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.

[FR Doc. 00–5454 Filed 3–6–00; 8:45 am]

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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

applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval prior to distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures in reporting labeling changes to FDA. Section 601.12(f)(4) requires advertising and promotional labeling and any changes to be reported to FDA. Section 601.45 requires applicants to submit to the agency for consideration, during the preapproval review period, copies of all promotional materials, including promotional labeling as well as advertisements. In addition to §§ 601.2 and 601.12, there are other regulations that relate to certain information submitted in a license application or supplement as follows: Part 640 (21 CFR part 640), specifically §§ 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a), and (b)(2); 21 CFR 660.51(a)(4) and 680.1(b)(2)(iii) and (c). The burden associated with the information collection requirements in these regulations is included in the burden estimate for § 601.2, reported under OMB Control No. 0910–0427, and § 601.12 in table 1 of this document. Sections 600.15(b) and 610.53(d) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 601.25(b) requests interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of biological products that have been licensed prior to July 1, 1972. Section 601.26(f) requests that licensees submit to FDA a written statement intended to show that studies adequate and appropriate to resolve questions raised about a biological product have been undertaken for a product if designated as requiring further study under the reclassification procedures. Section 601.5(a) requires a licensee to give notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the licensee to notify selling agents and distributors upon suspension of its license, and provide FDA with records of such notification.

Form FDA 2567 is used by manufacturers of licensed biological products to submit labeling (*e.g.,* circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. The labeling information is submitted with the form for license applications, supplements, or as part of an annual report. Form FDA 2567 is also used for the transmission of advertisements and promotional labeling. Form FDA 2567 serves as an easy guide to assure that the manufacturer has provided the information required for expeditious handling of their labeling by the Center for Biologics Evaluation and Research (CBER). For advertisements and promotional labeling, manufacturers of licensed biological products may submit to CBER either Form FDA 2567 or 2253. Form FDA 2253 was previously used only by drug manufacturers regulated by the Center for Drugs Evaluation and Research. In August of 1998, FDA revised and harmonized Form FDA 2253 to enable the form to be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised, harmonized form updates the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted; clarifies the intended audience for the advertisements or promotional labeling (*e.g.,* consumers, professionals, news services); and helps ensure that the submission is complete.

The number of respondents is based on the estimated annual number of manufacturers that submitted the required information to FDA. There are an estimated 350 licensed biologics manufacturers. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total annual responses is based on the estimated number of submissions (*i.e.,* license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) received annually by FDA. The rate of submissions are not expected to change significantly in the next few years. The hours per response are based on past FDA experience with the various submissions or notifications. Additional information regarding these estimates is provided below as necessary.

Under § 601.2(a), the total annual responses is based on the numbers of applications submitted to FDA for approval to market a biological product. The estimated burden hours include the time required to fill out the form and collate the documentation. The estimated burden hours to prepare the labeling information submitted with a license application are included in the burden hours to submit a license application which are reported under OMB Control No. 0910–0427.

Under § 601.12(f)(1), (f)(2), and (f)(3), the estimated burden hours include the time to prepare the supplement, fill out the form, and collate the documentation.

Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use either Form FDA 2567 or Form FDA 2253 to submit advertising and promotional labeling. In fiscal year 1999, CBER received 3,784 submissions of advertising and promotional labeling from 114 manufacturers. FDA estimates that approximately 55 percent of those submissions were received with Form FDA 2567 resulting in an estimated 2,081 submissions by 63 manufacturers. The estimated burden hours include the time to prepare the submission, fill out the form, and collate the documentation. The burden hours for the remaining submissions received using Form FDA 2253 are reported under OMB Control No. 0910–0376.

Under §§ 601.12(b) through (d), and 601.12(e), the estimated burden hours include the time to prepare the appropriate supplement or protocol, respectively, and collate the documentation.

Under §§ 600.15(b) (21 CFR 600.15(b)) and 610.53(d), FDA receives very few requests for an exemption or modification to the requirements, therefore, FDA has estimated one respondent per year in table 1 of this document to account for the rare instance in which a request may be made. The estimated burden hours include the time to prepare the request for modification or exemption.

Under § 601.25(b)(3), FDA estimates no burden for this regulation because all requested data and information had been submitted by 1974. Under § 601.26(f), FDA estimates no burden for this regulation because there are no products designated to require further study and none are predicted in the future. However, based on the possible reclassification of a product, the labeling for the product may need to be revised, or a manufacturer, on its own initiative, may believe further study is necessary. As a result, any changes to product labeling would be reported under § 601.12. The information collection requirements for § 601.12 are reported under OMB control number 0910–0315.

Under § 601.5(a), the total annual responses are based on the estimated annual number of notifications received by FDA to discontinue either an establishment and/or product license(s). The estimated burden hours include the time to prepare and submit a letter of discontinuance.

Under § 601.6(a), the number of respondents (21) is based on FDA estimates that establishments would need to notify an average of 20 selling agents and distributors of such suspension and provide FDA with the records of such notification. The number of respondents is based on the estimated annual number of suspensions by FDA of an establishment or product license(s). The estimated burden hours includes the time to prepare a notification letter and submit record of such notification to FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Form FDA No.	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total Hours
601.2(a)	2567 and 356h [2]	17	3.71	63	2	126
601.12(f)(1)	2567	12	1	12	40	480
601.12(f)(2)	2567	10	1	10	20	200
601.12(f)(3)	2567	70	1.43	100	10	1,000
601.12(f)(4) and 601.45	2567	63	33.03	2,081	10	20,810
601.12(b)(1) and (b)(3)	356 h[2]	190	4.75	903	80	72,240
601.12(c)(1) and (c)(3)	356h [2]	98	2.60	255	50	12,750
601.12(c)(5)	356h [2]	34	1.21	41	50	2,050
601.12(d)	356h [2]	166	1.37	227	10	2,270
601.12(e)	356h [2]	14	1.43	20	20	400
600.15(b)	356h [2]	1	1	1	8	8
610.53(d)	356h [2]	1	1	1	8	8
601.25(b)(3)	NA	0	0	0	0	0
601.26(f)	NA	0	0	0	0	0
601.5(a)	NA	33	1	33	.33	11
601.6(a)	NA	2	10.50	21	.33	7
Total						112,360

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The burden hours for the use of Form FDA 356h are reported under OMB Control No. 0910–0427.

Dated: February 29, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–5416 Filed 3–6–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0725]

Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealers Certificate

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 Form 3038, ''Interstate Shellfish Dealer's Certificate.''

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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Interstate Shellfish Dealers Certificate—(OMB Control Number 0910–0021)—Extension

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of