RECKITT BENCKISER
PHARMACEUTICALS INC.

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Food and Drug Administration
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Docket No. 2005N-0479

Re: WHO Questionnaire for Collection of Information for Review of Dependence-Producing Psychoactive Substances - #8 **BUPRENORPHINE** 1. IMPACT OF TRANSFER TO SCHEDULE I OF THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, ON MEDICAL AVAILABILITY

Reckitt Benckiser Pharmaceuticals manufactures buprenorphine products, Subutex® (buprenorphine HCl) and Suboxone® (buprenorphine HCl and naloxone HCl) and markets them in the United States for the treatment of opiate dependence.

Buprenorphine for the treatment of opiate dependence was developed under a Cooperative Research and Development Agreement between the National Institute on Drug Abuse (NIH/NIDA) and Reckitt Benckiser Pharmaceuticals over a 15-year period. Concurrent with this development, the U.S. Congress considered how best to bring more patients into treatment for opiate dependence using the newly-developed buprenorphine products, and on October 17, 2000 enacted the Drug Addiction Treatment Act (DATA) expressly for the purpose of allowing qualified physicians to treat patients for opiate dependence in the privacy of the physician's office with these products. This legislation was required because under then-existing U.S. law such treatment was prohibited. The DATA provision which specifies that patients may be treated with Schedule III substances which have been approved for the indication by physicians who are exempt from provisions of then-existing law and regulation was included after considerable interagency consultation and discussion with the Congress and the understanding that while the Scheduling of buprenorphine (then in Schedule V under the Controlled Substances Act) would be rescheduled, it would be placed no higher than Schedule III, thus conforming to the DATA provisions designed to allow such treatment.

It should be noted that during those discussions, a meeting was held in the office of the Administrator of DEA to discuss how best to handle buprenorphine rescheduling. Participants in that meeting included the former Chairman of the Commerce Committee of the House of Representatives and principal sponsor of the DATA legislation, Thomas Bliley and the former DEA Administrator Asa Hutchinson as well as other DEA and Reckitt Benckiser Pharmaceuticals officials. The specific purpose of the meeting was discussion of differential scheduling of the two products which were about to be approved by the FDA. The company had agreed that it was not inappropriate for buprenorphine to be rescheduled because these products were intended for use by patients with a history of abusing medications. Additionally, the

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company had developed a treatment paradigm in concert with FDA and developed a marketing plan to encourage the use of the combination Suboxone® product for regular treatment, and reserving Subutex® for minimal use. This plan included differentiating the products by price and level of control. The company planned to market Suboxone® at a lower price and asked the DEA to consider placing it in Schedule IV while placing Subutex® in Schedule III. At that meeting, the DEA held the position that it did not have the authority to differentially schedule the drug products, that its authority only allowed it to reschedule drug substances. As a result of this interpretation of its authority under the CSA by the DEA, the company could not fully implement its plan to reinforce encouragement of physicians to use the combination product.

We call your attention to this discussion and interpretation because in recent conversations with various U.S. government agencies and World Health Organization (WHO) staff, our experts have been told that the DEA has expressed an opinion to both US government agencies and WHO staff that should the UN Commission on Narcotic Drugs place buprenorphine in Schedule I of the Single Convention on Narcotic Drugs, the drug products could remain in Schedule III of the CSA and the drug substance placed in Schedule II. This opinion seems to differ from the position taken at the above-mentioned meeting. Consequently, we would suggest that the response to Question No. 8 of the WHO Questionnaire be answered in the affirmative.

If buprenorphine were to be placed in Schedule I of the Single Convention on Narcotic Drugs tens of thousands of patients now undergoing treatment for opiate dependence with buprenorphine would be denied this their existing treatment, and such a change in scheduling would eviscerate the intent of the Congress when it enacted DATA.

We have had an opportunity to review the November 15, 2005 letter from Dr. William Steiger at HHS to Dr. Vladimir Lepakhin at WHO, as well as Dr. Lepakhin's response, and concur with the US positions regarding the upcoming meeting. Consequently there is no need to address those issues here. We concur with the views expressed by Senators Levin, Hatch and Biden as well as the US position outlined in Dr. Steiger's letter that buprenorphine should not be included on the agenda of the upcoming WHO/ECDD meeting. However, Dr. Lepakhin's response seems to indicate that buprenorphine will remain on the agenda. If this is the case, we trust that the U.S. response to the WHO questionnaire will indicate that the placement of buprenorphine in Schedule I of the Single Convention would severely affect medical availability in the United States. We also trust that the U.S. response will indicate that the only "final decision" that the ECDD could make regarding buprenorphine is one which determines that buprenorphine must remain in its current scheduling classification.

The availability of buprenorphine for the treatment of opiate dependence in the US is a significant public health issue, and we trust that the US response to WHO will make this clear.

Sincerely,

Rolly E. Johnson, Pharm. D.
Vice President
Regulatory and Scientific Affairs
Reckitt Benckiser Pharmaceuticals, Inc.