Dated: April 1, 1998.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–9182 Filed 4–7–98; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Community/Tribal Subcommittee and the Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following subcommittee and committee meetings.

Name: Community/Tribal Subcommittee.

Times and Dates: 1:30 p.m.–5 p.m., April 28, 1998. 8:30 a.m.–5 p.m., April 29, 1998.

Place: ATSDR, 35 Executive Park Drive, Training Room, Atlanta, Georgia 30329, telephone 404/639–0708.

Status: Open to the public, limited by the available space. The meeting room accommodates approximately 60 people.

Purpose: This subcommittee will bring to the Board advice, citizen input, and recommendations on community and tribal programs, practices, and policies of the Agency.

Matters to be Discussed: Agenda items include identifying issues and concerns of the Subcommittee related to ATSDR community and tribal programs, policies, and activities. Recommendations will be developed and a report will be presented to the Board.

Name: Board of Scientific Counselors, ATSDR.

Times and Dates: 8:30 a.m.–5 p.m., April 30, 1998. 8:30 a.m.–3:45 p.m., May 1, 1998.

Place: ATSDR, 35 Executive Park Drive, Training Room, Atlanta, Georgia 30329, telephone 404/639–0708.

Status: Open to the public, limited by the available space. The meeting room accommodates approximately 60 people.

Purpose: The Board of Scientific Counselors, ATSDR, advises the Secretary; the Assistant Secretary for Health; and the Administrator, ATSDR, on ATSDR programs to ensure scientific quality, timeliness, utility, and dissemination of results. Specifically, the Board advises on the adequacy of science in ATSDR-supported research, emerging problems that require scientific investigation, accuracy and currency of the science in ATSDR reports, and program areas to emphasize and/or to de-emphasize. In addition, the Board recommends research programs and conference support for which the Agency seeks to make grants to universities, colleges, research institutions, hospitals, and other public and private organizations.

Matters to be Discussed: Agenda items will include a report from the Community/Tribal Subcommittee on issues and concerns related to hazardous waste sites; a report on the TCE speech and hearing study; a report by the external evaluation panel on the ATSDR Program of Research for Historically Black Colleges and Universities; workgroup reports on the Great Lakes Health Effects Research Program and Uncertainty in Health Guidance Values; a report of findings and public health implications of the Agency's Hazardous Substances Emergency Events Surveillance; and updates on the Environmental Cancer Registry and the Mississippi Delta Project Needs Assessment Profiles.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Charles Xintaras, Sc.D., Executive Secretary, BSC, ATSDR, M/S E–28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–0708.

Dated: April 1, 1998.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office.

[FR Doc. 98–9179 Filed 4–7–98; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0192]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The purpose of the proposed collection of information is to enable manufacturers of biological products to use specific establishment and product license application (PLA) forms in submissions seeking FDA approval of their products.

DATES: Submit written comments on the collection of information by April 20, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13 because the information is essential to the agency's mission. The agency cannot reasonably comply with the normal clearance provisions of the PRA of 1995 because the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Establishment and Product License Applications: Forms FDA 2599, 2599a, 2600, 2600b, 3066, 3086, 3096, 3098, 3098a, 3098b, 3098c, 3098d, 3098e, 3210, 3213, 3214, and 3314—21 CFR 601.2 and 601.12—(OMB Control Number 0910–0124—Reinstatement)

FDA is the Federal agency charged with responsibility for insuring the safety and effectiveness of drugs and the safety, purity, and potency of biological products. Manufacturers of biological products for human use must file an application for FDA approval of the product prior to introducing it into interstate commerce. The information provided by manufacturers on these license application forms is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that biologics for human use have been shown to be safe, pure, and potent. The uniform format of the forms provides for orderly, efficient review by

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