Disposition of Applications

1. Approval, Disapproval, or Deferral

On the basis of the review of an application, the ASPE will either (a) approve the application in whole, as revised, or in part for an amount of funds and subject to such conditions as are deemed necessary or desirable for the research project; or (b) disapprove the application; or defer action on the application for such reasons as a lack of funds or a need for further review.

2. Notification of Disposition

The ASPE will notify the applicants of the disposition of their application. A signed notification of the award will be issued to notify the applicant of the approved application.

3. The Assistant Secretary's Discretion

Nothing in this announcement should be construed as to obligate the Assistant Secretary for Planning and Evaluation to make any awards whatsoever. Awards and the distribution of awards among the priority areas are contingent on the needs of the Department at any point in time and the quality of the applications which are received.

Components of a Complete Application

A complete application consists of the following items in this order:

1. Application for Federal Assistance (Standard Form 424, Revised 4–88);
2. Budget Information—Non-construction Programs (Standard Form 424A, Revised 4–88);
3. Assurances—Non-construction Programs (Standard Form 424B, Revised 4–88);
4. A Table of Contents;
5. Budget Justification for Section B—Budget Categories;
6. Proof of nonprofit status, if appropriate;
7. A copy of the applicant's approved indirect cost rate agreement if necessary;
8. Project Narrative Statement, organized in five sections addressing the following topics:
   (a) Abstract,
   (b) Goals, Objectives and Usefulness of the Project,
   (c) Methodology and design,
   (d) Background of the Personnel and Organizational Capabilities and
   (e) Work plan (timetable);
9. Any appendices/attachments;
10. Certification Regarding Drug-Free Work place;
11. Certification Regarding Debarment, Suspension and Other Responsibility Matters;
12. Certification and, if necessary, Disclosure Regarding Lobbying;

Reports

The grantee must submit quarterly progress reports and a final report. The specific format and content for these reports will be provided by the project officer.

State Single Point of Contact (E.O. No. 12372)

The Department of Health and Human Services has determined that this program is not subject to Executive Order No. 12372, Intergovernmental Review of Federal Programs, because it is a program that is national in scope and does not directly affect State and local governments. Applicants are not required to seek intergovernmental review of their applications within the constraints of E.O. No. 12372.

Dated: June 13, 1997.

David F. Garrison,

Principal Deputy Assistant Secretary for Planning and Evaluation.

[FR Doc. 97–16083 Filed 6–18–97; 8:45 am]

BILLING CODE 4151–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Availability of Report of NIH Panel To Define Principles of Therapy of HIV Infection and Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults

AGENCY: Office of Public Health and Science, HHS.

ACTION: Request for comments.

SUMMARY: The Department of Health and Human Services (DHHS), Office of Public Health and Science, is requesting comments from all interested parties on the following two documents: ''Report of the NIH Panel to Define Principles of Therapy of HIV Infection'' developed by the subject NIH Panel and ''Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents,'' developed by the Panel on Clinical Practices for Treatment of HIV Infection, convened by the Department of Health and Human Services and the Henry J. Kaiser Family Foundation. The principles of therapy document describes 11 scientific principles that define the fundamental HIV pathogenic-based rationale for guiding therapeutic decisions. The guidelines document contains recommendations for practitioners in conjunction with patients to use in providing appropriate treatment regimens in light of new combination therapies. The guidelines cover the following areas: methods for testing to establish HIV infection; considerations for when to initiate therapy; methods for and frequency of monitoring the effectiveness of therapy; therapy in patients with established and advanced stage disease; the treatment of acute HIV infection; interruption of therapy; considerations for changing therapy and available therapeutic options; and considerations for therapy in the HIV-infected pregnant woman.

DATES: Written comments should be written on or before July 21, 1997.

ADDRESSES: Written comments to this notice should be submitted to: The HIV/AIDS Treatment Information Service, P.O. Box 6363, Rockville, MD 20849–6303. Due to the significantly large response expected, only written comments will be accepted. After consideration of the comments, the final documents will be published in the Centers for Disease Control and Prevention (CDC) ''Morbidity and Mortality Weekly Report'' (MMWR). A notice of their availability will also be published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Copies of the ''Report of the NIH Panel to Define Principles of Therapy'' and ''Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents'' are available from the National AIDS Clearinghouse (1–800–458–5231) and on the Clearinghouse website (hhtp://www.cdcnac.org) and from the HIV/AIDS Treatment Information Service (1–800–448–0400; FAX 301–529–6616; TTY: (1–800–243–7012) and on their website (http://www.hivatis.org).

SUPPLEMENTARY INFORMATION: The NIH Panel to Define Principles of Therapy of HIV Infection was convented to conduct a review of the current status of the clinical studies of HIV antiretroviral therapy with the goal of delineating scientific principles that would guide therapeutic decisions. The NIH Panel was chaired by Charles Carpenter, M.D., Professor of Medicine, Brown University School of Medicine. The Panel on Clinical Practice for Treatment of HIV Infection is a three-year public/private partnership convened in December 1996 by Eric P. Goosby, M.D., Director, Office of HIV/AIDS Policy, DHHS, and Mark Smith, M.D., former Vice President of the Henry J. Kaiser Family Foundation, at the request of DHHS Secretary Donna E. Shalala. The Panel's mission is to develop an initial set of comprehensive clinical practices providing current state-of-the-art recommendations, options and guidance to practitioners, patients, and payers regarding effective and appropriate treatment for HIV infection on a variety of areas. The Panel is cochaired by Anthony S. Fauci, M.D., Director,

National Institute of Allergy and Infectious Diseases, and John G. Bartlett, M.D. Professor of Medicine and Chief of Infectious Diseases at Johns Hopkins University School of Medicine. The 32-member panel includes Federal, private sector and academic experts in the clinical treatment and care HIV-infected people and representatives of AIDS interest groups, health policy groups and payer organizations.

Dated: June 16, 1997.

John M. Eisenberg,

Principal Deputy Assistant Secretary for Health, U.S. Department of Health and Human Services.

[FR Doc. 97–16228 Filed 6–17–97; 1:39 pm]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0221]

Benzodiazepines and Related Substances; Criteria for Scheduling Recommendations Under the Controlled Substance Act; Notice of Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing.

SUMMARY: The Food and Drug Administration (FDA) in conjunction with other Federal agencies will convene a part 15 public hearing on benzodiazepines and related substances. The purpose of the hearing is to gather evidence in order to assess the abuse potential of benzodiazepines and related compounds and to develop criteria that will distinguish the substances in order to address their appropriate scheduling under the Controlled Substance Act (the CSA).

DATES: The hearing will be held on Thursday and Friday, September 11 and 12, 1997, from 9 a.m. to 4 p.m. Written notice of participation should be filed by August 14, 1997. The closing date for comments will be October 17, 1997.

ADDRESSES: The public hearing will be held at the Renaissance Hotel, 999 Ninth St. NW., Washington, DC 20001–9000. Written notices of participation and any comments are to be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Transcripts of the public hearing may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the hearing, at a cost of 10 cents per page. The transcript of the public hearing, copies of data and information submitted during the hearing, and any written comments will be available for review at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nicholas P. Reuter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, rm. 15–22, Rockville, MD 20857, 301–827–1696, FAX 301–443–0232, e-mail ''nreuter@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

Benzodiazepines and related drug substances have consistently ranked among the most widely prescribed drug products in the United States. These products are used extensively as anxiolytics, sedatives, and hypnotics. Concomitant with the widespread use of these products have been concerns associated with benzodiazepine abuse, misuse, and the level of domestic and international control applied to these substances.

Benzodiazepines act upon the central nervous system (CNS). In addition, benzodiazepine substances have the potential for abuse and the capacity to produce physical and psychological dependence. As such, benzodiazepine substances have been subject to domestic and international drug control reviews. For the most part, until recently, these international and domestic reviews have resulted in uniform domestic and international controls. Essentially, all benzodiazepines and related compounds are controlled domestically in schedule IV of the CSA. In the most recent benzodiazepine-type substance domestic scheduling review, Ambien® (Zolpidem), was added to Schedule IV of the CSA in 1993. Internationally, most benzodiazepines are controlled in Schedule IV of the Convention on Psychotropic Substances, 1971 (the Convention). However, in 1990, the World Health Organization (WHO) reviewed, but did not recommend control of, three benzodiazepine substances (brotizolam, etizolam, and quazepam).

In response to a request from the Drug Enforcement Administration (DEA), the Department of Health and Human Services (DHHS) is currently evaluating the abuse liability of quazepam, a benzodiazepine controlled in Schedule IV of the CSA. The DEA request followed a petition from the company that manufactures a drug product containing quazepam as the active ingredient (Doral®). In its petition, the manufacturer requests that quazepam be removed from Schedule IV of the CSA and decontrolled.

A. International Reviews

Benzodiazepines and related substances are psychotropics and are subject to the Convention. The domestic review and control of many benzodiazepine substances has been directly influenced by international scheduling actions. This is because the United States is expected to control substances domestically to fulfill international scheduling actions under the Convention. In addition, although the findings necessary for control under the Convention and the CSA are not identical, the schedule structure and issues surrounding the international and domestic control actions on benzodiazepines are similar and overlap. As discussed in section I.A.1., 2., and 3 of this document, the international scheduling review policy has evolved between the initial class reviews in the 1980's and the more recent substance oriented assessments.

1. The 1984 Review

The United Nations (UN) Commission on Narcotic Drugs added 33 benzodiazepine substances to Schedule IV of the Convention (NAR/CL.4/1984; DND 421/12(1-7)) in March, 1984. The UN action followed an extensive review by the WHO, which had recommended that all 33 substances be controlled in Schedule IV. The WHO considered the following information in evaluating the need for international control:

(1) Chemical structure, receptor binding characteristics, sedative-hypnotic, anticonvulsant, and anxiolytic profile of CNS effects;

(2) Animal data on psychological and physical dependence potential;

(3) Human experimental data on both dependence and abuse potential;

(4) Clinical data on dependence and public health problems;

(5) Epidemiological data on public health and social problems;

(6) Extent of abuse or likelihood of abuse and seriousness of public health and social problems resulting from such abuse; and

(7) Utilization and usefulness in therapy.

The WHO found that for many of the 33 benzodiazepine substances, no data were available other than for items (1) and (4) listed previously. In recommending international control, however, the WHO determined that if a