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April 4, 2006

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

Re: Docket No. 2006D-0017--Notice: Human Subject Protection-Information for Institutional Review Boards, Clinical Investigators, and Sponsors; Rescission, Reissuance, and Development of Food and Drug Administration Guidance Documents; Availability

Dear Madam/Sir:

AdvaMed supports FDA's effort to update its clinical trial information sheets and in response to FDA's Information Sheet Guidance Initiative, is pleased to provide specific comments on three of the updated Information Sheet Guidances: Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators; Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies; and Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors: Frequently Asked Questions About Medical Devices.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the \$80 billion in health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. More than 70 percent of our members have less than \$30 million in domestic sales annually.

AdvaMed has specific comments on the information sheet guidance documents below.

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Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators

Section III (Page 2) – The sentence explaining that clinical investigators are required to retain records for a period of two years needs to be expanded to include device-specific regulations per 21 CFR 812.140(d) which requires sponsors and investigators to retain records for a period of two years after the *latter* of either the date on which the investigation is terminated or completed *or* the date the records are no longer required for purposes of *supporting a premarket approval application*. A specific example might be helpful. The current text applies only to drug studies and is misleading guidance for device studies. Record retention for devices may be much longer than two years.

Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies

Section IV. A. For Nonsignificant Risk Devices (Page 4) – A statement should be included that sponsors need to obtain agreement from investigators that they will comply with all applicable Nonsignificant Risk regulations (i.e., 21 CFR Parts 50 and 56 and 21 CFR 812.2(b)), including requirements that address labeling, IRB approval, informed consent, monitoring, records, reports and prohibition against promotion. Many investigators are unaware that there are regulations governing NSR studies and are unaware of the requirements of those regulations.

Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors: Frequently Asked Questions About Medical Devices

General Comment: AdvaMed recommends that FDA include an additional question in the FAQ that validates that recruiting referral physicians to refer patients to investigators is acceptable practice and considered part of the “Notice of Availability.” This is an issue that occurs with some frequency and clarification of FDA’s perspective on this practice would be valuable.

Conclusion

In conclusion, thank you for the opportunity to review and comment on FDA’s revised clinical trial information sheets. If you have any questions, please feel free to contact me.

Sincerely,



Tara Federici
Associate Vice President
Technology and Regulatory Affairs