Dated: March 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–6906 Filed 3–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0148]

International Drug Scheduling; Convention on Psychotropic Substances; Dihydroetorphine; Ephedrine; Remifentanil; Isomers of Psychotropic Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting interested persons to submit data or comments concerning abuse potential, actual abuse, medical usefulness, and trafficking of three drug substances. This information will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding abuse liability, actual abuse, and trafficking of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting information is required by the Controlled Substances Act (CSA).

DATES: Submit written comments by April 17, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nicholas P. Reuter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1696, E–mail: NReuter@bangate.FDA.gov.

SUPPLEMENTARY INFORMATION: The United States is a party to the 1971 Convention on Psychotropic Substances. Article 2 of the Convention on Psychotropic Substances provides that if a party to that convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary General of the United Nations and provide the Secretary General with information in support of its opinion.

The CSA (21 U.S.C. 811 *et seq.*) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Convention on Psychotropic Substances that it has information that may justify adding a drug or other substance to one of the schedules of that convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (the Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments to assist HHS in preparing scientific and medical evaluations about the drug or substance. The Secretary of HHS received the following notices from WHO:

I. WHO Notification

Ref. : C. L.23 .1997

WHO questionnaire for collection of information for review of dependence-producing psychoactive substances

The Director-General of the World Health Organization presents his compliments and has the pleasure of informing Member States that the Thirty-first Expert Committee on Drug Dependence will meet from 23 to 26 June 1998 to review the following substances:

1. Dihydroetorphine
2. Ephedrine
3. Remifentanil
4. With regard to all substances in Schedules I and II of the Convention on Psychotropic Substances, 1971:

(a) their isomers, except where expressly excluded, whenever the existence of such isomers is possible;

(b) their esters and ethers, except where included in another schedule, whenever the existence of such esters and ethers is possible;

(c) salts of those esters, ethers and isomers, under the conditions stated above, whenever the formation of such salts is possible;

(d) a substance resulting from modification of the chemical structure of a substance already in these schedules and which produces pharmacological effects similar to those produced by the original substance.

One of the essential elements of the established review procedure is for the Secretariat to collect relevant information from Member States to prepare a Critical Review document for submission to the Expert Committee on Drug Dependence. The Director-General invites Member States to collaborate, as in the past, in this process by providing all pertinent information mentioned in the attached questionnaire[1] concerning the substances mentioned in items 1 to 3 above. The questionnaire does not include any questions about the groups of substances specified under item 4, since the required information is already being sought by the Secretary-General of the United Nations in his Circular Letter NAR/CL.4/1997.

Further clarification on any of the above items can be obtained from Psychotropic and Narcotic Drugs (PND), Division of Drug Management and Policies, WHO, Geneva, to which replies should be sent not later than *1 March 1998.*

GENEVA, 30 December 1997

Questionnaire for data collection for use by the World Health Organization and the Commission on Narcotic Drugs of the Economic and Social Council

Substance reported on:

1. Availability of the substance (registered, marketed, dispensed, etc.).
2. Extent of abuse of the substance.
3. Degree of seriousness of the public health and social problems[2] associated with abuse of the substance.
4. Number of seizures of the substance in the illicit traffic during the previous three years and the quantities involved.
5. Identification of the seized substance as of local or foreign manufacture and indication of any commercial markings.
6. Existence of clandestine laboratories manufacturing the substance.

II. United Nations Notifications

The U.S. Government has received two notifications from the Secretary General of the United Nations. The first notification (NAR/CL./1997, signed May 28, 1997), transmits under to Article 2, paragraph 1 of the Convention on Psychotropic Substances, 1971, a request from the Government of Spain to amend Schedules I and II of the Convention to include:

''(a) isomers, except where expressly excluded, of substances listed in those Schedules, whenever the existence of such isomers is possible;

''(b) esters and ethers of substances in those Schedules, except where included in another Schedule, whenever the existence of such esters or ethers is possible;

''(c) salts of those esters, ethers and isomers, under the conditions stated above, whenever the formation of such salts is possible;

''(d) a substance resulting from modification of the chemical structure of a substance already in Schedule I or Schedule II and which produces pharmacological effects similar to those produced by the original substance.''

The May 28, 1997, notification included as annexes, the original request from the Government of Spain, along with a questionnaire. A subsequent notification from the United

[1] For Ministries of Health only.

[2] Examples of public health and social problems are acute intoxication, accidents, work absenteeism, mortality, behaviour problems, criminality, etc.

Nations Secretary General dated February 23, 1998 (NAR/CL.2/1998), identified additional issues to be considered within the context of the Government of Spain's request.

These notifications appear to relate to the amendment of the Convention and not to the addition of specific substances to the schedules of the Convention (See 21 U.S.C. 811 (d)). Therefore, they are not published in this notice. The notifications are on display and copies may be obtained by contacting Nicholas Reuter (address above). Comments submitted in response to the United Nations notifications will be forwarded to the WHO through the United Nations Secretariat.

III. Background

None of the three substances under consideration by WHO are controlled internationally. Dihydroetorphine is a hydrogenated derivative of etorphine and a potent μ-opioid-receptor agonist used as a short-acting analgesic in China. It is neither marketed nor controlled in the United States.

Ephedrine is available in the United States as an over-the-counter bronchodilator. Further, ephedrine has been designated as a listed chemical and is subject to chemical diversion regulations under 21 CFR part 1310 which are enforced by the Drug Enforcement Administration. According to WHO, information is now available to indicate that illicit trafficking in ephedrine has increased significantly in recent years. Further, although the substance is illicitly used primarily in the manufacture of stimulants, WHO has evidence to indicate the increasing abuse of ephedrine preparations in some countries.

Remifentanil is a selective μ-opioid-receptor agonist of the fentanyl group. Remifentanil is approved in the United States as an anesthetic for use in animals and is controlled domestically as a narcotic in schedule II of the CSA.

IV. Opportunity to Submit Domestic Information

As required by section 201(d)(2)(A) of the Controlled Substances Act (21 U.S.C. 811(c)(2)(A)). FDA on behalf of the Department of Health and Human Services (DHHS) invites interested persons to submit data or comments regarding the eight named drugs. Data and information received in response to this notice will be used to prepare scientific and medical information on these drugs, with a particular focus on each drug's abuse liability. DHHS will forward that information to WHO, through the Secretary of State, for WHO's consideration in deciding whether to recommend international control 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 1998 or early 1999. Any DHHS position regarding international control of these drugs will be preceded by another **Federal Register** notice soliciting public comment as required by 21 U.S.C. 811(d)(2)(B).

V. Comments

Interested persons may, on or before April 17, 1998, submit to the Docket Management Branch (address above) written comments regarding this action. This abbreviated acceptance period is necessary to allow sufficient time to prepare and submit the domestic information package by the deadline imposed by WHO. Although WHO has requested comments and information by March 1, 1998, WHO will accept and consider material transmitted after the March date. Respondents should submit material in the format set forth by the WHO Questionnaire reprinted previously.

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 office above between 9 a.m. and 4 p.m, Monday through Friday.

This notice contains information collection requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB). The requirements were approved and assigned OMB control number 0910–0226.

Dated: March 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–6910 Filed 3–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0067]

Draft Guidance for Industry on Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA).'' This draft guidance is intended to assist developers of drugs, biological products, or medical devices intended for the treatment of rheumatoid arthritis (RA). It provides guidance on the types of claims that could be considered for such products and on clinical evaluation programs that could support those claims. The draft guidance also contains recommendations on the timing, design, and conduct of preclinical and clinical trials for RA products and on special considerations for juvenile RA. The agency is seeking comments on the draft guidance.

DATES: Written comments may be submitted on the draft guidance document by April 17, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm and at http://www.fda.gov/cber/guidelines.htm.

Submit written comments on the draft guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5468.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA).'' The draft guidance also contains recommendations on the timing, design, and conduct of preclinical and clinical