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December 4, 2003

STATE OF VERMONT

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AGENCY OF ADMINISTRATION

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act and any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 C.F.R. § 5.10 to request the Commissioner of Food and Drugs to waive or revoke the current FDA interpretation of statutes and regulations that prohibits the Vermont State Employee Medical Benefit Plan ("VTSEMBP") from establishing a program for plan participants to obtain prescription medications from sources in Canada, or otherwise issue guidance that such a program would be lawful under the statutes and regulations enforced by the Commissioner of Food and Drugs. In addition, the undersigned requests that the FDA promptly establish regulations to provide for importation of prescription drugs from Canada into the U.S. as provided by section 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (amending 21 U.S.C.A. § 804).

A. Action Requested

This petition requests FDA to issue regulations or otherwise commit to exercise its enforcement discretion to allow the VTSEMBP to establish a program for the orderly individual importation of prescription medications in a manner that promotes the safety

2003P-0479

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and health of its members. VTSEMBP seeks authority to contract with providers to create a system under which its members have the option of forwarding a prescription to a Canadian firm where the prescription would be reviewed by a physician familiar with the member's medical history and re-written as a Canadian prescription, which would be forwarded to a licensed Canadian pharmacy to be filled and sent by mail to the member in the United States.

Additionally, the undersigned requests that the FDA promptly promulgate regulations as called for by Section 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (amending 21 U.S.C.A. § 804) to facilitate the wholesale importation of prescription medications from Canada to allow VTSEMBP and its members to take advantage of the lower prices available for similar products in Canada.

B. Statement of Grounds

The FDA has issued administrative guidance in its *Regulatory Procedures Manual* regarding the personal importation of prescription medications. In the subchapter entitled *Coverage of Personal Importations*, the agency has declared that it will not commit its resources to controlling importation by individuals of prescription medications from outside the United States for their own use. A substantial percentage of the members of the VTSEMBP live less than an hour by road from the Canada-U.S. border. The vast majority live within a two- or three-hour drive of the border. The reality is that many plan members regularly travel to Canada and have the ability to bring back prescription medications under the published FDA enforcement policy. The fact

that the cost of prescription drugs poses a substantial financial burden to many Americans and the fact that many prescription drugs are available in Canada at a substantially lower price are well known. The financial realities and our proximity to Canada, coupled with the FDA policy, create a situation in which members are likely to import prescription medications on an ad-hoc, personal level. When that occurs, the VTSEMBP does not have an opportunity to intervene to minimize the risks associated with prescription medications obtained outside the U.S., as identified by the FDA.

By granting this petition, the FDA will be promoting the health of VTSEMBP members by allowing the plan to manage and minimize potential health risks. Health risks would be reduced by using service providers who are knowledgeable about prescription drugs in the U.S. and Canada, including which medications sold in Canada are manufactured in FDA-approved facilities or the equivalent of U.S. medications, and by having prescriptions written in the U.S. reviewed and reissued by Canadian physicians who would be familiar with local pharmacy practices. In addition, if the plan was able to bring such Canadian prescription purchases back into our plan mechanism, as opposed to after-the-fact reimbursement as occurs with any other out-of-network purchase, we may be able to make those purchases subject to other safety and health promotion features of our pharmacy benefit management program, such as drug-interaction warnings and disease management.

C. Environmental Impact

This petition does not require an EA or EIS as it meets the requirements for categorical exclusion as provided by 21 C.F.R. § 25.30.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Dated at Montpelier, Vermont, this 1st day of December 2003.

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Secretary of Administration
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