

February 26, 2015

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

Re: Docket ID No. FDA-2015-N-0045-0001, International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; AH-7921; Gamma- Butyrolactone; 1,4-Butanediol; Ketamine; 9 Additional Substances; Request for Comments

The National Association of Chemical Distributors (NACD) submits the following comments in response to the January 27, 2015, *Federal Register* request for information regarding **Docket Number FDA-2015-N-0045-0001**.

About NACD

The National Association of Chemical Distributors is an international association of more than 440 chemical distributors and supply-chain partners. NACD's membership comprises businesses representing in total more than 85% of the chemical distribution capacity in the nation and generating 93% of the industry's gross revenue. NACD members, operating in all 50 states through nearly 1,800 facilities, are responsible for more than 155,000 direct and indirect jobs. NACD members are predominantly small regional businesses, many of which are multigenerational and family owned. The typical chemical distributor has 26 employees and operates under an extremely low margin.

Chemical distributors play a unique and integral role in the supply chain. Manufacturers increasingly rely on chemical distributors to market and sell their products in a variety of packaging sizes to an incredibly varied customer base. Every seven seconds, an NACD member company moves chemical products to and from their facility. This constant movement of those products results in chemicals being frequently added to and removed from inventory. Unlike the regular changes in inventory, NACD members' safety processes remain the same.

NACD strongly urges the U.S. government to reject the World Health Organization's (WHO) recommendations to list 1,4-butanediol (BDO) and gamma-butyrolactone (GBL) under Schedule I of the 1971 United Nations Convention on Psychotropic Substances (1971 Convention).

The U.S. government recently communicated to WHO the opinion that neither BDO nor GBL should be considered for control under the 1971 Convention.

In its response to a preparatory questionnaire for the WHO's Thirty-sixth Expert Committee Meeting on Drug Dependence, the U.S. stated for BDO:

1,4-butanediol should not be considered for control under the 1971 Convention. . . 1,4-butanediol is a widely used industrial chemical where

millions of pounds a year are utilized. The U.S. has specific controls if the material is intended for human consumption. Controls of the industrial material as a psychotropic substance would be largely ineffective due to the large volumes available and perceived to be burdensome to legitimate industry.

For GBL, the U.S. government stated:

GBL should not [emphasis in original] be considered for control under the 1971 Convention. . . GBL is a widely used industrial chemical where thousands of pounds of metric tons a year are utilized. The U.S. has specific controls if the material is intended for human consumption, and as a listed chemical. Controls of the industrial material as a psychotropic substance would be largely ineffective due to the large volumes available and perceived to be burdensome to legitimate industry.¹

BDO and GBL are high-volume industrial chemicals with multiple uses that touch nearly every part of the economy. According to the U.S. Environmental Protection Agency, over 583 million pounds of BDO and 249 million pounds of GBL were either manufactured in or imported into the United States in 2012, the most recent year for which such information is available.² BDO and GBL are important industrial chemicals used in a variety of applications, including (but not limited to): adhesive, paint, and coating formulation; cleaning circuit boards in the electronics and high-tech industries; manufacturing high performance, energy-efficient plastics for automotive, electronics, construction, and consumer applications; manufacture of spandex fibers for use in textiles; and as intermediates in the manufacture of pharmaceuticals, crop protection products, and other industrial chemicals.

The potential benefits of controlling BDO and GBL under the 1971 Convention would not justify the enormous costs and burdens such controls would impose. If BDO and GBL are placed under Schedule 1 of the Convention, all firms that handle BDO or GBL would have to be registered with the Drug Enforcement Administration (DEA) and have physical(vault), alarm, and personnel security measures in place. In addition, initial applications for bulk manufacturers could take as long as a year to process. The total amount that could be manufactured annually would be determined by a quota set by DEA based on data submitted by bulk manufacturers. The amount each bulk manufacturer could produce would be subject to a manufacturing quota, and the amount any other manufacturer could receive from a bulk manufacturer would be subject to a procurement quota. The amount manufactured and individual distributions would be reported to DEA. All firms handling the materials would be subject to inventory, recordkeeping, and reporting requirements. BDO and GBL could only be imported or exported by properly registered firms, and a DEA issued permit would be required for each import or export. Most significant is the fact that the control requirements for

¹ USG Response to WHO Questionnaire for Review of Dependence-Producing Psychoactive Substances for the Thirty-sixth Expert Committee Meeting on Drug Dependence. Available at Docket No. FDA-2013-N-1676. ID: FDA-2013-N-1676-0005. Posted by U.S. Food & Drug Admin. on Sept. 2, 2014.

² U.S. Envntl. Prot. Agcy. Chemical Data Access Tool. http://java.epa.gov/oppt_chemical_search/.

substances in Schedule I under the treaty are extremely restrictive and do not provide for industrial use.

Members of NACD generate millions of dollars of gross profit by the safe and legal sale of these materials into legitimate industrial commerce, and the chemical distribution industry would be negatively impacted by having BDO and GBL listed on Schedule 1. The listing of these substances would require extra time and resources for industry members to track and manage all the DEA requirements, which would be measured in additional full time equivalents and expenses across the industry. The DEA already tracks suspicious activity for individuals trying to buy or purchase known drug pre-cursors.³ NACD strongly believes regulatory and law enforcement of drugs at the consumer level would have a greater impact on tracking and managing illicit use of these substances than the creation of burdensome and unnecessary regulatory requirements for manufacturers and distributors.

NACD members are committed to ensuring DEA-regulated chemicals are not being used for illicit purposes. All NACD members must practice Responsible Distribution® --NACD's mandatory third-party verified program that assures members uphold the highest standards in environment, health, safety, and security. Product stewardship is one of the 13 Responsible Distribution Codes of Management Practice. This requires NACD companies to have a process in place that qualifies customers as prescribed by governmental regulations. These provisions mirror DEA requirements and call for NACD members to follow up on any "red flags" in chemical product transactions. NACD is willing to work with FDA and DEA stakeholders on a voluntary basis for tracking and monitoring on an individual or case-by-case basis, when warranted.

Conclusion

NACD appreciates the opportunity to submit comments on these important issues. NACD and its member companies share the concern regarding the misuse of GBL and BDO and are committed to prevent such misuse while recognizing the wide industrial application of these chemicals. We believe the existing regulatory and voluntary controls described above have been effective at controlling the supply chain and end-users of BDO and GBL; therefore, we **strongly urge the U.S. delegation to the March U.N. Commission on Narcotic Drugs meeting to reject the WHO's recommendations to list BDO and GBL under the 1971 Convention.**

If you have questions or require additional information, please do not hesitate to contact me.

Sincerely,



Jennifer C. Gibson
Vice President, Regulatory Affairs

³ 21 U.S.C. § 802(32)(A) and 21 U.S.C. § 841(a)