GENEVA, 12 January 2000

WHO Questionnaire for review of dependence-producing psychoactive substances by the Thirty-second Expert Committee on Drug Dependence.

Substance reported on:

1. Availability of the substance (registered, marketed, dispensed, etc.);

2. Extent of the abuse or misuse[3] of the substance;

3. Degree of seriousness of the public health and social problems associated with the abuse of the substance (statistics on cases of overdose deaths, dependence, etc.); and

4. Any information on the nature and extent of illicit activities involving the substance (clandestine manufacture, smuggling, diversion, seizure, etc.).

In addition to the above, with regard to Diazepam (INN) report on:

5. The impact of transferring diazepam from Schedule IV to Schedule III of the Convention on Psychotropic Substances, 1971, and its effect on availability for medical use.

In addition to items 1 to 4 above, with regard to Zolpidem (INN) report on:

6. The impact of placing zolpidem in Schedule IV of the Convention on Psychotropic Substances, 1971, and its effect on availability for medical use.

II. Background

The substance 4-Bromo-2,5-dimethoxyphenethylamine (2C-B) is a structural analogue of the phenethylamine hallucinogens. In various preclinical and clinical studies, it has been described as a stimulant, depressant, and hallucinogen, but appears to more closely fit the profile of the latter. It is not marketed in the United States, however, it is controlled domestically in Schedule I of the CSA.

Gamma-hydroxybutyric acid (GHB) is a substance classified as a central nervous system depressant. It is not marketed in the United States. The Drug Enforcement Administration published a final rule on March 13, 2000 (65 FR 13235), placing gamma-hydroxybutyric acid and its salts, isomers, and salts of isomers into Schedule I of the CSA under Public Law 106–172. The final rule imposes Schedule III security requirements for registered manufacturers and distributors of GHB when it is manufactured, distributed, or possessed in accordance with FDA authorized investigational new drug exemptions under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)). If drug products containing GHB are approved by FDA, the final rule places FDA approved products containing GHB into Schedule III of the CSA under Public Law 106–172.

The substance 4-Methylthioamphetamine (4-MTA) is a compound structurally similar to amphetamine. 4-MTA is reported to have physiological effects similar to that of 3,4-methylenedioxyamphetamine (MDA) and 3,4-methylenedioxymethamphetamine (MDMA/ecstasy). The substance is not marketed in the United States. It is not specifically listed as a controlled substance in the United States. However, it is considered a Schedule I controlled substance as an analogue of either MDA or MDMA under the analogue provisions of the CSA.

N-Methyl-l-(3,4-methylenedioxyphenyl)-2-butanamine (MBDB) is a positional isomer of MDE (3,4-methylenedioxy-*N*-ethylamphetamine) which is controlled domestically in Schedule I. The psychoactive effects of MBDB have been described as hallucinogenic. It is not marketed in the United States. As an isomer of MDE, MBDB is a Schedule I substance in the United States.

Diazepam (INN) is a benzodiazepine derivative. It is marketed in the United States for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety; in acute alcohol withdrawal, it is used in the symptomatic relief of acute agitation, tremor, impending or acute delirium tremens, and hallucinosis; as an adjunct for the relief of skeletal muscle spasm; spasticity caused by upper motor neuron disorders; athetosis; stiff-man syndrome; tetanus; as an adjunct in convulsive disorders; and as a premedication for relief of anxiety and tension in patients who are to undergo surgical procedures. Domestically, it is controlled in Schedule IV of the CSA. Diazepam is controlled internationally in Schedule IV of the Psychotropic Convention.

Zolpidem (INN) is a hypnotic agent with a chemical structure unrelated to benzodiazepines, barbiturates, or other drugs with known hypnotic properties. It interacts with a GABA–BZ receptor complex and shares some of the pharmacological properties of the benzodiazepines. It is marketed in the United States for the short-term treatment of insomnia. Domestically, it is controlled in Schedule IV of the CSA.

III. Opportunity to Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA (21 U.S.C. 811 (d)(2)(A)), FDA, on behalf of the Department of Health and Human Services (DHHS), invites interested persons to submit comments regarding the six named drugs. Any comments received will be considered by DHHS when it prepares a scientific and medical evaluation of these drugs. DHHS will forward a scientific and medical evaluation of these drugs to WHO, through the Secretary of State, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drugs. Such control could limit, among other things, the manufacture and distribution (import/export) of these drugs and could impose certain recordkeeping requirements on them.

DHHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, DHHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in late 2000. Any DHHS position regarding international control of these drugs will be preceded by another **Federal Register** notice soliciting public comments as required by 201(d)(2)(B) of the CSA.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the drugs by May 15, 2000. This abbreviated comment period is necessary to allow sufficient time to prepare and submit the domestic information package by the deadline imposed by WHO. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 24, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–10631 Filed 4–27–00; 8:45 am]

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[3] In this questionnaire, ''abuse or misuse'' refers to use of the substance other than for medical or scientific purposes.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1132–N]

Medicare Program; May 23, 2000, Meeting of the Competitive Pricing Advisory Committee

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Competitive Pricing Advisory Committee (the CPAC) on May 23, 2000. The Balanced Budget Act of 1997 (BBA) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. The BBA requires the Secretary to create the CPAC to make recommendations on demonstration area designation and appropriate research designs for the project. The CPAC meetings are open to the public.

DATES: The meeting is scheduled for May 23, 2000, from 9 a.m. until 1 p.m., e.d.s.t.

ADDRESSES: The meeting will be held at the Double Tree Hotel Park Terrace, 1515 Rhode Island Avenue, NW., Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT: Sharon Arnold, Ph.D., Executive Director, Competitive Pricing Advisory Committee, Health Care Financing Administration, 7500 Security Boulevard C4–14–17, Baltimore, Maryland 21244–1850, (410) 786–6451. Please refer to the HCFA Advisory Committees Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (http://www/hcfa.gov/fac) for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION:

Section 4011 of the Balanced Budget Act of 1997 (BBA), Public Law 105–33, requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. Section 4012(a) of the BBA requires the Secretary to appoint a Competitive Pricing Advisory Committee (the CPAC) to meet periodically and make recommendations to the Secretary concerning the designation of areas for inclusion in the project and appropriate research design for implementing the project. The CPAC has previously met on May 7, 1998, June 24 and 25, 1998, September 23 and 24, 1998, October 28, 1998, January 6, 1999, May 13, 1999, July 22, 1999, September 16, 1999, October 29, 1999, and January 12, 2000.

The CPAC consists of 15 individuals who are independent actuaries; experts in competitive pricing and the administration of the Federal Employees Health Benefit Program; and representatives of health plans, insurers, employers, unions, and beneficiaries. The CPAC members are: James Cubbin, Executive Director, General Motors Health Care Initiative; Robert Berenson, M.D., Director, Center for Health Plans and Providers, HCFA; John Bertko, Actuary Principal, Humana Inc.; David Durenberger, Vice President, Public Policy Partners; Gary Goldstein, M.D., Healthcare Consultant; Samuel Havens, Healthcare Consultant; Margaret Jordan, Executive Vice President, Texas Health Resources; Chip Kahn, President, The Health Insurance Association of America; Cleve Killingsworth, President and CEO, Health Alliance Plan; Nancy Kichak, Director, Office of Actuaries, Office of Personnel Management; Len Nichols, Principal Research Associate, The Urban Institute; Robert Reischauer, President, The Urban Institute; John Rother, Director, Legislation and Public Policy, American Association of Retired Persons; Andrew Stern, President, Service Employees International Union, AFL–CIO; and Jay Wolfson, Director, The Florida Information Center, University of South Florida. The Chairperson is James Cubbin and the Co-Chairperson is Robert Berenson, M.D. In accordance with section 4012(a)(5) of the BBA, the CPAC will terminate on December 31, 2004.

The agenda for the May 23, 2000, meeting will include a discussion of the components of a Report to Congress being prepared by the CPAC. Section 533 of the Medicare, Medicaid, and State Child Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999, Public Law 106–113, revised section 4011 of the BBA to require the CPAC to submit a report on the following topics:

- Incorporation of original Medicare fee-for-service into the demonstration.
- Requirements of quality activities under the demonstration.
- Inclusion of a rural area in the demonstration.

sbull Requirements of a benefit structure under the demonstration.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director, by 12 noon, May 18, 2000, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director, no later than 12 noon, May 22, 2000. Anyone who is not scheduled to speak, may submit written comments to the Executive Director, by 12 noon, May 22, 2000.

The meeting is open to the public, but attendance is limited to the space available. Individuals requiring sign language interpretation for the hearing impaired or other special accommodation should contact the Executive Director at least 10 days before the meeting.

(Section 4012 of the Balanced Budget Act of 1997, Public Law 105–33 (42 U.S.C.1395w–23 note) and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 18, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–10555 Filed 4–27–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3053–N]

Medicare Program; Open Town Hall Meeting To Promote and Establish Partnerships Between the Medicare Peer Review Organizations (PROs) and Entities in the Health Care Community To Foster Health Care Quality Improvement—May 15, 2000

AGENCY: Health Care Financing Administration (HCFA), DHHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the second in a series of Partnership Open Town Hall Meetings for the purpose of exploring and exercising opportunities for the entire health care community to collaborate with the PROs on quality improvement projects that will raise the quality of care provided to Medicare beneficiaries and to all patients. The primary focus of the quality improvement partnerships will be six national clinical topics, including acute myocardial infarction, breast cancer, diabetes, heart failure, pneumonia, and stroke. We view this meeting as an opportunity to develop partnerships with the provider, practitioner, plan, purchaser and beneficiary communities. The meeting is open to the public, but attendance is limited to space available.

DATES *The meeting:* The meeting will be held on Monday, May 15, 2000, from 9:00 a.m. until 4:00 p.m., EDT.