MEMORANDUM

Via E-Mail

DATE: November 4, 2014

TO: The Ethylene Oxide Sterilization Association, Inc.

FROM: B&C® Consortia Management, L.L.C.

RE: Comments to the Chemical Assessment Advisory Committee (CAAC) for the Integrated Risk Information System (IRIS) Evaluation of the Inhalation Carcinogenicity of the Ethylene Oxide

As you know, the U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) has developed a revised draft of the "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide," which was released in August 2014. The Science Advisory Board (SAB) CAAC will review the revised draft from **November 18-20, 2014**, during a public meeting. The results of this peer review and the final IRIS assessment will have significant impacts on the ethylene oxide (EO) sterilization industry. Details on the peer review and all available documentation can be found online at http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Eto%20Inhalation%20Carcinogenicity?OpenDocument.

The current assessment includes an overall cancer risk estimate of $1.8x10^{-3}$ per microgram per cubic meter of air (per $\mu g/m^3$), or $3.3x10^{-3}$ per part per billion (ppb). This is significantly stricter than the value of $1x10^{-4}$ per $\mu g/m^3$, calculated by EPA previously. These limits would result in severe adverse public health consequences. Such lowered limits will unnecessarily expose patients and healthcare workers to the risks of inadequately sterilized medical devices and healthcare products. It is critical that we reinforce to the CAAC the benefits of EO sterilization and the significant adverse impacts to public health that will result from the IRIS assessment if it is made final in its current form.

Comment Submission

The Ethylene Oxide Sterilization Association, Inc. (EOSA) is working to prepare detailed written comments to the SAB CAAC for consideration during the peer review. These comments will be circulated on or before **November 5, 2014**. We strongly encourage all EOSA members to submit individually comments to the CAAC that stress the benefits of EO

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sterilization and highlight the consequences of the assessment. Suggested talking points are provided later in this memorandum.

Stakeholders should submit written comments to Mr. Aaron Yeow, Designated Federal Officer (DFO), via e-mail. The e-mail address for Mr. Yeow is yeow.aaron@epa.gov. Written comments should be submitted no later than **November 11, 2014**. We note that stakeholders should submit unsigned versions of comments as the SAB Staff Office does not publish documents with signatures to its website. Stakeholders may also present oral comments during the peer review meeting. Oral comments will be limited to five minutes in length.

Public Meeting of the SAB CAAC

The public meeting of the SAB CAAC for the EO peer review is scheduled from **November 18-20, 2014**, at the Hyatt Regency Crystal City Hotel, 2799 Jefferson Davis Highway, Arlington, VA 22202. An agenda is not yet available, but is expected to be released within the next few days.

Suggested Comment Points

As EOSA members work to prepare comments, we suggest members incorporate the following talking points, in addition to their own specific input:

- Address the critical role EO sterilization plays in protecting the public health and the safe delivery of sterile devices and medical care;
- The current draft IRIS assessment will have significant adverse health impacts on those who use EO to sterilize healthcare products, including increased risk of infection through inadequate sterilization;
- The IRIS assessment, as currently written, could force users to switch to less effective, impractical alternatives with significant adverse public health impacts;
- EO is the most widely used sterilization method for medical devices;
- Numerous medical, hospital, and laboratory processes rely on EO to sterilize devices and equipment to protect patients from the real risks of infectious disease;
- Many critical healthcare products can only be sterilized by EO, in some cases due to the heat or radiation sensitive nature of the components or the internal design of the device;

- EO sterilization is critical in the safe delivery of sterile devices and medical care;
- EO sterilization has led to the advancement and evolution of numerous delicate and complex medical devices and healthcare products, many of which can only be sterilized by EO; and
- A change in sterilization technology could introduce risks of medical device integrity and biocompatibility that may exceed the currently known risks of EO sterilization.

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We hope this information is helpful. As always, please call if you have any questions.