Submissions in Electronic Format—NDAs.'' The draft guidance is intended to assist applicants who wish to submit new drug applications (NDA's) in electronic format. Submissions of NDA's in electronic format should reduce the amount of paperwork for applicants and the agency. Submissions in electronic format are voluntary.

DATES: Written comments may be submitted on this draft guidance document by June 8, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments are to be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Kenneth Edmunds, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3276, e-mail: ESUB@CDER.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Traditionally, FDA has required that regulatory submissions, such as investigational new drug applications and NDA's, be submitted as paper documents. In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records; electronic signatures regulation, which provided for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). The agency also established public docket number 92S–0251 to provide a list of the agency unit(s) that are prepared to receive electronic submissions and the specific types of records and submissions that can be accepted in electronic format (62 FR 13467, March 20, 1997). Shortly after establishing the docket, the Center for Drug Evaluation and Research (CDER) published a guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's'' (62 FR 49695, September 23, 1997), to assist applicants wishing to make electronic submissions. The September 1997 guidance provided specific information on submitting case report forms (CRF's) and case report tabulations (CRT's) as part of the NDA archival submission.

This draft guidance for industry expands on the September 1997 guidance and provides information on submitting a complete archival copy of the NDA in electronic format, including CRF's and CRT's. This draft guidance for industry contains much new information on submitting NDA's in electronic format. As a result, the agency is publishing the guidance in draft and is soliciting comments. Once comments have been received and addressed, a final guidance will be published that will replace the guidance on case report forms and case report tabulations issued on September 23, 1997.

CDER anticipates that as this effort proceeds, sponsors, investigators, and CDER staff will improve procedures for submitting electronic applications. As a result, CDER believes that guidance on electronic submissions will be updated periodically.

Applicants planning to submit parts or all of their NDA's in electronic format should consult public docket number 92S–0251 to determine which agency units are prepared to receive electronic submissions and the specific types of documents that can be submitted in electronic format.

This draft guidance represents the agency's current thinking on providing regulatory NDA submissions in electronic format. 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.

II. Comments

Interested persons may submit written comments 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. Submit written requests for single copies of the draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—NDA's'' 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. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access connect to CDER at ''http://www.fda.gov/cder/guidance/index.htm''.

Dated: April 1, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–9103 Filed 4–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Abuse 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Drug Abuse Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on April 27, 1998, 1:30 p.m. to 5 p.m. and April 28, 1998, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4090, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 27, 1998, the committee will discuss and review trade secret and/or confidential information. On April 28, 1998, the committee will: (1) Discuss the scientific evidence for initiating a scheduling action for ULTRAM® (tramadol hydrochloride), R. W. Johnson Pharmaceutical Research Institute, under the Controlled Substances Act; (2) evaluate the effectiveness of the independent steering committee in detecting, moderating, and preventing the physical

dependence and abuse of ULTRAM®; and (3) suggest improvements for surveillance of misuse.

Procedure: On April 28, 1998, from 8:30 a.m. to 5:30 p.m., 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 April 17, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 28, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 17, 1998, 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.

Closed Committee Deliberations: On April 27, 1998, from 1:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The investigational new drug application (IND) and Phase I and Phase II drug products in process will be presented, and recent action on selected new drug applications (NDA's) will be discussed. This portion of the meeting will be closed to permit discussion of this information.

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

Dated: April 1, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–9102 Filed 4–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices 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: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on April 30, 1998, 9:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Mary J. Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194, ext. 118, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12523. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a lithotripter used to fragment biliary stones.

Procedure: 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 April 20, 1998. Oral presentations from the public will be scheduled between 9:30 a.m. and 10 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 20, 1998, 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.

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

Dated: April 1, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–9187 Filed 4–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indians Into Medicine Programs

AGENCY: Indian Health Service, HHS.

ACTION: Notice of competitive grant applications for the Indians Into Medicine Program.

SUMMARY: The Indian Health Service (IHS) announces that competitive grant applications are being accepted for the Indians Into Medicine (INMED) Program established by sec. 114 of the Indian Health Care Improvement Act of 1976 (25 U.S.C. 1612), as amended by Pub. L. 102–573. There will be only one funding cycle during fiscal year (FY) 1998. This program is described at 93.970 in the Catalog of Federal Domestic Assistance and is governed by regulations at 42 CFR 36.310 et seq. Costs will be determined in accordance with applicable OMB Circulars. Executive Order 12372 requiring intergovernmental review does not apply to this program.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2000,* a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Educational and Community-based programs. *Healthy People 2000,* the full report, is currently out of print. You may obtain the objectives from the latest *Healthy People 2000* Review. A copy may be obtained by calling the National Center for Health Statistics, telephone (301) 436–8500.

Smoke Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

DATES: A. Application Receipt Date—An original and two (2) copies of the completed grant application must be submitted with all required documentation to the Grants Management Branch, Division of Acquisition and Grants Operations, Twinbrook Building, Suite 100, 12300 Twinbrook Parkway, Rockville, Maryland 20852, by close of business June 2, 1998. Applications shall be considered as meeting the deadline if they are either: (1) received on or before the deadline with hand carried applications received by close of business 5 p.m.; or (2) postmarked on or before the deadline date and received in time to be reviewed along with all other timely applications. A legibly dated receipt from a commercial carrier or the