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

trials for RA products and on special considerations for juvenile RA.

This draft guidance has been under development since 1995. The first version of the draft guidance was completed in March 1996. An additional section on juvenile RA was added in May of that year. A second version was completed in January 1997. Two public workshops have been held on the topic: One was held on March 27, 1996 (61 FR 8961, March 6, 1996), and the other was held on July 23, 1996 (61 FR 32447, June 24, 1996). On February 5, 1997 (62 FR 4535, January 30, 1997), the draft guidance was discussed at a meeting of the Arthritis Advisory Committee. This draft guidance is the result of those efforts.

The draft guidance represents the agency's current thinking on rheumatoid arthritis. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Written requests for single copies of the draft guidance for industry should be submitted to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–6908 Filed 3–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3000–N]

Medicare Program; Solicitation of Proposals for a Demonstration Project for the Use of Informatics, Telemedicine, and Education in the Treatment of Diabetes Mellitus in the Rural and Inner-City Medicare Populations

AGENCY: Health Care Financing Administration (HCFA).

ACTION: Notice.

SUMMARY: This notice announces our intent to solicit proposals from eligible health care telemedicine networks for a demonstration project to use high capacity computing and advanced networks for the improvement of primary care and prevention of health care complications for Medicare beneficiaries with diabetes mellitus, who are residents of medically underserved rural areas or medically underserved inner city areas. We are soliciting these proposals under the authority of section 4207 of the Balanced Budget Act of 1997, section 1875 of the Social Security Act, and sections 402(a)(1)(B) and (a)(2) of the Social Security Amendments of 1967.

This notice also describes the requirements for submitting proposals and applications for this demonstration project.

DATES: For consideration, letters of intent must be received by April 17, 1998 and mailed to the following address: Lawrence E. Kucken, Health Care Financing Administration, Office of Health Standards and Quality, Mailstop C3–24–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online data base through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the data base by using the World Wide Web (the Superintendent of Document's home page address is http://www.access.gpo.gov/su_docs/), by using local WAIS client software, or by telnet to swais.access.gpo.gov, then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in as guest (no password required).

FOR FURTHER INFORMATION CONTACT: Lawrence E. Kucken, (410) 786–6694

SUPPLEMENTARY INFORMATION:

I. Background

A. Diabetes Mellitus in the Medicare Population

Diabetes is one of the most prevalent and costly diseases in the Medicare population. The National Health Interview Survey reported a prevalence of 10.4 percent in individuals aged 65 and older, based on the American Diabetes Association (ADA) diagnostic criteria of fasting blood glucose greater than 140. Medical costs for patients with diabetes are two to five times higher than costs for patients without diabetes. Cardiovascular disease, stroke, renal disease, and amputation occur more frequently in the elderly patient with diabetes than in those without diabetes.

A significant percentage of the morbidity associated with diabetes can be reduced or delayed in the Medicare population by appropriate diagnosis, preventive strategies, and management. Appropriate foot care, eye examinations and treatment of retinopathy, and other interventions on the part of the health care team, and involvement of the patient in his or her own self-care, such as intense blood glucose monitoring for patients on insulin have been shown to significantly reduce poor outcomes associated with diabetes.

B. Current HCFA Initiatives in Medicare Diabetes Treatment

We have undertaken several major initiatives aimed at improving quality of life, decreasing morbidity and mortality, and providing the most appropriate, cost-effective care for Medicare beneficiaries with diabetes. Peer Review Organizations in each State have been charged with identification of quality of care issues in their State and