DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Injury Prevention and Control: Family and Intimate Violence Prevention Subcommittee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following subcommittee meeting.

Name: ACIPC Family and Intimate Violence Prevention Subcommittee (FIVP).

Time and Date: 12:30 p.m.–5 p.m., March 21, 2000.

Place: Radisson Hotel Atlanta-Northlake, 4156 LaVista Road, Atlanta, Georgia 30084.

Status: Open to the public, limited only by the space available.

Purpose: To provide and make recommendations to ACIPC and the Director, National Center for Injury Prevention and Control, regarding feasible goals for prevention and control of family and intimate violence and sexual assault. The Subcommittee will make recommendations regarding policies, strategies, objectives and priorities.

Matters To Be Discussed: The Subcommittee will review, discuss, and approve the Family and Intimate Violence Prevention Team's (FIVPT) FY 2001 budget priorities and the Team's proposed FY 2002 budget priorities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Ileana Arias, Ph.D., Team Leader, FIVPT, Division of Violence Prevention, NCIPC, CDC, 4770 Buford Highway, NE, M/S K60, Atlanta, Georgia 30341–3724, telephone 770/488–4410.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 1, 2000.

Carolyn J. Russell,

Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0726]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions: Changes to an Approved Application, Labeling, and Revocation and Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirement relating to the general licensing provisions regarding changes to an approved application, labeling, and revocation and suspension.

DATES: Submit written comments on the collection of information by May 8, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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.

General Licensing Provisions: Changes to an Approved Application, Labeling, and Revocation and Suspension (OMB Control Number 0910–0315)—Extension

Under Section 351 of the Public Health Services Act (PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to insure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations.

In part 601 (21 CFR part 601), § 601.2(a) requires a manufacturer of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce. Section 601.12(b), (c), and (d) requires applicants to follow specific procedures in informing FDA of each change, established in an approved license application, in the product, production process, quality controls, equipment, facilities, or responsible personnel depending on the potential for the change to have a substantial, moderate, minimal or no adverse effect on the safety or effectiveness of the product. Section 601.12(e) requires