (SVPs) and (Pharmaceutical Bulk Parenterals) PBPs containing 25 mcg/L or less of aluminum may state: "Contains no more than 25 mcg/L of aluminum" instead of stating the exact amount of aluminum they contain.
2. With regard to extending the effective date under the Proposed Implementation Plan, AdvaMed supports an extension and believes it would provide the necessary time for the proposed amendment to be finalized. The agency should clarify that the proposed extension will apply to all products falling within the scope of the January 26, 2000 rule, including SVPs, PBPs, and Large Volume Parenterals (LVPs).
3. AdvaMed believes that a minimum 18-month extension to the January 26, 2003 implementation date would allow industry sufficient and reasonable time to meet the requirements set forth in the final rule dated January 26, 2000.

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Significant progress has been achieved to date to comply with the January 26, 2000 final rule as summarized in the bulleted items below. Nonetheless, this progress has entailed a number of analytical, technical and logistical challenges and difficulties that would benefit from additional time to resolve specific issues.

- The purchase and installation of analytical equipment in remaining manufacturing facilities;
- Aluminum test method development, validation, and transfer to manufacturing test labs;
- Establishment of new requirements for raw material vendors;
- Historical sample testing; and
- Completion of a major portion of the regulatory labeling submissions (“changes being effected,” or CBEs) for affected products.
- The rule’s labeling requirements will be implemented in ongoing manufacturing for a number of products by January 26, 2003.

There are also a certain number of LVP products that will necessitate additional development work to comply with the new aluminum regulation. As a result, manufacturers must file prior approval supplements with the agency. This obligation was not contemplated by the January 26, 2000 rule, but was discussed in a June 1, 2000 meeting AdvaMed and FDA representatives. Once FDA approval is obtained on these products, approximately six months will be required to fully implement the labeling and manufacturing changes and prepare the products for distribution. An extension of the implementation date would provide additional time to complete these submissions and pursue full compliance of the final rule. AdvaMed believes that an extension would be reasonable and would enable these medically necessary drug products to remain on the market and be available for use as deemed appropriate by clinicians. The extension would be particularly important for those LVP products that do not meet the 25mcg/L limit.

Thank you for consideration of our concerns. AdvaMed appreciates the agency’s willingness to work cooperatively with industry in resolving all issues arise throughout this rule’s development and implementation process. We would be happy to meet with you to discuss any questions or concerns you may have with our comments or any remaining implementation challenges. Feel free to contact me at 847-968-5512 or tcammack@advamed.org at your convenience.

Sincerely,



Tess Cammack
Associate Vice President
Technology & Regulatory Affairs