the Center for Biologics Evaluation and Review (CBER) staff and expedites the licensing process as well as documenting for future reference the methods and procedures that have been approved for use at each manufacturing location. Statutory authority for this collection of information is found in section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262).

Section 601.2 (21 CFR 601.2) requires that manufacturers of biological products regulated under the PHS Act submit an establishment license application (ELA) and a PLA, or a biologic license application (BLA) to CBER for review and approval prior to marketing a biological product in interstate commerce. Blood and blood components fall within the category of biological products. All establishments collecting and/or preparing blood and blood components for sale or distribution in interstate commerce are subject to the licensing application provisions of section 351 of the PHS Act. Section 601.12 (21 CFR 601.12) requires manufacturers of a biologic for human use to file supplemental applications for all important changes to applications previously approved prior to implementing such changes. In addition to §§ 601.2 and 601.12, other regulations impose additional standards relating to certain information submitted in a license application, including 21 CFR 640.17, 640.21(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), and 680.1(b)(2)(iii) and (c). The information collection requirements in the preceding regulations and their associated reporting burdens are included with the burdens estimated for §§ 601.2 and 601.12 and cleared, together with application form 356h, under OMB control number 0910–0338.

As outlined in the President's November 1995 National Performance Review's document entitled ''Reinventing the Regulation of Drugs Made From Biotechnology,'' FDA intends to use a single harmonized application form for all drug and licensed biological products. FDA revised Form FDA 356h, ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use,'' for this purpose and announced its availability in the **Federal Register** of July 8, 1997 (62 FR 36558). This notice described FDA's intent to phase in the use of the new Form FDA 356h for all biological products and stated that applicants submitting new drug applications (NDA's), abbreviated new drug applications (ANDA's), abbreviated antibiotic drug applications (AADA's), and biologics license applications (BLA's) for biologic products specified in § 601.2(c) could begin to use the new Form FDA 356h immediately. The notice also advised such applicants that they would be required to use revised Form FDA 356h beginning January 8, 1998. In the interim period, the old Form FDA 356h and the new Form FDA 356h were to be acceptable alternatives for NDA's, ANDA's, AADA's, and BLA's.

In future **Federal Register** notices, FDA will advise applicants for the products not yet using the new Form FDA 356h, when they may voluntarily begin, and when they will be required to use the new Form FDA 356h. FDA is in the process of preparing guidance documents on the content and format of the chemistry, manufacturing, and controls section, and establishment description section of the new Form FDA 356h for those biological products not yet using the new form. As these guidance documents are completed, FDA will begin accepting the new Form FDA 356h. Until further notice, if the biological product is not specified in § 601.2(c), applicants should continue to submit an ELA and a PLA application on the CBER forms listed below in this notice.

Because all applicants have not completed the transition to Form FDA 356h, this notice seeks clearance for the continued use of the following forms: Form FDA 2599, ''Establishment License Application for the Manufacture of Blood and Blood Components;'' Form FDA 2599a, ''Supplement to Establishment License Application for the Manufacture of Blood and Blood Components;'' Form FDA 2600, ''Product License Application for the Manufacture of Source Plasma;'' Form FDA 2600b, ''Product License Application for Therapeutic Exchange Plasma;'' Form FDA 3066, ''Product License Application for Manufacture of Blood Grouping Reagents;'' Form FDA 3086, ''Product License Application for the Manufacture of Reagent Red Blood Cells;'' Form FDA 3096, ''Product License Application for the Manufacture of Anti-Human Globulin;'' Form FDA 3098, ''Product License Application for the Manufacture of Whole Blood and Blood Components;'' Form FDA 3098a, ''Product License Application for Red Blood Cells;'' Form FDA 3098b, ''Product License Application for Plasma;'' Form FDA 3098c, ''Product License Application for Platelets;'' Form FDA 3098d, ''Product License Application for Cryoprecipitated Antihemophilic Factor;'' Form FDA 3098e, ''The Manufacture of Products Prepared by Cytapheresis;'' Form FDA 3210, ''Application for Establishment License for Manufacture of Biological Products;'' Form FDA 3213, ''Application for License for the Manufacture of Allergenic Products;'' Form FDA 3214, ''Application for the Manufacture of a Human Plasma Derivative;'' and Form FDA 3314, ''Product License Application for the Manufacture of Human Immunodeficiency Virus for In-Vitro Diagnostic Use.''

Respondents to this collection of information are manufacturers of biological products. The reporting burden for the current collection of information was reported to OMB as part of the total burden for the agency's collection of information using Form FDA 356h. This collection of information using Form FDA 356h was assigned OMB control number 0910–0338 and approved by OMB on April 23, 1997.

Under OMB control number 0910–0338, FDA estimated that CBER's portion of the reporting burden for the collection of information using Form FDA 356h was 76,200 hours. The 76,200 hours reflected the future use of Form FDA 356h by all manufacturers of biological products. The number of manufacturers of biological products that are already using Form FDA 356h would account for approximately 3,000 hours of the total burden. Thus, the other 73,200 hours would account for manufacturers who have not completed the transition to using Form FDA 356h and who still need to use the other license application forms described in this notice. FDA expects that all manufacturers of biological products will begin to use Form FDA 356h during 1998.

Dated: April 1, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–9101 Filed 4–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 97D–0381]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—NDA's; 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 ''Providing Regulatory

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