June 12, 2017

Mr. Edward Gresser
Chair of the Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Comments on Negotiating Objectives Regarding Modernization of the North American Free Trade Agreement with Canada and Mexico, Docket Number USTR-2017-0006

Dear Mr. Gresser:

Consumer Health Products Canada ("CHP Canada"), the Consumer Healthcare Products Association ("CHPA"), and La Asociación de Fabricantes de Medicamentos de Libre Acceso, A.C. ("AFAMELA"), and their members welcome this opportunity to provide comments on negotiating objectives regarding modernization of the North American Free Trade Agreement ("NAFTA"), pursuant to the request for comments published in the Federal Register on May 23, 2017 (82 Fed. Reg. 23699).

CHP Canada, CHPA, and AFAMELA are the leading health care products associations of Canada, the United States, and Mexico, respectively, representing manufacturers of over-the-counter medicines such as pain relievers and allergy medications, and natural health products such as vitamins and supplements. The three associations are taking the unusual step of jointly requesting that the United States Trade Representative ("USTR") include in its negotiating objectives for the modernization of NAFTA the incorporation of data protection for new claims on existing healthcare products where new clinical data is essential to obtain approval to "switch" from prescription products to non-prescription status ("Rx-to-OTC").

Specifically, we believe the United States should include as a negotiating objective securing a three-year period of data protection period for Rx-to-OTC switches, a period that reflects the standard of protection found in United States law, namely the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). We make this joint submission because we believe the benefits of this policy change are so compelling to all stakeholders in all three countries.

Current Canadian law establishes a period of eight continuous years of data protection for new chemical entities, but data to support new uses for existing drugs, such as that required for Rx-to-OTC switches, does not benefit from any form of protection. Furthermore, Canada's current system for Rx-to-OTC switches is ingredient based, rather than product based. Therefore, the act of switching an ingredient is considered a technical regulation under the World Trade Organization's ("WTO") Technical Barriers to Trade ("TBT") Agreement, triggering a mandatory notification and comment period. This additional process, which is not required

where switches are product based as in the United States, delays the finalization of the switch for at least six months.

The combination of Canada's lack of data protection for Rx-to-OTC switches with the additional delays resulting from an ingredient-based system has a stifling effect on innovation and on Canadian consumer's access to OTC medicines. This is because healthcare companies are not incentivized to invest in the additional research necessary to achieve Rx-to-OTC switches, as the lengthy approval process means that competitors often reach the market at essentially the same time as the innovator. Ensuring the same standard of protection for Rx-to-OTC switches as provided in the United States will encourage innovators to actively pursue Rx-to-OTC switches in Canada, resulting in significant benefits to all stakeholders, including governments, pharmaceutical companies, and consumers.

Attached to this letter, we provide a study conducted by the Conference Board of Canada regarding the impact of Rx-to-OTC switches. As indicated in the study, the economic value of switching just three categories of products would result in $1 billion in savings. These savings come in the form of decreased costs for payers of prescription medicine, such as provincial governments, employers, private drug plan sponsors, and individuals who currently do not have access to prescription drug coverage. Pharmaceutical companies also stand to gain as they are incentivized to pursue Rx-to-OTC switches, which will give these companies access to a broader OTC market. In fact, an analysis of the effect of switching nine drug categories found that use of the drug increased by 30 percent following the first switch. Most importantly, Rx-to-OTC switches act as an important policy tool for increasing access to medicines. OTC medicines are easier, faster, and more convenient to obtain, allowing consumers to take greater control of their health care decisions. Greater access to OTC medicines also reduces health care costs generally by allowing consumers to self-medicate rather than visit the doctor for routine issues.

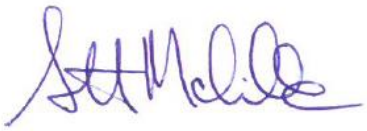
In short, providing data protection for Rx-to-OTC switches in Canada will lower the cost of medicines, lower health care costs more generally, increase access to medicines, increase market access for health care companies, and bring Canadian intellectual property law up to the standard in United States law. This presents one of those truly rare issues where all stakeholders unambiguously stand to benefit from a policy change.

We firmly believe that the incorporation of a 3-year data protection period for clinical data essential to obtain approval for Rx-to-OTC switches in Canada falls squarely within the goals of modernizing NAFTA, and will better align Canada's data protection provisions with those of the United States. We therefore respectfully request that USTR include this important

issue in its negotiating priorities.

Respectfully submitted,

Karen Proud
President
Consumer Health Products Canada



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