Recommendation

Although GHB is an endogenous compound that exists in the human body, GHB has psychoactive and toxic effects when administered. The pattern and consequences of its abuse in a number of countries in Europe and the USA seem to suggest that its liability to abuse constitutes a significant risk to public health. The current easy availability of GHB and some of its precursors has contributed to its recent abuse. The wide availability is likely to be reduced once GHB is placed under international control. On these bases, it is recommended that GHB be placed in Schedule IV of the 1971 Convention on Psychotropic Substances.

Zolpidem (INN) Substance Identification

Zolpidem is chemically N,N,6-trimethyl-2-p-tolylimidazo [1,2-a]pyridine-3-acetamide; N,N,6-trimethyl-2-(4-methylphenyl)imidazo[1,2-a]pyridine-3-acetamide (CAS 82626–48–0). Trade names include: Ambien, Bikalm, Niotal, Stilnoct, Stilnox.

Similarity to Known Substances and Effects on the Central Nervous System

Though chemically different from benzodiazepines, zolpidem produces benzodiazepine-like effects. It acts as an agonist binding with high and low affinity to BZ_1 and BZ_2 receptor subtypes, respectively. It is generally believed to produce relatively greater hypnotic effects than other benzodiazepine-like effects.

Dependence Potential

The results of human laboratory studies suggest that zolpidem and triazolam are generally similar in terms of producing subjective reinforcing effects. As with many of the benzodiazepines, there have been a number of case reports describing withdrawal symptoms after cessation of zolpidem administration. Though withdrawal discomfort does not necessarily lead to compulsory drug taking (drug dependence) in humans, there are reports of clinically diagnosed cases of drug dependence resulting from a prolonged use of zolpidem.

Actual Abuse and/or Evidence of Likelihood of Abuse

Epidemiological studies indicate that zolpidem is associated with relatively low incidence of abuse. Sporadic case reports in the scientific literature have indicated that zolpidem is abused, but these cases usually involved patients with histories of drug abuse or chronic psychiatric disorders. Cases of zolpidem overdose requiring emergency treatment have been reported. Death due to zolpidem overdose is rare. Rates of actual abuse and dependence of zolpidem appear to be similar to other hypnotic benzodiazepines in Schedule IV. In terms of the numbers of cases of abuse, dependence and withdrawal reported as adverse drug reactions to the WHO adverse drug reaction database, less than ten benzodiazepines are ranked higher than zolpidem.

Therapeutic Usefulness

Zolpidem is used for treatment of insomnia in more than 80 countries.

Recommendation

Although zolpidem has a somewhat novel neuropharmacological profile relative to classic benzodiazepines, studies of its abuse potential suggest that it may be comparable to that of many benzodiazepines. Furthermore, rates of actual abuse and dependence of zolpidem in medical use, as well as the risk to public health of its abuse, appear to be similar to hypnotic benzodiazepines presently placed in Schedule IV. On these bases, it is recommended that zolpidem be placed in Schedule IV of the 1971 Convention on Psychotropic Substances.

I. Discussion

Although WHO has made specific scheduling recommendations for each of the drug substances, the CND is not obliged to follow the WHO recommendations. Options available to the CND for substances considered for control under the Psychotropic Convention include: (1) Acceptance of the WHO recommendations; (2) acceptance of the recommendations to control, but control the drug substance in a schedule other than that recommended; or (3) rejection of the recommendations entirely.

4-Bromo-2,5-dimethoxyphenethylamine (2C-B) is a Schedule I controlled substance in the United States. The U.S. Drug Enforcement Administration (DEA) placed 2C-B (including salts, isomers, and salts of isomers: isomers include optical, positional, and geometric) in Schedule I of the Controlled Substance Act (CSA) in June 1995. 4-methylthioamphetamine (4-MTA) is not marketed in the United States and is not currently a controlled substance in the United States. Gamma hydroxybutyric acid (GHB) is a Schedule I controlled substance in the United States. GHB, including its salts, optical isomers, and salts of optical isomers, became a Schedule I controlled substance in March 2000. Registered manufacturers and distributors of GHB when it is manufactured, distributed, or possessed in accordance with an FDA authorized investigational new drug exemption under Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(i)) are subject to Schedule III security requirements. If FDA approves a drug product containing GHB for marketing, the approved product will be placed into Schedule III under Public Law 106–172. Zolpidem, its salts, isomers, and salts of isomers, is a Schedule IV controlled substance in the United States. The DEA placed zolpidem in Schedule IV in February 1993. With the exception of 4-MTA, current controls in the United States on the substances under consideration for international control appear to meet the requirements of the recommended Psychotropic Convention schedules.

IV. Comments

Interested persons may, on or before March 15, 2001, submit to the Dockets Management Branch (address above) written comments regarding this notice. This abbreviated comment period is necessary to allow HHS to furnish a recommendation to the Secretary of State in time for the March 2001 meeting of the United Nations Commission on Narcotic Drugs. 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 (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 27, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–5218 Filed 2–28–01; 11:36 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and

recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 15, 2001, from 8:30 a.m. to 6 p.m. and on March 16, 2001, from 8:30 a.m. to 12 noon.

Location: Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 15, 2001, the committee will hear presentations, discuss and make recommendations on the comparative sensitivity of Hepatitis B Virus nucleic acid testing versus Hepatitis B Surface Antigen testing. In the afternoon, the committee will hear presentations, discuss and make recommendations on the implementation of nucleic acid testing for Hepatitis C Virus and human immunodeficiency virus, testing donor and product management, and blood bags for diversion of the initial collection. On March 16, 2001, the committee will hear updates on the following topics: (1) Summaries of the Transmissible Spongiform Encephalopathies Advisory Committee Meeting and the Public Health Service Advisory Committee Meeting on blood safety and availability, and (2) The Office of Inspector General's report on tissue and organ regulation. The committee will additionally hear presentations, discuss and make recommendations on the topic of guidance on malaria, applicability to plasma.

Procedure: On March 15, 2001, from 8:30 a.m. to 6 p.m. and on March 16, 2001, from 8:30 a.m. to 12 noon, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 9, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m., 1:30 p.m. and 2:30 p.m., and 4:30 p.m. and 5:30 p.m. on March 15, 2001, and 10:15 a.m. and 10:30 a.m. on March 16, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 9, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the March 15 to 16, 2001, Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 28, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–5375 Filed 3–1–01; 11:53 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1728]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Home Health Agency Cost Report and Supporting Regulations in 42 CFR 413.20, 413.24 and 413.106; *Form No.:* HCFA–1728 (OMB No. 0938–0022); *Use:* Participating providers are required to submit annual information to HCFA in order to achieve settlement of costs for health care services rendered to Medicare beneficiaries. The HCFA–1728 is the form used by Home Health Agencies to report their health care costs to determine the amount reimbursable for services furnished to Medicare beneficiaries; *Frequency:* Annually; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local or Tribal Gov.; *Number of Respondents:* 7,310; *Total Annual Responses:* 7,310; *Total Annual Hours Requested:* 1,293,870.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: February 15, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–5181 Filed 3–2–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–108]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the