seriousness of the public health and social problems associated with the abuse of methcathinone is assessed to be especially serious. On the basis of this and the assessment of its therapeutic usefulness, it is recommended that methcathinone be included in Schedule I of the Convention on Psychotropic Substances, 1971.

Zipeprol

1. Substance identification

Zipeprol (INN; CAS 34758–83–3), chemically o-(α -methoxybenzyl—4-(β -methoxyphenethyl)-1-piperazineethanol, is also know as Antituxil-Z, Carm-3024, Chilvax, Delaviral, Dovavixin, Jactus, Eritos, Mirsol, Ogyline, Rospilene, Respirase, Respirax, Sanotus, Sentus, Silentos, Sousibim, Talasa, Tusigen, Tussiflex and Zitoxil. Zipeprol has three asymmetric carbon atoms in the molecule, so that eight stereoisomeric forms are possible. 2. Similarity to already known substances and affects on the central nervous system

In laboratory animals, zipeprol has been shown to have an antitussive activity weaker than codeine and comparable to dextromethorphan. Its pharmacological properties are different from those of opioid antitussives, such as codeine, in that zipeprol has anti-cholinergic activities. It also does not produce respiratory depression, bile duct constriction or constipation, which are often associated with narcotic antitussives.

Unlike opioids, zipeprol is essentially devoid of analgesic activity, but at higher doses, zipeprol acts like a weak opioid agonist. Zipeprol showed a bi-phasic effect in competing for binding sites in rat brain homogenates.

3. Dependence potential

In rats, lower doses of zipeprol amplify some opioid withdrawal manifestations whereas at higher doses it suppresses several morphine withdrawal symptoms. In the monkey, zipeprol suppresses morphine abstinence. Zipeprol is assessed to have a moderate dependence potential.

4. Actual abuse and/or evidence of likelihood of abuse

There have been a number of reports on the abuse of zipeprol from Brazil, Chile, Italy, Mexico, the Republic of Korea, Switzerland, and the former Yugoslavia. These reports suggest that its sedative, hallucinatory and euphorigenic effects, and its ability to suppress some signs of opioid withdrawal at high doses, may be the reasons for its abuse. Over-the-counter distribution of zipeprol preparations may have contributed to its widespread abuse in some places. Taking this into account, zipeprol is assessed to have a moderate abuse liability.

Adverse health consequences of zipeprol abuse include seizures, hallucinations, confusion and amnesia. Dose escalation is not uncommon and fatal cases from intoxication were reported from several countries. The tablet form has been used for intravenous administration.

Therapeutic usefulness

A number of clinical studies have demonstrated the therapeutic efficacy of zipeprol in the treatment of cough. The therapeutic usefulness of zipeprol is assessed to be within the range between little to moderate.

6. Recommendation

Although zipeprol is a weak opioid agonist at high doses, its toxicity, hallucinogenic and other psychotropic effects constitute a significant element in its abuse. It is therefore appropriate to consider its control under the Convention on Psychotropic Substances, 1971.

Based on the available data concerning its pharmacological and toxicological profile, dependence potential and likelihood of abuse, the degree of seriousness of the public health and social problems associated with the abuse of zipeprol is assessed to be substantial. On the basis of this and the assessment of its therapeutic usefulness, it is recommended that zipeprol be included in Schedule II of the Convention on Psychotropic Substances, 1971.

III. Discussion

Although WHO has made specific scheduling recommendations for each of the drug substances, CND is not obliged to follow the WHO recommendations. Options available to CND include:

- 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) reject the recommendations

Methcathinone, etryptamine and aminorex, are controlled under the CSA in Schedule I. The proposed international drug scheduling actions, if adopted by CND, will result in no greater degree of control of these substances than are currently applied domestically. Flunitrazepam is controlled domestically in Schedule IV of the CSA; additional controls may be necessary if the United Nations moves this substance to Schedule III of the Convention. Brotizolam, mesocarb, and zipeprol are neither controlled domestically nor currently marketed for medical use in the United States. In order to comply with obligations under the Convention, these three substances would have to be controlled under the CSA if the United Nations endorses the WHO recommendations.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the United Nations notifications concerning these seven drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, pursuant to section 811(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting

on the recommendations at the CND meeting in March 1995.

IV. Submission of Comments and Opportunity for Public Meeting

Interested persons may, on or before February 9, 1995, submit to the Dockets Management Branch (address above) written comments regarding this notice. FDA does not presently plan to hold a public meeting. If any person believes that, in addition to its written comments, a public meeting would contribute to the development of the U.S. position on any of these two substances, a request for a public meeting and the reasons for such a request should be sent to Nicholas P. Reuter (address above) on or before January 30, 1995. The short time period for the submission of comments and requests for a public meeting is needed to assure that HHS may, in a timely fashion, carry out the required action and be responsive to the United Nations. 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: January 17, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy. [FR Doc. 95–1553 Filed 1–19–95; 8:45 am] BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The