Dated: June 3, 1998.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 98–15158 Filed 6–3–98; 2:12 pm]

BILLING CODE 6210–01–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 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 reinstatement 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 use of establishment license application (ELA) and product license application (PLA) forms by manufacturers of biological products.

DATES: Submit written comments on the collection of information by August 4, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. 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 reinstatement 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 listed below.

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 determining that drugs and biological products are safe and effective. 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 and effective. The uniform format of the forms provides for orderly, efficient review by the Center for Biologics Evaluation and Research (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 the collection of this information is provided by 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 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 provide additional standards for human blood and blood products, which require submission of certain information 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 provided under the burden estimated for §§ 601.2 and 601.12 and the application form in approved 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 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 will 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.

This collection of information involves 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 using CBER's license application forms under OMB control number 0910–0124 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. The approval for OMB control number 0910–0338 expires on April 30, 2000. The announcement of OMB's approval was published in the **Federal Register** of May 19, 1997 (62 FR 27262).

Under OMB control number 0910–0338, FDA estimated that CBER's portion of the reporting burden for 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 hours. The other 73,200 hours would account for manufacturers who may not have completed the transition to using Form FDA 356h and still need to use other license application forms. FDA expects that all manufacturers of biological products will begin to use Form FDA 356h during 1998. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Forms	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
601.2 and 601.12	FDA 2599, 2599a, 2600, 2600b, 3066, 3086, 3096, 3098, 3098a, 3098b, 3098c, 3098d, 3098e, 3210, 3213, 3214, and 3314	376	4.9	1,830	40	73,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14916 Filed 6–4–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0336]

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 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, and each proposed reinstatement of an existing collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on premarket notification submission 510(k), subpart E, to require a person/manufacturer who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for