February 26, 2015

U.S. Federal Food and Drug Administration
Division of Dockets Management (HFA–305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: International Drug Scheduling; Convention on Psychotropic Substances Proposed Listing of BDO and GBL as Psychotropic Substances (Docket No. FDA–2015–N–0045)

IPC is very supportive of the concept and purpose of the Convention on Psychotropic Substances and appreciate the opportunity to comment on the proposed listing of 1,4-butanediol (BDO; CAS No. 110-63-4) and gamma-butyrolactone (GBL; CAS No. 96-48-0) as psychotropic substances. However, our member companies are deeply concerned with the proposed listings of these two particular substances as they are widely used within the electronics industry and cannot be easily replaced. As such, IPC urges the U.S. Government to recommend the Members of the United Nations Commission on Narcotic Drugs to oppose listing BDO and GBL under the 1971 Convention on Psychotropic Substances during the upcoming fifty-eighth session of the Commission on Narcotic Drugs, 9-17 March 2015 meeting. While we recognize concerns with potential misuse of GBL and BDO, the 1971 Convention was not designed for the control of substances with such wide and significant industrial uses. The Critical Review Reports for GBL and BDO (June 2014), submitted to the World Health Organization Expert Committee on Drug Dependence concluded that controlling GBO and BDL as a psychotropic substance would not likely result in benefits sufficient to justify the burdens such controls would impose.

IPC, a global trade association, represents 3,400 member facilities in the global electronic interconnection industry, including design, printed board manufacturing and electronics assembly. Printed boards and electronic assemblies are used in a variety of electronic devices that include computers, cell phones, pacemakers, and sophisticated defense systems.

Classifying BDO and GBL as psychotropic substances under the convention would essentially ban the legitimate commercial uses of these compounds. These substances are used in a variety of electronic manufacturing applications including, but not limited to:

- GBL is a critical material in semiconductor manufacturing used as a solvent in lithography (printing) process formulations.
- GBL is used as an electrolyte in several types of rechargeable batteries.
- GBL is used in the manufacture of polyimide and potentially additional other base materials for printed boards used in high temperature applications.
- GBL and BDO are also essential precursors in the production of N-Methylpyrrolidone (NMP), a solvent vital in production of semiconductors, batteries and electronic motors.
- BDO is used to manufacture poly-butyl-terephthalate (PBT) plastic resin, which is extensively used in the connector and automotive industry.
• GBL and BDO are important components for the manufacture of polyurethanes used in coatings, adhesives and inks.
• GBL is used in electrolytic capacitors and integrated components (ICs).

Currently, the marketplace is not readily equipped to replace the use of these substances in the electronics industry. The proposed restriction of the use of these substances would be challenging to the market place to find viable alternatives. The decision to prohibit a substance should not be undertaken lightly. Electronics manufacturers use specific materials because of their unique performance, safety and/or energy efficiency characteristics. Commitment of scarce societal resources must be guided by the best available science. Elimination of specific substances requires a great deal of research and development of suitable alternative substances, requiring substantial investment of time and resources by electronics manufacturers, if indeed such alternative substance can be identified. Should a technically feasible alternative be identified, manufacturers must undergo a series of qualification testing and notification to customers that takes years to complete. Before a ban of BDO or GBL could practically be implemented, viable alternatives must be identified in order to ensure the utmost overall benefit to human health and the environment.

For the reasons stated above, IPC requests that global governments oppose efforts to add BDO and GBL to the 1971 Convention. We appreciate your consideration and support in this matter.

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