



April 19, 2005

Ms. Nancy Stanisic
Division of Dockets Management (HFA-305)
Food and Drug Administration
5600 Fishers Lane
Room 1061
Rockville, Maryland 20857

Re: Docket # 2005N – 0038

Dear Ms. Stanisic:

This comment is filed on behalf of the Cook Group, Inc. (“Cook”), a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gynecology, gastroenterology, wound care, emergency medicine, and surgery. Cook pioneered the development of products used in the Seldinger technique of angiography, and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention using minimally invasive techniques, as well as by providing innovative products for surgical applications. Cook sells over 15,000 different products which can be purchased in over 60,000 combinations.

Cook would like to add its voice to the growing consensus within the IRB community that having IRBs review all adverse event reports is overly burdensome, and not conducive to focusing efforts on the broad objectives of protecting patients’ rights and welfare. Currently, most adverse events reported to IRBs are anticipated, and causality and outcome attributes are often unclear due to the many confounding variables of the target patient population. Therefore, Cook believes that the types of events warranting individual review within a designated time frame (such as within 10 days) should be limited to those that are unanticipated and serious (similar to the “suspected unexpected serious adverse event reactions” or SUSARs described in the European Clinical Trials Directive). Other adverse events should only be required to be reported by the sponsor and investigator annually (or at minimum pre-determined intervals). With the sponsor report including a summary of adverse events at all sites participating, the IRB could determine whether the incidences at sites under their jurisdiction differ from incidences across all sites. Accordingly, there is no need to have different reporting criteria for single- and multi-site studies.

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In addition to streamlining the volume of adverse event reports, steps must be taken to better categorize data being reported to IRBs. Useful information includes event causality (probability of being associated with the study product or study protocol), type of patient intervention required as a result of the event, patient outcome at time of report, and number of previous study patients experiencing the same or possibly related event.

In closing, Cook notes that adverse event reporting requirements should be streamlined for both drug and device studies, but may need to be more frequent for drug studies due to larger patient populations involved in pharmaceutical clinical trials.

Cook appreciates this opportunity to provide comment on the issue of adverse event reporting to institutional review boards, and looks forward to working with the agency to ensure adequate reporting of meaningful adverse events.

Sincerely,

Merry Lee Bain
Vice-President, Regulatory Affairs
Cook Biotech

