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AdvaMed

Advanced Medical Technology Association

November 5, 2002

Margaret M. Dotzel
Associate Commissioner for Policy
Food and Drug Administration (HFA-305)
5360 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 02N-0445

Dear Ms. Dotzel: *Rygg*

AdvaMed would like to express its concern regarding the scheduling of the Public Hearing on Combination Products. In a *Federal Register* notice dated October 28, 2002, FDA announced a public hearing, scheduled for November 25, to discuss the assignment, premarket review, and postmarket regulation of combination products. In addition, FDA presented several issues for discussion including 7 questions for which FDA requests answers. These issues related to combination products are important issues for both FDA and the industry; therefore, adequate participation in the public hearing and sufficient time to develop thoughtful responses to these questions are both needed.

We have two concerns regarding the date of this hearing. Now that Congress passed legislation requiring the agency to establish an Office of Combination Products with very specific roles and responsibilities, it is critical that the issues under discussion at this meeting be addressed in the context of the new legislation. In order to develop comments that take into consideration all facets of the issues, interested stakeholders require sufficient time to prepare both their comments. Delaying the meeting for another 15 to 45 days will provide the additional time.

Secondly, in our experience, holding a meeting during the week of a national holiday, particularly one that traditionally is associated with heavy travel, makes it extremely difficult to get the full range of participants needed to have a complete discussion of the issues. In fact, many AdvaMed member companies have already expressed concern regarding how difficult it will be to arrange business travel during this time. Therefore, we urge FDA to reschedule the meeting to a time that is more conducive to having the full participation of interested persons.

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Again, we recommend that FDA consider changing the date of this meeting to ensure adequate participation by its stakeholders and to allow interested persons sufficient time to develop comments. Thank you for your consideration of this request.

Sincerely,

A handwritten signature in black ink, appearing to read "Janet Trunzo". The signature is written in a cursive, flowing style with a large initial "J".

Janet Trunzo
Vice President
Technology and Regulatory Affairs